



**Asia-Pacific  
Economic Cooperation**

**Advancing** Free Trade  
for Asia-Pacific **Prosperity**

# Regulatory Reform – Case Studies on Promoting Innovation



---

**APEC Policy Support Unit**  
October 2014

Prepared by:

Dr Lyndal Thorburn BSc (Hons) Grad Dip Ed Grad Dip Legal Studies PhD  
Principal Associate, Sustineo Pty Ltd  
27 Torrens St BRADDON ACT 2602  
Australia

For the

Asia-Pacific Economic Cooperation Policy Support Unit  
Asia-Pacific Economic Cooperation Secretariat  
35 Heng Mui Keng Terrace  
Tel: (65) 6891-9600 Fax: (65) 6891-9690  
Email: [psugroup@apec.org](mailto:psugroup@apec.org) Website: [www.apec.org](http://www.apec.org)

Produced for:

Asia-Pacific Economic Cooperation  
Policy Support Unit

APEC#214-SE-01.21



This work is licensed under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 Singapore License. To view a copy of this license, visit <http://creativecommons.org/licenses/by-nc-sa/3.0/sg/>.

---

The views expressed in this paper are those of the authors and do not necessarily represent those of APEC Member Economies.

The authors would like to thank all those that provided assistance in development of these case studies, particularly those who provided their time freely for interviews

---

## EXECUTIVE SUMMARY

### Objectives

This report contains three case studies commissioned by the Asia-Pacific Economic Cooperation (APEC) to investigate the role of regulatory reforms and practices in the promotion of innovation. The case studies draw lessons and suggest policy recommendations based on APEC member economies' experiences of implementing regulatory reforms to promote innovation.

### Background

The Organisation for Economic Co-operation and Development (OECD) classifies regulations into three types:

- economic regulations try to increase competition and improve the operations of markets;
- social regulations aim to promote society wellbeing and to induce economic players to internalise the costs associated with meeting societies' standards; and
- administrative (institutional) regulations relate to the operations of the public and private sectors.

Administrative regulations may be designed to directly affect innovation, whereas innovation, or its inhibition, can be a secondary effect of economic and social regulations. Regulations can be implemented using a number of approaches, including bans, technical standards, planning standards, levies/pricing and permits.

Innovation can take many forms and, in line with current academic understanding, can include new methods of production; management-determined changes in rules and procedures; selection and training policies for human resource management; modifications in equipment and facilities; and new institutions or relationships between institutions. Regulation can have a positive, negative or neutral effect on innovation.

The case studies were selected to examine different types of regulations in both developed and developing APEC economies. Relevance to a range of APEC fora were sought e.g. regulatory harmonization, financial inclusion (in relation to public-private partnerships), small to medium enterprise development, and service industries. The case studies selected were intellectual property (IP) regulation in Korea, clinical trials regulation in Malaysia and water regulation in Australia and Singapore.

### Approach

The case studies were developed using a combination of critical literature analysis and semi-structured interviews. Peer reviewed and public sources were used for the literature analysis. Field work was conducted in a single trip in Asia and separately within Australia. Field work interviews explored issues which arose from the preliminary literature reviews and desk research on each case study economy. A total of 34 people were interviewed. An expert panel provided input during planning stages and commented on the draft case studies.

The OECD-APEC Integrated Checklist on Regulatory Reform and the Good Regulatory Practices (GRP) criteria discussed at APEC were used as the basis for the regulatory analysis in each case study.

## Results

The results from the analysis of the cases against the OECD-APEC checklist and GRP criteria are shown in the table below. All case studies could demonstrate compliance with the transparency requirements and all had taken steps to achieve alignment with other regulations. Some required new institutional structures to support this. Compliance costs increased in all cases but it can be argued that social and/or environmental benefits are greater in all cases.

**Table ES: Summary of Application of OECD-APEC Checklist to the Case Studies**

OECD/APEC GRP criterion	Korea	Malaysia	Singapore and Australia
Transparency	All available on internet except industry members of IP Council not named	All available on internet and structured process for stakeholder input	All available on internet; complexities of Australian governance can confuse those to whom regulations apply
Alignment	International harmonization requirements dominate; IP legislation requires alignment with other laws	International harmonization requirements dominate; established coordination mechanisms	Local coordination dominates in both Singapore and Australia. In Australia multiple layers of government have required establishment of new coordinating agency. In Singapore single agency simplifies alignment
Costs and Benefits	Costs of utility patents similar to full patents; benefits of utility patents highest in specific industry sectors; SME training efforts by KIPO adds administrative costs but benefits SMEs	Direct compliance costs high but broader societal benefits	Targets and measures focus on technical levels. Ability to measure impact on society level limited by lack of frameworks and distribution of measuring equipment
Scientific integrity	No, historical basis	Yes, based on internationally accepted science	Strong scientific basis in both economies
Flexibility and 21st century regulation	Mainly technical, no sunset clauses. Complies with continuous review requirement but in response to informal inputs	Combination of technical and permit-based, complies with continual review requirement through informal mechanisms and through Master Plan process	Technical performance-based in both economies but measurement framework measuring ultimate impact not fully developed. No sunset clauses. New initiatives in Singapore harness public-private-people partnerships

Source: Drawn from the case studies

The greatest divergence from the APEC ideal framework is in scientific integrity, with the IP case study showing the importance of historical influence in decisions to implement certain regulatory regimes. The cases also showed that sunset clauses are the exception rather than the rule, but that there are review processes in place in all economies, with Malaysia probably the most formal, followed by Australia, Korea then Singapore.

Through comparing the case studies, five key conclusions emerge:

1. leadership has been important in the initiation of regulatory change – in response to global issues in the case of Korea and Malaysia, and in response to resource constraints for both Australia and Singapore;
2. policy makers need to consider the impacts on innovation of their regulations and identify the common links with industry policy in order to harness this innovation to enhance economic benefit;
3. regulation is a process rather than an event and is most effective when coupled with education campaigns prior to enforcement of compliance regimes;
4. institutional structures need to engage all relevant parties but can take many forms; and
5. all case studies show some compliance to best practice regulation but that none meet all the Good Regulatory Practices criteria discussed within APEC and included in the OECD-APEC checklist .

### **Applications/recommendation**

Recommendation for policy makers arising from the case studies are as follows:

#### **1. Policy makers need to consider the potential effect of new regulations on innovation and economic development, and actively monitor their impacts.**

As can be seen from all three case studies there is potential for regulation to affect innovation, both positively and negatively, and hence overall economic growth. Hence, policymakers need to consider potential impacts of regulation on innovation and establish systems to be able to measure such impacts, and make changes to the regulation or its administration should the overall impact be negative.

Establishment of monitoring measures is best done at the time of implementing the regulation, so that indicators can be objective and statistics can be collected from when the new regulation is implemented. In Malaysia, for example, statistics collected by the national regulator are forming the basis of reports to the Prime Minister's Department/ on progress in meeting the goals set for increasing clinical trials under the Third Industrial Master Plan (IMP3).

#### **2. Where a regulation has the potential to promote innovation, industry policy needs to be harnessed to initiate industry change.**

It can be seen from the Korean case study that regulation can have no impact on innovation until some other event happens to initiate change in industry. This was also the case in Malaysia, where international regulatory harmonization had limited impact until the economy's leaders decided to promote capacity development in clinical trials – from this point, economic capacity started to increase, enabled by the regulatory framework.

#### **3. New or amended regulations should be preceded by industry and public consultation and the impact on both needs to be continually monitored so that administration can be adjusted to support compliance and industry development.**

In Singapore, public and industry education campaigns have preceded the introduction of new water regulations so that there is general acceptance when the new law is finally enforced. While Korea has implemented regulatory changes without substantial public and industry consultation, KIPO is monitoring the impact of such changes on SMEs and is amending its patent law administration to minimise negative effects and costs for SMEs.

**4. Policymakers need to implement formal review processes to help SMEs to provide input to regulatory evaluations.**

As can be seen from the Korean case study, regulatory review systems can be skewed towards larger companies which have the capacity to interact at senior levels of government. This issue is better addressed in Malaysia, where formal committees provide clear avenues for industry input and include provision for smaller players to provide comment.

**5. End-point impact measures need to be identified during regulatory development (possibly through inclusion in formal Regulatory Impact Statements) so broader impacts on society and the environment can be effectively measured.**

In Australia a Regulatory Impact Statement has become part of standard government practice when considering new regulations. Their purpose is to provide evidence of the key steps taken during the development of a proposal, including consultation with key stakeholders, and assess the costs and benefits different options under consideration. Development of a regulatory impact statement prior to introduction of new regulations enables governments to not only consider longer term impacts but also provides a framework for identification of impact measures that can help agencies measure such impacts in both the short and long term.

**6. Policy makers need to avoid or manage regulatory gaps in order to enhance both understanding and compliance.**

The Australian case study provides an excellent example of how gaps in regulatory coverage can cause confusion amongst those that are being asked to implement it or comply with it. The Victorian government had addressed this through establishment of the Office of Living Victoria; however OLV's recent abolition calls into question the capacity for the current responsible agency, the Department of Environment and Primary Industries, to manage engagement with its key target audience, who are urban planners. In the other three case studies the national operation of the regulations minimizes these gaps.

The overlap with APEC's trade agenda also needs to be considered – harmonization is made more difficult when there are gaps in the regulatory framework.

**7. Policy makers must actively enforce regulations to ensure compliance and to enhance capacity.**

The case studies show the impact of effective enforcement of regulation, in particular in the comparison between Indonesia's and Malaysia's approach to clinical trial regulation. In the latter case strong enforcement has enhanced economic capacity to

conduct clinical trials. Similarly, in Singapore, enforcement of new water re-use regulations provided the impetus for enhanced capacity in both research institutions and industry and the eventual creation of significant industrial capacity in the Singaporean economy.

**8. Relevant APEC Committees, Working Groups and Fora should work together to address the impact of regulations so that the impact of regulations on specific industries can be better understood.**

While focus of these case studies has been OECD-APEC Good Regulatory Practices Criteria, the studies are relevant to a number of APEC Working Groups. There is potential for these working groups to work together to consider the issues raised here, possibly led by the APEC Economic Committee (EC). Of particular importance is the potential for this committee to coordinate with the work at other APEC sub-fora such as the Small and Medium Enterprises Working Group, the Life Sciences Innovation Forum, the Intellectual Property Rights Experts Group and the Policy Partnership on Science, Technology and Innovation.

## TABLE OF CONTENTS

<b>1. INTRODUCTION .....</b>	<b>1</b>
APPROACH AND METHODOLOGY .....	1
STRUCTURE OF THIS REPORT .....	1
<b>2. BACKGROUND .....</b>	<b>2</b>
REGULATION .....	2
INNOVATION .....	3
RELEVANCE TO APEC .....	4
Innovation and SMEs .....	5
INNOVATION AND REGULATION .....	6
THE CASE STUDIES .....	7
Utility patents in Korea .....	8
Pharmaceutical clinical trials in Malaysia .....	8
Urban water supply and re-use in Singapore and Australia .....	8
Limitations .....	8
<b>3. PATENTS AND UTILITY MODELS IN KOREA.....</b>	<b>10</b>
INTRODUCTION .....	10
WHAT IS INTELLECTUAL PROPERTY (IP).....	10
Regulation of intellectual property through international patent systems .....	11
Utility model patents .....	12
IMPACT OF PATENTS ON INNOVATION.....	13
Costs and benefits of the patent system .....	13
Patents and innovation .....	14
DEVELOPMENT OF THE PATENT SYSTEM IN THE REPUBLIC OF KOREA.....	15
General patent laws .....	15
Utility model laws .....	16
The balance between use of utility and full patents in Korea .....	18
Link between patent regulations and technical standards .....	19
Link between patent regulations and industry policy .....	19
KIPO'S DEVELOPMENT AND REVIEW OF REGULATIONS.....	21
International regulatory harmonization.....	21
Economy-level IP law reviews .....	22
Transparency .....	22
Evaluation of impact of patent regulations .....	23
Alignment amongst authorities .....	24
Costs and benefits .....	24
Flexibility and 21 <sup>st</sup> century regulation .....	25
THE CURRENT SITUATION.....	25
Patenting in Korea.....	25
The balance of utility models and full patents .....	26
Types of innovation .....	28
Korea compared to other economies.....	29
POLICY IMPLICATIONS .....	30
Importance of international harmonization.....	30
Matching the regulatory system to technological development.....	30
Procedures to enhance contact with SMEs .....	31
CONCLUSION.....	31

<b>4. MALAYSIAN PHARMACEUTICAL CLINICAL TRIALS .....</b>	<b>33</b>
INTRODUCTION .....	33
THE NEED FOR PHARMACEUTICAL DEVELOPMENT .....	33
Global pharmaceutical markets .....	33
Steps in the development of new drugs .....	34
Trends in clinical trials .....	35
REGULATION AND DRUG DEVELOPMENT .....	37
Drug development regulatory framework .....	37
Global harmonization of approval systems for new drugs .....	38
Global harmonization of intellectual property protection for drug developers .....	39
PIC/S .....	39
Other global harmonization initiatives .....	40
Regional harmonization .....	40
REGULATORY AND POLICY FRAMEWORKS IN MALAYSIA .....	41
Malaysian Country Health Plan .....	41
Third Industrial Master Plan 2006-2020 (IMP3) .....	41
CLINICAL TRIAL REGULATION AND APPROVAL .....	42
Gaining approval to run a clinical trial .....	43
Ethics approvals for clinical trial plans .....	43
Public registration of clinical trials .....	44
Export of clinical trials samples .....	44
Drug approval following successful trials .....	44
ENCOURAGING CLINICAL TRIALS .....	44
Institutional arrangements .....	44
The NPCB'S Development and Review of Regulations .....	45
Transparency .....	45
Alignment amongst authorities .....	46
Costs and benefits .....	46
Scientific integrity .....	46
Flexibility and 21 <sup>st</sup> century regulation .....	47
THE CURRENT SITUATION .....	47
GCP has laid the groundwork .....	47
The complementary role of industry policy .....	47
Impact on innovation .....	48
Malaysia compared to other Asian economies .....	49
Changes in trial phases over time .....	51
POLICY IMPLICATIONS .....	52
Regulatory system is necessary but not sufficient to support innovation .....	52
Enforcement must be a focus .....	53
Capacity building and training go hand in hand with regulation .....	53
Support from industry policy is required for innovation .....	53
CONCLUSION .....	54
<b>5. URBAN WATER SUPPLY AND MANAGEMENT .....</b>	<b>56</b>
INTRODUCTION .....	56
REGULATIONS AND WATER MANAGEMENT .....	57
Water regulations .....	57
Trade regulations and free trade agreements .....	57
INNOVATION AND WATER MANAGEMENT .....	58
Changes in water management technologies .....	58
Water-sensitive urban design .....	59

Services and water-sensitive urban design.....	61
APPROACHES TO WATER MANAGEMENT IN AUSTRALIA .....	62
History of water management .....	62
Development of water regulations in Australia .....	63
APEC Regulatory Analysis.....	65
Innovation incentives in water management.....	70
Policy implications.....	70
Conclusions for Australia.....	72
APPROACHES TO WATER MANAGEMENT IN SINGAPORE .....	72
History of water management .....	72
Development of water regulations in Singapore.....	74
APEC regulatory analysis .....	75
Innovation incentives in water management.....	77
Policy implications.....	77
Conclusion for Singapore.....	78
COMPARING SINGAPORE AND AUSTRALIA.....	79
<b>6. CONCLUSIONS .....</b>	<b>81</b>
CONCLUSIONS.....	81
RECOMMENDATIONS .....	83
AREAS FOR FURTHER RESEARCH.....	85

**LIST OF FIGURES**

Figure 3-1: Classification of Intellectual Property.....	11
Figure 3-2: Top 5 technologies claims in PCT applications, 2013.....	14
Figure 3-3: Top 15 Companies Filing PCT Applications, 2013.....	15
Figure 3-4: Relative Use of Utility Models and Full Patents in Korea, 2003-2012 .....	18
Figure 3-5: Korean IP Regulations and Major Industry Developments .....	21
Figure 3-6: Technology focus of Utility Model Applications in Korea .....	27
Figure 3-7: Correlation between GDP and Patent Applications, Korea, 1980-2112.....	28
Figure 3-8: Trends in PCT applications, 2003-2012, Top Ten Economies .....	29
Figure 3-9: Total patents granted, Selected Economies, 2002-2012 .....	30
Figure 4-1: Stages in development of a new drug .....	35
Figure 4-2: International Harmonization of Drug Development Regulations .....	39
Figure 4-3: Malaysian Regulations to Extend Clinical Trials Capacity .....	42
Figure 4-4: Number of trials in Asian economies, 2012.....	49
Figure 4-5: Clinical Trials Rate per 100,000, Asia.....	50
Figure 4-6: Growth of Clinical Trials in Malaysia .....	51
Figure 4-7: Trials commenced 2012, by Phase.....	52
Figure 5-1: Generic Approaches to Water Supply and Disposal.....	56
Figure 5-2: Urban Water Management Frameworks .....	60
Figure 5-3: Balance of Equipment and Services in Water Management, by Region .....	61
Figure 5-4: Victorian Government Water Conservation Hierarchy .....	64
Figure 5-5: Victorian government Ministries with Urban Water Responsibilities.....	66

**LIST OF TABLES**

Table 2-1: Approaches to Regulation, by Purpose .....	3
Table 2-2: Conceptual Framework for Understanding Innovation.....	3
Table 2-3: Summary of the OECD-APEC Integrated Checklist on Regulatory Reform* .....	5
Table 2-4: Negative and Positive effects of Regulation on Innovation .....	7
Table 3-1: Approaches to Patent Regulation .....	11
Table 3-2: Major Differences between Utility Models and Full Patents in Korea .....	17
Table 3-3: Development history of Korean economy.....	20
Table 3-4: Protection of “Electronic” Inventions, Top Ten Companies.....	26
Table 3-5: Protection of Electronic Inventions, Samsung Suppliers .....	27
Table 3-6: Summary of Impacts of Utility Patent Regulations on Innovation .....	29
Table 3-7: Summary of Korea IP Regulatory Analysis .....	32
Table 4-1: Value of Global Pharmaceutical Markets in 2012 .....	33
Table 4-2: Pharmaceutical Sales in APEC Region Economies, 2011 .....	34
Table 4-3: Summary of Top 50 Economies’ Clinical Trial Sites, 2007 .....	36
Table 4-4: Approaches to Drug Development Regulation .....	37
Table 4-5: Summary of Impacts of Clinical Trial Regulations on Innovation .....	49
Table 4-6: Summary of Malaysia Clinical Trials Regulatory Analysis.....	55
Table 5-1: Approaches to Water Regulation .....	57
Table 5-2: Summary of Australian Water Regulatory Analysis .....	72
Table 5-3: Summary of Singapore Water Regulatory Analysis .....	78
Table 5-4: Impact of Water Regulations on Innovation in Victoria (Australia) & Singapore .....	80
Table 6-1: Summary of Application of OECD-APEC Framework to the Case Studies .....	82



**GLOSSARY****INTELLECTUAL PROPERTY CASE STUDY**

IP – intellectual property  
 KIPA – Korean Intellectual Property Association  
 KIPO – Korea Intellectual Property Office  
 KIPRIS – Korea Industrial Property Rights Information Service  
 National phase – point at which a patent application is examined for granting in the economy in which it was first lodged  
 PCT – Patent Cooperation Treaty  
 R&D – research and development  
 SME/s – small to medium enterprise/s  
 TRIPS – Trade-related Aspects of Intellectual Property Rights  
 WIPO – World Intellectual Property Office

**PHARMACEUTICAL CLINICAL TRIALS CASE STUDY**

ASEAN – Association of South East Asian Nations  
 CRC – Clinical Research Centre  
 CTD – Common Technical Dossier  
 CTIL – Clinical Trial Import License (Malaysia)  
 CTU – Clinical Trials Unit  
 CTX – Clinical Trial Exemption (Malaysia)  
 EPP – Entry Point Projects  
 GCP – Good Clinical Practice  
 ICH – International Conference on Harmonization of Technical Requirement for Registration of Human-Use Pharmaceuticals  
 IMP3 – Malaysia’s Third Industrial Master Plan 2006-2020  
 KRA – Key Result Area/s (under the 10<sup>th</sup> Malaysian Health Plan)  
 NCCR – National Committee on Clinical Research  
 NCE or NME – New Chemical Entity or New Molecular Entities, the term for new molecules that are being developed as drugs  
 NKEA – National Key Economic Area  
 NMRR – National Medical Research Register  
 NPCB – National Pharmaceutical Control Bureau  
 PhAMA – Pharmaceutical Association of Malaya  
 PIC/S – Pharmaceutical Inspection Convention and the Pharmaceutical Inspection Cooperation Scheme  
 WHO – World Health Organization  
 EFTA – European Free Trade Association

**WATER RECYCLING CASE STUDY**

CRC – Cooperative Research Centre  
 EGS – Environment Goods and Services  
 EWI – Environment and Water Initiative  
 NEA – National Environment Agency  
 PUB – Public Utilities Board (Singapore)  
 SAF – Sanitary Appliance Fee  
 TPPA – Trans-Pacific Partnership Agreement  
 WBF – Water Borne Fees  
 WSUD – Water-sensitive Urban Design



## 1. INTRODUCTION

This report contains three case studies commissioned by APEC to investigate the role of regulatory reforms and practices in the promotion of innovation. The case studies draw lessons and suggest policy recommendations based on APEC member economies' experiences of implementing regulatory reforms to promote innovation. The case studies, in intellectual property (IP) regulation in Korea, clinical trials regulation in Malaysia and water regulation in Australia and Singapore, describe the background and the impact of regulatory reforms on innovation.

### ***Approach and Methodology***

The case studies were developed using a combination of critical literature analysis and semi-structured interviews.

Peer reviewed and public sources were used for the literature analysis. These included academic papers on the broad issue of regulation, innovation and their interaction, and, as relevant, academic studies of particular issues in the case study and other economies. Within each case study, government and industry publications also provided an important source of preliminary information. The initial literature review was completed prior to undertaking the field work.

Field work was conducted in a single trip to Korea, Malaysia and Singapore and separately within Australia. The field work interviews explored the topic with key informants, including issues arising from the preliminary literature reviews and desk research on each economy. The interviews used a set of questions to guide discussion but allowed participants to raise and discuss issues relevant to the topic. The interviews provided additional technical details on the nature of regulatory reform in each economy and its impact on innovation in the sectors selected for this project. A total of 34 people were interviewed directly for the case studies – 9 in Korea, 10 in Malaysia, 7 in Singapore and 8 in Australia.

An expert panel, comprising Mr Alex Erskine, a leading economist, and Associate Professor Karen Hussey, of the Fenner School of Environment at the Australian National University, provided input in the planning stages and commented on the draft case studies. Their input has been invaluable and is acknowledged.

### ***Structure of this report***

This report is divided into 6 chapters, including this introduction. Chapter 2 provides the background to the case studies including the framework used for understanding innovation and regulations and the rationale for choosing each of the case study sectors and economies. Chapters 3, 4 and 5 then contain the case studies – first Korea, then Malaysia, then Australia and Singapore together. Chapter 6 draws a number of conclusions and recommendations across all case studies.

## 2. BACKGROUND

The approach employed in this project used three frameworks. Two frameworks were employed to analyse regulations and one to analyse innovation. These are summarised in the following sections. The frameworks are then used in each case study to draw observations and form conclusions regarding the introduction, implementation and review of the regulations themselves, and their impact on innovation.

### **REGULATION**

The OECD has defined regulation as the implementation of rules by public authorities and governmental bodies to influence businesses and citizens.<sup>1</sup> There are a variety of typologies that can be applied to regulatory analysis but we have chosen two as particularly relevant for these case studies.

The first is to classify regulation by its purpose. The OECD identifies three major types of regulation: economic, social, and administrative or institutional:

- Economic regulations try to increase competition and improve the operations of markets<sup>2</sup> e.g. competition policy, antitrust policy, merger and acquisition policy, market entry policy, pricing and policies which influence public enterprises.
- Social regulations aim to promote society wellbeing and to induce economic players to internalise the costs associated with meeting society's standards,<sup>3</sup> e.g. environmental protection, worker health and safety, labour rights and protection of consumers against fraud and negligence.
- Administrative (institutional) regulations relate to the operations of the public and private sectors, e.g. regulations on taxes, business operations, intellectual property and distribution systems.

In addition to this broad classification by purpose, regulations can also be classified by approach or method. Internationally, there are five main approaches used to give effect to regulations:

- Bans, where organisations are prevented from certain actions.
- Technical standards, where organisations must meet certain scientifically-based criteria – these may be defined by presence or absence and can be tested objectively.
- Planning standards, where organisations must meet certain criteria, possibly in particular locations, due to the impact of local geology, demography and topology.
- Levies/pricing, which can induce or prevent (or reduce) certain behaviours.

---

<sup>1</sup> Organisation for Economic Co-operation and Development: The OECD Report on Regulatory Reform – Synthesis (Paris, OECD, 1997), 40pp.

<sup>2</sup> Parker, D and Kirkpatrick, C: Measuring Regulatory Performance – the Economic Impact of Regulatory Policy, Expert Paper 3, August 2012, OECD Regulatory Policy Committee, 2012

<sup>3</sup> OECD (nd): Regulatory Reform and Innovation, page 11. Available at: [www.oecd.org/science/inno/2102514.pdf](http://www.oecd.org/science/inno/2102514.pdf) accessed June 2014

- Permits, which allow organisations to do something which might otherwise be prevented, but on payment of a fee to the government.

The OECD framework can be used to map regulatory purpose onto regulatory approach (Table 2-1).

**Table 2-1: Approaches to Regulation, by Purpose**

Purpose of Regulation	Approaches to Implementation				
	Bans	Technical standards	Planning standards	Levies and pricing	Permits
Economic	Trade bans	Technical import requirements	Free trade areas	Tariffs	Import permits
Social	Labour laws re young workers	Transport/disposal of chemicals	Co-locating housing and manufacturing	Green technology rebates	Licensing of health care providers
Administrative	Domestic manufacture by multinational co.	Products that can be patented	Location of business	Small business tax c	Establishing types o businesses

Source: Author's analysis

## **INNOVATION**

Innovation has been recognised since the 1930s as the key to economic growth and industry renewal and emergence. While academic studies of innovation originally focused on of the role of formal research and development (R&D) within large companies,<sup>4</sup> more recent work has focused on the firm within its economic and external environment at economy-wide<sup>5</sup> and regional levels<sup>6</sup>, and organizational learning.<sup>7</sup> The focus has moved beyond the firm to regions, sectors<sup>8</sup> and supply chains.<sup>9</sup> The current understanding of innovation includes “softer” changes such as new organisational hierarchies, structures and learning. This framework has been adopted for these case studies (Table 2-2).

**Table 2-2: Conceptual Framework for Understanding Innovation**

Type	Description
Process	New methods of production or manufacturing processes
Procedural	Management-determined changes in rules and procedures
Personnel-related	Selection and training policies, human resource management
Structural	Modifications in equipment and facilities
Institutional	New institutions or relationships between institutions

Source: Extended from Koberg et al (2003)<sup>10</sup>

<sup>4</sup> Mansfield: Contribution of R&D to Economic Growth in the United States, *Science* 175(4021): 477-486, 1972.

<sup>5</sup> Nelson R and Rosenberg, N *National Innovation Systems – a Comparative Analysis*, OUP 1993

<sup>6</sup> Cooke, P and K Morgan: *The Creative Milieu – A Regional and Perspective on Innovation*, in Dodgson, M. and Rothwell, R., (eds.), “*The Handbook of Industrial Innovation*”, Edward Elgar, 1994

<sup>7</sup> Asheim, B and Isaksen, A: *Regional Innovation Systems – the Integration of Local ‘Sticky’ and Global ‘Ubiquitous’ Knowledge*, *Jnl of Technology Transfer* 27(1): 77-86, 2002

<sup>8</sup> Lee, KR (2014): *University–Industry R&D Collaboration in Korea’s National Innovation System*, *Science and Technology in Society* March 2014 19:1-25

<sup>9</sup> For example, Teece, D et al (2001): *The Analysis of Market Definition and Market Power in the Context of Rapid Innovation*, *International Journal of Industrial Organization*, 19:5 (2001), 665-693

<sup>10</sup> Koberg et al (2003): *An Empirical Test of Environmental, Organizational and Process Factors Affecting Incremental and Radical Innovation*, *Jnl of High Technology Research Management*, 14(1):21-4, Spring 2003

Innovation is more than invention. In order to innovate, organisations need resources. They need skills to convert an invention into a product or service, and these skills either need to be part of the innovating organisation, or provided as services or education.<sup>11</sup>

Innovating organisations also need funds to finance the work that needs to be done to provide and standardize such products and services so they can be sold to multiple customers. Academic studies also show that financial capacity is important to systemic innovation.<sup>12</sup>

While a full review of innovation literature is not possible here, it should be noted that a wide literature exists on the growth of innovative organisations, firms and regions and that this is relevant to the discussions on industry policy that are brought into the individual case studies presented here.

### ***Relevance to APEC***

Innovation and regulation has been addressed in a range of APEC fora including in the APEC Life Sciences Innovation Forum's Regulatory Harmonization Steering Committee, and the APEC-sponsored Forum on Financial Inclusion.<sup>13</sup> APEC's work also includes a major study examining regulatory coherence across several industries.<sup>14</sup> These case studies are also relevant to these APEC fora because of their focus on regulatory harmonization and economic development.

As part of this project, APEC required an analysis of the regulations based on the APEC-OECD 2005 Integrated Checklist on Regulatory Reform and the Good Regulatory Practices criteria discussed within APEC.<sup>15</sup> The Checklist is based on OECD declarations and policy recommendations from 1995 to 1999 and considerations of competition and trade policy. It contains a number of principles which were used to review government documents and frame the questions asked during the field work for this project. The Good Regulatory Practices criteria were the result of the discussions by APEC Senior Officials in 2011. The framework is summarised in Table 2-3.

---

<sup>11</sup> For example see Cohen, W and Levinthal, D: Absorptive Capacity – A New Perspective on Learning and Innovation, *Administrative Science Quarterly* 35(1): 128-152 (1990)

<sup>12</sup> Cooke, P, Uranga, MG and Etxebarria, G: Regional Innovation Systems – Institutional and Organisational Dimensions, *Research Policy* 26(4-5) pp 475-491 (1997)

<sup>13</sup> E.g. the APEC Forum on Financial Inclusion in 2013 focussed on public-private partnerships see [www.apec.org](http://www.apec.org)

<sup>14</sup> Geard, K et al (nd): Strategic Framework for Regulatory Coherence in APEC: Impact Assessment of the Dairy, Electronics and Off-Highway Vehicle Industries, [www.ncapec.org](http://www.ncapec.org)

<sup>15</sup> OECD: APEC-OECD Integrated Checklist on Regulatory Reform – a Policy Instrument for Regulatory Quality, Competition Policy and Market Openness, OECD Regulatory Reform Programme (Directorate for Public Governance and Territorial Development) and the APEC Competition Policy and Deregulation Group (CPDG), 2005

**Table 2-3: Summary of the OECD-APEC Integrated Checklist on Regulatory Reform\***

<i>Political and Administrative Viability</i>	
Transparency	How are stakeholders' views reflected and balanced when regulations are established or revised and can regulations be easily accessed by the public?
Alignment	How have government agencies taken steps to harmonize, simplify, and coordinate policies and regulations?
<i>Economic Efficiency and Effectiveness</i>	
Costs and benefits	What regulations promote innovation; what other factors reduce incentives for innovation; and have policies and regulations contributed to maximizing benefits in the society while minimizing costs?
Scientific integrity	Have regulations been formulated based on scientific evidences or analysis?
Flexibility and twenty-first century regulation	Are regulations performance-based rather than product-based; are regulations flexible enough to be revised and if necessary, adapted to the changing environment that stakeholders face; and what measures could help to improve the existing situation?

Source: OECD (2005) *op cit* \*Full title is OECD-APEC Integrated Checklist on Regulatory Reform\* and Good Regulatory Practices Criteria

This framework is used as the basis for analysis and commentary on approaches to regulatory development and review in each case study.

### **Innovation and SMEs**

Small to medium enterprises (SMEs) are of particular interest to APEC. They account for 90% of businesses and employ 60% of the workforce, but only generate 30% of exports.<sup>16</sup> APEC's SME Working Group (SMEWG) aims encourage SME development and capacity by sharing of information on best practice initiatives and conducting capacity-building activities.

Studies of innovation by SMEs have now shown that the uptake of information and knowledge from outside the firm is particularly important, as they may have limited technical or business expertise (termed 'tacit knowledge' in the literature) and need to acquire such information or skills from third parties. This can be achieved by recruiting new skilled staff, attending formal training or using skilled consultants. Such 'technology diffusion' is also important within sectors, where those that adopt new technologies or business approaches (early adopters) can gain competitive advantage and access to new markets ahead of their 'laggard' competitors.

Resources to enhance knowledge, skills and innovation can be made available to SMEs from other organizations within their domestic or regional economy or by linking with organisations at an international level. The latter can be achieved through SMEs gaining international

---

<sup>16</sup> [www.apec.org/Groups/SOM-Steering-Committee-on-Economic-and-Technical-Cooperation/Working-Groups/Small-and-Medium-Enterprises.aspx](http://www.apec.org/Groups/SOM-Steering-Committee-on-Economic-and-Technical-Cooperation/Working-Groups/Small-and-Medium-Enterprises.aspx)

experience (e.g. by exporting) or by linking with incoming multinationals for the purposes of technology transfer.<sup>17</sup>

Evidence shows that productivity grows in economies which have imported more from the worlds' technology leaders, when compared with those that have not imported such technology.<sup>18</sup> This is why so many developing economies, including APEC economies,<sup>19</sup> have focused on collaboration and technology transfer in dealings of foreign-based multinationals in their economies. It has been found, however, that inbound technology transfer needs to be accompanied by technical and "soft" skill development (e.g. marketing skills) in order to be effective.<sup>20</sup>

All three case studies in this report comment on the impact of regulation on SME's and their innovation.

### **Innovation and Service Industries**

APEC has taken a keen interest in Environmental Goods and Services and has sponsored or is monitoring a number of projects which aim to promote sustainable development and to enhance regional capacity building. Projects include the Asia-Pacific Environmental Innovation Strategy Project and the Southeast Asian Urban Environmental Management Application.<sup>21</sup> APEC's Committee for Trade and Investment has also sponsored a trade in environmental services project and has established an Environmental Goods and Services Information Exchange. The water supply and management case study in this report discusses the development of domestic environmental services after regulatory impetus, and contributes to this debate.

### ***INNOVATION AND REGULATION***

While the innovation literature is well-defined and extensive, the interplay between regulation and innovation is less well studied. Broad reviews such as that sponsored by Nesta<sup>22</sup> have found that innovation is usually a second order effect of a regulation. Rather, regulation is developed for other purposes and that regulatory policy makers are often ignorant of the potential of their intervention to affect innovation.

Examples of positive and negative effects of regulation, and a summary of academic study in particular types of regulations, are shown in Table 2-4.

---

17 Mayor, J Globalization, technology transfer and skill accumulation in low-income countries, UNCTAD/OSG/DP/150, 2000, part of UNCTAD WIDER project - Globalization and the Obstacles to the Successful Integration of Small Vulnerable Economies.

18 Coe, D, Helpman E, and Hoffmaister A: North South R&D Spillovers, The Economic Journal 107(440): 134-149, 1997

19 APEC Policy Partnership on Science, Technology and Innovation (PPSTI) and the APEC Virtual Center for Environmental Technology Exchange are two examples.

<sup>20</sup> Lan, P and Young, S: Foreign Director Investment and Technology Transfer – A Case of Foreign Director Investment in North-east China, UNCTAD Investment and Enterprise Case Study, Transnational Corporations Journal UNCTAD/DTCI/31 Vol.5 No.1, 1996

<sup>21</sup> See [www.egs.apec.org/projects](http://www.egs.apec.org/projects)

<sup>22</sup> Blind, K: The Impact of Regulation on Innovation, NESTA and University of Manchester, part of the Compendium of Evidence on the Effectiveness of Innovation Policy Intervention Project, 2012

**Table 2-4: Negative and Positive effects of Regulation on Innovation**

<b>Examples</b>	<b>Potential negative effects</b>	<b>Potential positive effects</b>	<b>Overall evidence</b>
Competition laws (Economic)	May inhibit collaboration	Increases incentives to invest in innovation	Mixed
Merger and Acquisition regulation (Economic)	Limit takeover pressures and market differentiation	Allows takeovers and protects from short term market pressures	Mixed
Market entry (Economic)	May prohibit innovative new comers and protect non-innovating incumbents	Reduces competition for incumbents especially infant industries	Indirect
Environment protection (social)	Increases compliance costs	Creates incentives for new products	Mainly positive
Worker health and safety (Social)	Increases compliance costs	Creates incentives for new products	Not tested
Public health and safety	Increase product testing and approval costs	Prevent injuries and deaths from new products	Mixed
Intellectual property rights (administrative)	Prevent innovation by restricting use by others	Create incentives to invest in research and development	Mixed
Immigration (administrative)	Costs of integration of foreign workers	Increases pressure on domestic workers to improve	No impacts

Source: derived from: Blind (2012) and Frontier Economics (2012)<sup>23</sup>

The impact of regulation on innovation also needs to take account of the following:<sup>24</sup>

- the length of time since the regulation was introduced – costs may be high in the introductory period and may reduce over time;
- the sector; and
- the size of the organisation – new regulations may place larger burdens on SMEs which have fewer staff and may have less ability to adapt to new requirements.

### **THE CASE STUDIES**

As a result APEC's requirements and the initial literature review, the focus of these case studies is

- regulations which aim to promote innovation; and
- regulations where analysis may lead to new insights into effective regulatory policy measures to support innovation, particularly in SMEs.

The selection process also favoured regulations which had been in place for several years, to ensure that the impact over time could be examined.

<sup>23</sup> Frontier Economics (2012): The Impact of Regulation on Growth, May 2012

<sup>24</sup> Blind (2012) *op cit*

These preferences, as well as the accessibility of relevant information, led to the decision to focus on regulation of IP protection in Korea; regulation of pharmaceutical clinical trials in Malaysia; and regulation of urban water management, including recycling and disposal, in Australia and Singapore. These are further expanded below.

### **Utility patents in Korea**

The patents system is an example of an administrative regulation which was introduced specifically to support innovation. International harmonization, through the operation of several treaties, has strongly influenced the regulatory frameworks established by central governments seeking to support trade by their own and other economies' companies.<sup>25</sup> Utility patent regimes have been introduced in many APEC economies, generally to enhance use of IP protection by SMEs. In Korea, the system has been in place since just after World War II, with two major changes in 1999 and 2006. Further, there have been significant efforts by the Korean government to enhance capability amongst SMEs. The case study provides an example of the use of full and utility patents by consumer electronics companies.

### **Pharmaceutical clinical trials in Malaysia**

Clinical trials regulations are part of a suite of pharmaceutical development regulations aimed primarily at public health and safety. International regulatory harmonization has been significant, but more recent than in the patent system,<sup>26</sup> and as a result there are significant differences in regulations between APEC member economies. Malaysia was an early adopter of international standards and has been active in ensuring compliance; hence there has been a greater development of indigenous capacity, which has been explored in the case study.<sup>27</sup>

### **Urban water supply and re-use in Singapore and Australia**

Access to and use/reuse of water are significant issues in APEC economies. Water management is an example of a social regulation aimed primarily at public health and safety, as well as resource management. There has been some interest in APEC and elsewhere on the adoption of new technologies in waste water treatment and in particular the opportunities offered to SMEs for new business initiatives through development of 'water-sensitive urban design'. Australia was chosen because of its innovative use of planning regulations at local level to promote innovation in water management and Singapore because of its rapid adoption of emerging water management methods, its long history of water management using domestic regulations, and its leverage of these for industry development.

### **Limitations**

As with all projects it has been important to limit the analysis in the case studies to certain issues in order to focus the discussion. Hence it is also important to recognise that there are other, broader, issues that have not been addressed in these case studies, but may be significant in other contexts.

---

<sup>25</sup> Hasson, I: Domestic Implementation of International Obligations – the Quest for World Patent Law Harmonization, Boston College International and Comparative Law Review, 2002 vol 25, Article 10 from the Symposium on Globalization and the Erosion of Sovereignty

<sup>26</sup> Watanawijistrasan, S: Drug Regulations and Incentives for Innovation – the Case of ASEAN

<sup>27</sup> Schulz, G (2012): Clinical Trials in Asia – Opportunities and Challenges

In relation to IP in Korea, apart from touching on some of the costs that the regulatory system adds to new product development, we have not explored the argument about whether intellectual property should be regulated or should be 'open source.'

Similarly, in the Malaysian case study we have not discussed the differing jurisdictional regulation of herbal drugs, nor the regulation of emerging 'medical foods.'

Finally, in the Australia/Singapore water case study, we have not discussed the impact of trade and competition regulation on trade in services.

On the broader matter of innovation, we have selected case studies where the impact on innovation is clear. Hence, we have not been able to consider whether these regulations have acted to maintain the status quo or have promoted diffusion of established technology, rather than inducing innovation.<sup>28</sup>

---

<sup>28</sup> Ashfor N: Understanding Technological Responses of Industrial Firms to Environmental Problems – Implications for Government Policy, in Environmental Strategies for Industry, pp 277-307.K Fischer, J. Schot (Eds.). 1993

### 3. PATENTS AND UTILITY MODELS IN KOREA

#### **INTRODUCTION**

This case study examines the impact of IP regulation, specifically the patent system, on innovation amongst firms in Korea, with special reference to consumer electronics firms. The Korean IP system is an example of an administrative regulation that has been introduced to support innovation, through protecting rights of owners of intellectual property to exploit it commercially.

The case study begins with an explanation of IP, and the role that patents play in the broader IP system, with particular focus on global harmonization of IP rights and the actions of the Korean government to introduce domestic laws that comply with global norms. Within this system, the specific role of utility patents is discussed.

The case study then moves on to discuss the impact of the patent regulations on innovation, in the broader Korean economic context, particularly since the mid-1980s. The interplay between the patent laws and industry policy is also discussed. The case study uses the APEC analytical framework to review the development, promulgation and review of patent regulations, focusing on SMEs as stakeholders. The case study concludes with a summary of how Korea compares internationally in its patenting activity and competitiveness as a result of harmonization of its patent system, and lessons for other APEC economies.

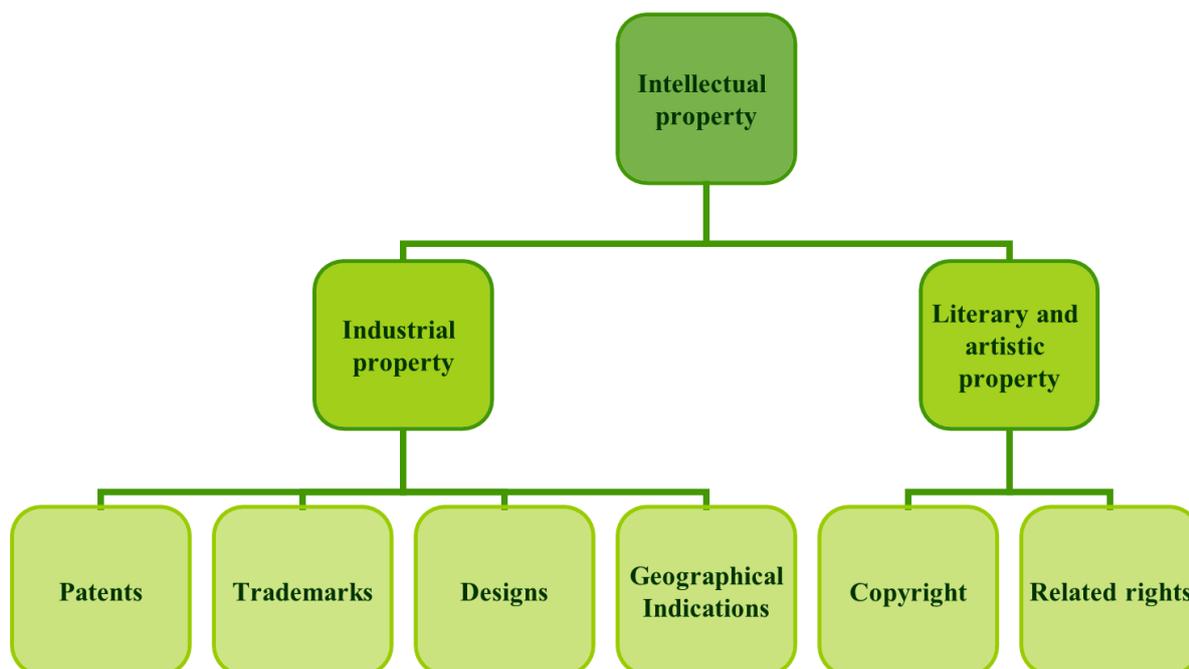
#### **WHAT IS INTELLECTUAL PROPERTY (IP)**

The World Intellectual Property Organization (WIPO) defines IP as “creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce.”<sup>29</sup> Broadly speaking, IP is protected under a framework that includes patents, copyright, trademarks, industrial designs, and geographical indications (Figure 3-1).

---

<sup>29</sup> WIPO (2004): World Intellectual Property Handbook, WIPO Publication 489E

Figure 3-1: Classification of Intellectual Property



Source: Author’s analysis

### Regulation of intellectual property through international patent systems

Patents are social regulations which aim to protect social rights. A patent is an exclusive right granted by an economy to an inventor. It allows the inventor to stop others from using their invention, or to control how that invention is used by third parties. Patents therefore promote innovation through granting limited monopolies. In general, patents are only granted on an invention that is novel (not already in the public domain and not part of other inventions); for an invention that is useful; and if enough information is disclosed to enable someone who is skilled in that field to practice it. Patents are granted for a period of 20 years and in most jurisdictions must not have been disclosed publicly or used commercially before the patent application is submitted.

The patent protection regulatory system uses a combination of approaches to give effect to the protections offered to patent holders, mainly bans and technical standards (Table 3-1).

Table 3-1: Approaches to Patent Regulation

Bans	Technical Standard	Planning Standards	Pricing and levies	Permits
Certain types of products and services may not be patented	Patents must meet technical criteria for novelty and “non-obviousness”	Not applicable	Usually on cost recovery basis.	Minimum technical standards required for patent examiners

Source: Author’s analysis

The regulatory framework for patents has been built up over the last 500 years, starting in the UK. Internationally, the WIPO now administers several treaties and conventions relating to protection of IP, dating back to the 1880s. Those relating to patents include the Paris Convention for the Protection of Industrial Property, the Patent Cooperation Treaty, the

Trade-related Aspects of Intellectual Property Rights (TRIPS) Agreement, the Patent Law Treaty and the Strasbourg Agreement on the International Patent Classification.<sup>30</sup> All APEC members (except for Hong Kong, China<sup>31</sup> and Chinese Taipei) have signed the Paris Convention and the Patent Cooperation Treaty and hence their IP can be protected and exploited internationally. Later treaties aim to improve administration of the international system by protecting IP rights in international trade, streamlining application processes, and agreeing on international classification schemes.

Each economy operates its own intellectual property offices, which administer their own regulations including those in force due to international obligations. Within those offices patent examiners, who usually have technical and legal qualifications, examine patent applications and determine whether they meet the requirements for novelty and non-obviousness by reference to other patents granted locally and internationally, and through reference to what is already in the public domain.

The Republic of Korea originally enacted laws to provide patent, trademark and design protection in 1908 (based on those in Japan).<sup>32</sup> In line with many jurisdictions, Korea has amended and extended its patent laws to align with international practice, firstly in 1974 when it signed a patent treaty with Japan.<sup>33</sup> The government agency with current responsibility for administering these laws, the Korea Intellectual Property Office (KIPO), was established in 1977. Korea joined WIPO in 1979 and from 1980 started introducing changes to align with its obligations under international harmonization principles. These changes included extended the scope of patentable subject matter and extending the patent term of full patents from 12 years from the date acceptance is published to 20 years from the date the application for a patent is lodged.

### **Utility model patents**

The utility model patent (also called petty patent or innovation patent and, more generally, second tier patents) has been introduced in many jurisdictions. Utility model patents differ from standard patents in the following ways:<sup>34,35</sup>

- a utility model patent protection is generally for 7 to 10 years (cf. 20 years for standard patent);
- utility model patent rights may be granted without examination of the claims by the patent office (saving in time and application/examination costs);
- the protection granted may be less rigorous; and
- there may be limits on the types of subject matter that can be protected, compared to standard or full patents.

---

<sup>30</sup> [www.wipo.int](http://www.wipo.int), various

<sup>31</sup> Although Hong Kong, China has not signed the Paris Convention and the Patent Cooperation Treaty, China being a Contracting Party to each of these two international conventions, has applied them to Hong Kong, China since 1 July 1997

<sup>32</sup> Lee, K (2012): Intellectual Property and Economic Development in the Republic of Korea – An Introduction, in *The Economics of Intellectual Property in the Republic of Korea*, WIPO, 2012

<sup>33</sup> *Ibid* page 16

<sup>34</sup> Janis, M (1999): Second Tier Patent Protection, Faculty Publications. Paper 543; [www.repository.law.indiana.edu/facpub/543](http://www.repository.law.indiana.edu/facpub/543). Harvard International Law Jnl 40(1): 151-219

<sup>35</sup> WIPO provides a summary of the general characteristics of utility model patents at [www.wipo.int/sme/en/ip\\_business/utility\\_models/utility\\_models.htm](http://www.wipo.int/sme/en/ip_business/utility_models/utility_models.htm)

The use of utility models varies greatly between economies. In some economies, utility model patents can only be obtained for certain technologies e.g. mechanical technologies/products. Utility model applications are usually dominated by “resident” (domestic) inventors, and are more often likely to be from small to medium enterprises (SMEs); however application from domestic organisations can vary from 60% - 99% depending on the economy.

Therefore, utility model patents generally require lower technical standards, and there are more limits on the type of product or service, compare to full patents. A utility model patent may be lower cost than a full patent, but according to experts interviewed for this project, it is examination costs that are lower costs, rather than deliberate concessional pricing policies.

### **IMPACT OF PATENTS ON INNOVATION**

#### **Costs and benefits of the patent system**

In economic terms, patent regulations affect the propensity to innovate but at the same time limit the ability of others to exploit that innovation – thus there are costs and benefits of a patent system operating within an economy.

Costs arise to the patent applicant directly and at the time the patent is applied for and then granted. There is an argument that the costs of patenting, and the right granted to the inventor, can limit invention and hence innovation. Both IP and some components of regulatory systems can be perceived as barriers to innovation by many companies, despite their “enabling” effect, because of the costs associated with securing and prosecuting IP protection and the trial process itself.<sup>36</sup> Full examination of this topic, it has been noted previously, is beyond the scope of this work. However, it should be understood that patent rights granted within an economy are not monopolies on specific products, merely rights over the way a specific product can be manufactured. Hence, competition can (and clearly does) flourish in those economies which grant protection to inventors through the patent system.

While there may be direct costs to the inventor associated with patenting, academic studies have shown that economies which have strong patent protection regimes also have high R&D – this is because R&D expenditure can be protected by taking out patents on the outcomes of that R&D.<sup>37</sup> Hence, such studies often conclude that “protecting intellectual property should be a public policy goal of developing economies seeking sustained economic growth.”<sup>38</sup>

Costs must, of course, be weighed against benefits. Benefits of protecting IP may be immediate, because after submitting an application IP owners can then license the technology to third parties or can threaten competitors. Other companies also benefit from patenting because the patent application is granted (after a set period) so that others can find out about the invention, and avoid wasteful innovation efforts.<sup>39</sup>

---

<sup>36</sup> *Ibid*, Table 2 – Barrier Importance Ratings

<sup>37</sup> Rapp, R and Rozek, R: Benefits and Costs of Intellectual Property in Developing Countries, *Journal of World Trade*, Issue 5, pp77-102 (1990)

<sup>38</sup> *Ibid*, page 102

<sup>39</sup> Langinier, C and Moschino, G (2002): *The Economics of Patents – an Overview*, Iowa State University Working paper 02-WP93

The harmonization of IP regulation and the increasing importance of trade have led companies to increase patent applications in non-domestic markets. This is achieved through the Patent Cooperation Treaty (PCT) which allows companies to indicate, when lodging their first application, that they wish the application to be examined in any economy which is a party to the treaty. Hence, for example, a Korean company, lodging a PCT application with KIPO, can ask for the application to be examined for protection in the US, Europe, Australia etc.

Once granted, and on payment of fees, the patent is then in force in those jurisdictions and the company can take infringers to court for damages or other reparation. Granting a patent in another economy protects companies which export product or manufacture in those economies.

Patent applications are classified according to the International Patent Classification System, which is based around the type of technology. The top 5 technologies claimed by PCT applications in 2013 are shown in Figure 3-2.

**Figure 3-2: Top 5 technologies claims in PCT applications, 2013**



Source: WIPO Statistics, 2013

### Patents and innovation

It is important to realize that patents themselves are not innovation – patents become innovations when a new good or service has been developed and is being sold in the market. An inventor, or licensee of an invention, can pay for patent protection but may never reap its potential commercial rewards. This might be due to competitors, lack of funding, other regulations that affect whether the product can be sold or advertised, or the simple unattractiveness of the new product or service to consumers.

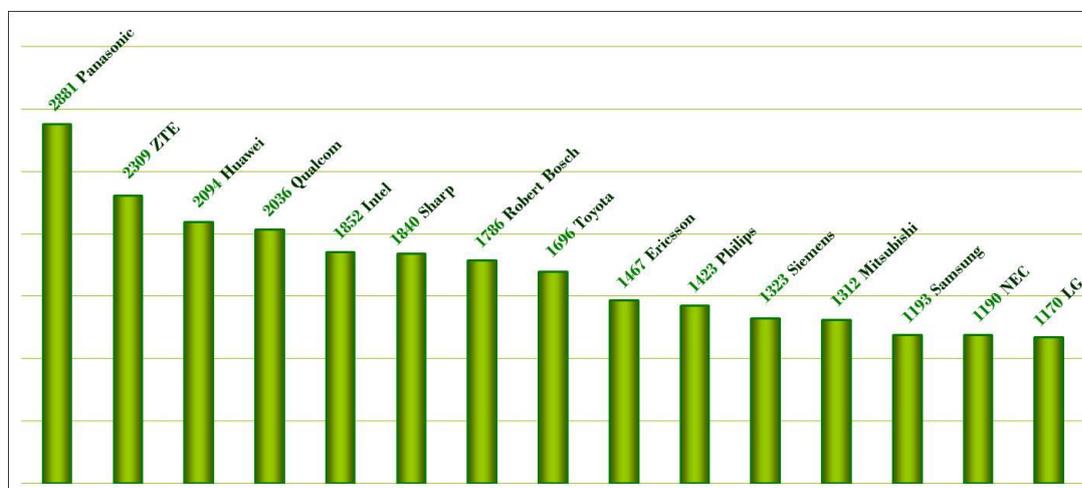
Companies that rely heavily on patentable inventions in order to develop and market their innovations are typically in industries where there is a long or complex development pathway and high amounts of value add,<sup>40</sup> and/or where inventions can be copied by competitors. Industries which rely heavily on patenting include healthcare (including biotechnology), telecommunications, office and electronic equipment, chemicals, and mineral processing.<sup>41</sup>

<sup>40</sup> i.e. the difference between the value of product inputs versus the amount for which the product can be sold on the market. At a national level, Gross Domestic Product is a measure of industry value-add.

<sup>41</sup> For further reading on this issue see for example Archibugi, D: Patenting as an Indicator of Technological Innovation – a review, *Jnl of Science and Public Policy*, Vol 19(6): 357-368, (1992)

It is unsurprising, therefore, to find that major patent filing companies are in industries such as electronics, consumer products and information technology. The top 3 filing companies in 2013, and 7 of the top 15 filing companies, were all in APEC member economies. The top three were Panasonic (Japan), ZTE (China) and Huawei (China).<sup>42</sup> Korean company Samsung was ranked 13<sup>th</sup> in this list (1,193 applications), and LG was ranked 15<sup>th</sup> (1,170 PCT applications) (Figure 3-3).

Figure 3-3: Top 15 Companies Filing PCT Applications, 2013



Source: derived from WIPO PCT statistics, 3

## DEVELOPMENT OF THE PATENT SYSTEM IN the REPUBLIC OF KOREA

### General patent laws

Korea has changed rapidly in the last 40 years, moving from a follower of technology to a creator of technology. This is due in part to the harmonization of IP law and the resulting opportunities provided to Korean firms.

Korea's first modern patent laws, introduced in 1946, were modelled on US laws.<sup>43</sup> The main features were a 17 year patent period and a 'first to invent' requirement – this means that the first person to invent can win a claim, even if another person has filed an earlier application for the same invention with the patent office.

This law continued unchanged until 1961. After 1961, the Korean government changed the 'first to invent' rule to a 'first-to-file' rule – thus bringing it into line with WIPO standards. First to file means that even if two people have made the same invention, the first person to lodge the patent application with the patent office has the first rights to be granted the invention. The review in 1961 also resulted in a reduction in the patent term to 12 years, and a narrowing of the subject matter that could be protected.

In the 1970s the laws were further updated to align with international standards, the first amendment being changes to the requirements for novelty, in 1973. Korea signed a patent treaty with Japan in 1974 and this led to an increase in Korean applications from Japanese

<sup>42</sup> WIPO International Filing Figures 2013 op cit

<sup>43</sup> Lee, K (2012): Intellectual Property and the Development of IP Law in Korea – An Introduction *in* Lee, K (ed): The Economics of Intellectual Property in the Republic of Korea, WIPO 2012

organisations. A similar treaty was signed with the US in 1978 and the patent term was extended to 15 years, another move to harmonize internationally.

Changes in the 1980s included further harmonization including adoption of new patentable subject matter, particularly in biotechnology/pharmaceuticals and business methods (information technology systems). This was further extended to plants in the 1990s and the patent term was extended to 20 years, bringing it into line with requirements under TRIPs. The government also established the Patent Court in 1998, a professional court established in which technical advisors sit beside judges and provide opinion in relation to cases involving patent and utility models.

Gradual harmonization by Korea has led to overall strengthening of its patent regime in the context of industry development, when considered against international best practice.<sup>44</sup> It should be noted that, over the period from 1960 to the 1990s, Korea was one of a small number of developing economies which substantially increased its patent protection when compared to other economies – and by the 1980's it had reached par with developed economies. This change paralleled an increase in market freedom in the Korean economy, which, together with investment in R&D, has been reported as a major determinant of implementation of patent protection regulations by economies.<sup>45</sup>

### **Utility model laws**

Korea introduced utility models in 1946, at the same time that the initial 'modern' law commenced.<sup>46</sup> The system also continued unchanged until 1961. During this period, utility models were not examined and could be granted relatively quickly, while over the same period examination of a full patent took 3-4 years. As a result, and also due to the domestic focus of most Korean firms, Korean organisations and individuals applied for more utility model patents than full patents right through to 1995. In 1961, as part of the review mentioned above, utility models had to pass examination before they could be registered. According to academic articles, these changes in 1961 were specifically intended to promote rapid industrialization.<sup>47</sup>

The law changed again in 1999, from which date all utility model applications in Korea were registered without examination. They were also processed very quickly, under a 'FastTrack' system which aimed to grant rights speedily, so that companies which had short life cycle products could gain protection for them.<sup>48</sup> While registration was quick, utility model patents still had to be examined before a company could rely on their rights in them, and this part of the process was quite slow.

Between 1999 and 2006 it was also possible to file a patent application and a utility model application for the same invention. Applicants then decided whether to cover the invention under either utility model or full patent law, after both were granted. In practice, this meant

---

<sup>44</sup> Park, (2008): International Patent Protection 1960-2005, Research Policy, 37:761-766

<sup>45</sup> Ginarte, J and Park, W: Determinants of Patent Rights – A Cross-National Study, Research Policy 26:283-301 (1997)

<sup>46</sup> Kim, Y K, Lee, K and Choo, KN Intellectual Property Rights and Innovation in Economic Development in Korea, *in* Lee, K (ed): The Economics of Intellectual Property in the Republic of Korea, WIPO 2012

<sup>47</sup> Han, J and Jang, K-C: Impact of the Intellectual Property System on Economic Growth, Fact Finding Analysis and Surveys in Asia, Country Report – Korea, 2007, WIPO-UNI Joint Research Project, 15pp

<sup>48</sup> Kim, YK (2012) *op cit*

that companies waited (up to three years) until the full patent was examined, and then made that choice.

The changes in 1999 had been introduced because of frustration with delays in examining applications. However, the ease with which utility model patents could be registered led to concern, among government and industry, about the quality of many utility model patents. There was also an increase in the number of inter-company disputes, caused by companies claiming utility model rights when similar rights were held or being claimed by others.

As a result of these events, industry lobbied KIPO to revise the law. Over this period, KIPO had also made considerable progress in speeding examination of full patents, so that the delays which previously inhibited companies from applying for full patents began to disappear – by 2006, full patent examination took only twelve months, and the fees charged to examine utility patent applications were similar to those charged for full patents.

All this led the government to decide that the law’s costs were greater than its benefits. While there was no formal cost-benefit analysis at the time, the fact that industry initiated the changes was a major influence. In 2006 the government reverted to the pre-1999 approach. This meant that from the end of 2006 both utility model applications and full applications had to pass examination before rights were granted.

The Korean utility model system now offers applicants the opportunity to obtain protection, following examination, for devices, tools and implements (but not processes or methods of production) for a period of 10 years. The inventive step for this protection is lower (less) than that required under Patent Law. A summary of the current differences in Korea between utility model patents and full patents are shown in Table 3-2.

**Table 3-2: Major Differences between Utility Models and Full Patents in Korea**

<b>Area</b>	<b>Utility Model</b>	<b>Full Patent (summary)</b>
Subject	A creation of a technical idea using rules of nature, covering shape, structure or a combination	A highly advanced creation of a technical idea using the rules of nature
Requirements	Basic Requirements	Requires novelty and inventive step
Period of Amendment	Within two months after application / Within one month after the order for correction	Before the examiner grants the patent or before applicant receives notice of reasons for rejection, and other reasons
Decisions	Registration for establishment of rights or decision to decline	Decision for registration of patent or decision for refusal of registration
Term	10 Years	20 Years
Condition of Enforcement	After submitting and giving notice of the certificate of the decision to maintain rights	Registration for establishment of rights
Opposition	Any person can request opposition within three months of the publication of registration	Any person can request opposition within three months of the publication of registration
Request for Examination	After registration, any person can request	Within 5 years from the date of application, any person can request
Renewals	Not permitted	Not permitted

Source: extracted from table at KIPO, <http://www.kipo.go.kr>; data are for post 2006

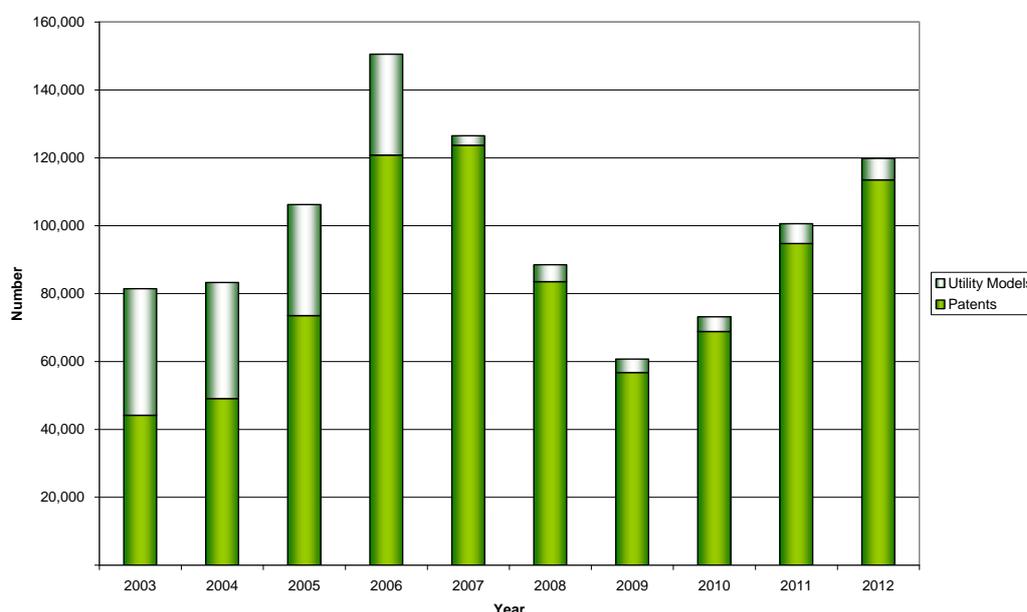
Since 2006 the utility model system has remained stable. There has been no formal review of the effectiveness of the changes implemented at that time but the number of patent disputes has fallen markedly and KIPO has taken this as an indicator that the change in policy has been successful.

### The balance between use of utility and full patents in Korea

Utility model patent dominated the Korean IP system from their inception through to the mid-1990s. From the mid-1980s individual applicants were gradually overtaken by company applicants, as the latter began to understand the value of patents more fully.<sup>49</sup> As a result, domestic organisations rose from 69% of all registrants in 2003 to 76% in 2012; whereas at the same time domestic registrants for utility patents held steady at around 97%-98%. By 1995, the number of full patent applications exceeded the number of utility model applications for the first time.<sup>50</sup>

Figure 3-4 shows utility model and full patent registrations over the last 10 years. Rapid growth from 2003 to 2006 is obvious and supports others' assertions that from 2000 to 2006, IP registrations in Korea grew at an average annual rate of 23%, bettered only by China which increased its patenting by 26.5% over that period.<sup>51</sup> The fall in overall patenting in 2008 and 2009 was most likely due to the combined effects of the Global Financial Crisis and also efforts by KIPO to moderate the workload on its examiners.

**Figure 3-4: Relative Use of Utility Models and Full Patents in Korea, 2003-2012**



Source: KIPO site search, all registrations, author's analysis

The falloff in utility model patents as a result of changes in the law in 2006 will also be noted. Utility model patents have now fallen from more than 55% of all patents in 2003 to around 5% in 2012. According to observers, by 2006 KIPO had also overcome many of the

<sup>49</sup> Lee, K and Kim, YK: IPR and Technological Catch-Up in Korea (2010), Intellectual Property Rights, *in*: Odagiri, H., Goto, A., Sunami A. and Nelson, R (eds): and Catch-up, London: Oxford University Press, 2010

<sup>50</sup> Kim, YK (2012) *op cit*, Figure 2

<sup>51</sup> Park, K (2012): *op cit* Figures 1 and 2 and page 45

delays in examining full patents, so that the only differences between obtaining a full patent and a utility model patent was a slight reduction in scope for utility model patents, and a shorter term. As the effort required to obtain a full patent was similar to that required for a utility model patent, companies began to emphasise full patents where their invention warranted and could gain that level of protection. Hence, the trend has now moved towards full patents.

This trend is in line with academic research that also notes a tendency for firms which have experience in utility model patents being more likely to apply for a full patent. It is also consistent with Korea's greater economic and technological development – once a firm becomes technologically advanced, utility models fall in importance relative to full patents.<sup>52</sup>

### **Link between patent regulations and technical standards**

Technical standards also play an important secondary role in the ability of IP owners to gain benefits from their inventions through manufacture and sale of goods and services. Equipment manufacturers, governments and industry groups interact in complex ways in the setting of standards. Governments can have a major role, and this has indeed been the case in the emergence of Korea as a major player in the mobile telecommunications markets.<sup>53</sup>

There is concern amongst APEC that standards act as non-tariff barriers to trade.<sup>54</sup> However, technical standards are also a necessity if appliances and equipment, including electronic and telecommunications equipment, is going to be able to be exported for use in other economies. APEC is particularly concerned about the ability of SMEs to participate in global supply chains and, while again this is not a subject for detailed consideration in this case study, harmonization of technical standards is also a necessary step in international exploitation of patented IP.

### **Link between patent regulations and industry policy**

Over the past 50 years Korea has moved from a net importer of technology to a technology-producer. Part of this change has been driven by government policy and part by companies' responses to external factors, as summarised in Table 3-3.

---

<sup>52</sup> Park, K: The Effectiveness of Patents and the Determinants of Patenting Activities in Korea, in Lee, K (ed): The Economics of Intellectual Property in the Republic of Korea, WIPO, 2012

<sup>53</sup> Jho, W: Global political economy of technology standardization: A case of the Korean mobile telecommunications market, *Telecommunications Policy*, 31(2): 124-138 (2007)

<sup>54</sup> 2011 Leaders' Declaration, "The Honolulu Declaration – Towards a Seamless Regional Economy, 19<sup>th</sup> APEC Economic Leaders' Meeting

**Table 3-3: Development history of Korean economy**

<b>Period</b>	<b>Government Policies</b>	<b>Economic characteristic</b>	<b>Innovation characteristics</b>
1960s to mid 1970s	Export led growth policy	Assembly or processing of imported parts	Low technological capacity, low R&D expenditure
1970s	Foreign Capital Inducement Act, Technology Development Promotion Act	Imports facilitated, foreign direct investment increases	Technology transfer facilitated
Mid 1970s to mid 1980s	Easing of import criteria	Shift towards heavy and chemical industries, emergence of chaebols (business groups)	Formal technology licensing and learning
Mid 1980s to mid 1990s	Relaxation of prior approval criteria for R&D institutes, tax waivers for private R&D	Rapid catch up led by major businesses in knowledge intensive products, foreign companies limit tech transfer	Establishment of in-house R&D centres
From mid 1990s	Korea joins OECD, capital market liberalization, SME policy	Major economic restructuring including emergence of SMEs	In-house technical capacity in large companies, enhanced SME education

Source: Derived from Lee, K (2012): *op cit*

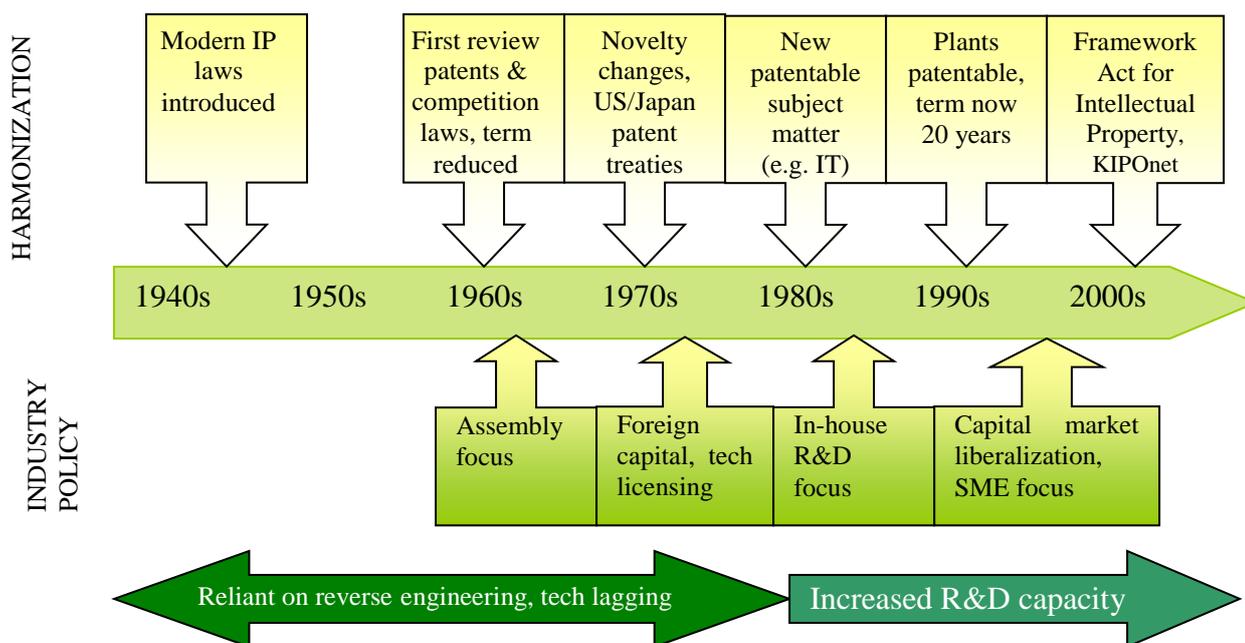
According to academic analyses, the development and the patent regime and domestic innovative capacity have been closely linked only since the mid-1980s, when in-house R&D began to be important for Korean firms. Such studies have also concluded that stronger patent rights protection is associated with more patenting after companies have become technologically advanced and/or have higher R&D intensity.<sup>55</sup> Other academic studies of Korean SMEs support the notion that use of domestic and international IP protection, be it patent or utility model (as appropriate) is a significant factor in determining whether a company is internationally leading.<sup>56</sup> R&D and its protection are a core issue for such SMEs in the face of increasing international competition, and hence reliance on the framework provided by IP regulations is likely to remain important.

The key relationships between Korean industry policy and IP policy over time are shown in Figure 3-5.

<sup>55</sup> Kim YK et al (2012): *op cit* page 31

<sup>56</sup> Suh, Y and Kim, M (2014): Internationally leading SMEs vs Internationalized SMEs – Evidence of Success Factors from South Korea, *International Business Review* 23: 115-129

Figure 3-5: Korean IP Regulations and Major Industry Developments



Source: Author's analysis

### ***KIPO's DEVELOPMENT AND REVIEW OF REGULATIONS***

#### **International regulatory harmonization**

The main driver of regulatory change in intellectual property law in Korea is international harmonization. This has been the most important factor in enabling Korean firms to take advantage of IP regimes in other economies, and thus being able to export their products and manufacture overseas.

In 2007 Korea and China commenced working with the 'IP3' to help improve administration of patents worldwide. The IP3, or trilateral patent offices, consist of the US Patent Office, European Patent Office and Japan Patent Office. This group agreed to cooperate in 1985 to improve the efficiency of the global patent system.<sup>57</sup> China and Korea are now in the top 5 patent offices worldwide, and their involvement in IP3 aims to try to predict patent applications and hence help patent offices to respond efficiently to demand.<sup>58</sup>

In this context, the most important stakeholders for Korea are other economies with which it trades and to which its companies export – the US and China being amongst these. Harmonization of patent law is the means by which the Korean government ensures that its companies are protected when they operate in international markets.

Only a subset of Korea's trading partners operate both full patent and utility model systems. However, it is the full patent system that is the more important of the two internationally.

<sup>57</sup> [www.trilateral.net](http://www.trilateral.net)

<sup>58</sup> Ollier, P (2007): China and Korea Boost Trilateral Ties, Managing Intellectual Property, archives at [www.managingip.com](http://www.managingip.com)

## **Economy-level IP law reviews**

The current overriding law within Korea is the Framework Act on Intellectual Property, enacted in 2011. The regulations, among other things, “aim to contribute to the common development of the international community by bringing harmony between domestic norms and international norms on intellectual property.”<sup>59</sup>

Within Korea, the government considers companies and the general public to be major stakeholders when considering regulatory change, bearing in mind that the overriding framework is governed by international harmonization. In this context, Korea will be unlikely to make major changes to its patent regulatory system, if such changes mean it moves away from harmonization.

When changes are considered to any laws Korean stakeholders are consulted through a multi-step process which provides an opportunity for input at many points along the way. The length of time available for public comment, when new or revised legislation is proposed, is 40 days (extended from 20 days in 1999 as a result of the Korea-USA Free Trade Agreement). Organisations such as KINPA are consulted and input is obtained through KIPO.

Once new or amended regulations are finalised (e.g. the changes to the utility patent laws in 2006) the final regulations are available online and are promulgated through specific educational programs (see below).

The First Strategic Plan for Intellectual Property, covering the period 2012-2016, was launched after the current IP Act was adopted.<sup>60</sup> The Action Plan has two main focuses – securing effective IP protection and promoting high value IP creation – effectively combining the management of IP regulation with industry policies designed to capture and commercialize IP. The focus of action on management is on administrative action – enhancing reliability of examination and registration, strengthening IP protection at home and overseas, improving dispute resolution.

## **Transparency**

KIPO has an extensive website and has offered an online application system for new patents since 1999. It also publishes its annual report, major statistics and other reports online so they are accessible in both Korean and English.

KIPO also works actively to assist all companies, but particularly smaller ones, to understand the patent system. According to WIPO, it is one of the few economies to do so, and in this it works with chambers of commerce, the Korean Patent Attorneys’ Association and the government SME support agency.<sup>61</sup>

KIPO offers free education for SMEs on the online patent information search systems (the New Patent/Utility Model Search System and the Korea Industrial Property Rights Information Service (KIPRIS)).<sup>62</sup> KIPO’s Innovation Promotion System operates 30 training

---

<sup>59</sup> Framework on Intellectual Property (2001) – Article 2

<sup>60</sup> Striving for IP Excellence – Korea’s National Strategy for Intellectual Property, Summary Document

<sup>61</sup> Burrone, E and Jaiya, GS: Intellectual Property Rights and Innovation in Small and Medium Enterprises, WIPO (2003, approx)

<sup>62</sup> WIPO - [www.wipo.int/sme/en/best\\_practices/kipo.htm#P25\\_488](http://www.wipo.int/sme/en/best_practices/kipo.htm#P25_488)

centres around Korea to enable SMEs to obtain advice. Its IP Training Centre is available for Korean citizens and entities (SMEs, general public) to attend courses on IP and its management. The IP Training Centre also runs courses for foreigners, mainly under the aid program, on IP management. The IP Training Centre is funded for these courses through the Korean Overseas International Cooperation Agency (aid agency).

KIPO also provides software for SMEs to do their own patent mapping (a patent search which enables a company to map competitors' technologies).<sup>63</sup> It also directly assists SMEs in patent searching and in reducing the cost of applying for and examining a patent. Fees for KIPO to conduct a "prior art" search for SMEs are lower than for larger companies, and KIPO also offers SMEs a patent management service.<sup>64</sup> SMEs and general members of the public can ask KIPO questions directly through their website.

Academic studies of SMEs in Korea have reported that assistance by KIPO has a positive impact on IP creation, as long as the service is customized to the needs of the companies it aims to assist.<sup>65</sup> This is particularly important for low income or poorly-informed groups, where education coupled with subsidization of the early stages of IP protection is essential to maximizing benefits.

A number of industry associations also provide assistance to their members in prosecuting patent breaches. Members of the Korean Electronics Association range from small to large firms. KEA's International Patent Assistance Center helps SMEs respond to patent infringement suits by US (and other) firms<sup>66</sup> and also advises on how to avoid patent disputes.<sup>67</sup>

### **Evaluation of impact of patent regulations**

KIPO does not have a formal program of evaluation of the effectiveness of regulatory changes, but pays attention to industry feedback and objective measures such as increases and decreases in patent disputes.

The main means by which KIPO obtains industry input is by occasional surveys of companies and patent attorneys, and through involvement in the Korean Intellectual Property Association (KINPA).<sup>68</sup> KINPA is a non-profit industry association with fewer than 110 members, and hence it represents the larger companies, mainly in chemicals, medicines, electrical, electronic and machinery industries. KINPA does, however, have an SME committee which makes policy proposals to government on behalf of smaller companies. KIPO attends KINPA meetings and obtains feedback from industry on regulatory matters through this mechanism.

---

<sup>63</sup> Lee, K (2012): *op cit* page 17

<sup>64</sup> These are searches conducted by an experience patent attorney and which seek to identify what has already been patented in particular field

<sup>65</sup> Park, N (2012): Intellectual Property Promotion Policies and their Impact in Korea, in: Lee, K (ed): The Economics of Intellectual Property in the Republic of Korea, WIPO, 2012

<sup>66</sup> The Electronic Times, IP Systems News: *Number of U.S. Patent Suits against Small Companies Increases*, 4 July 2012, sourced from [www.leemock.com](http://www.leemock.com)

<sup>67</sup> [www.kea.or.kr](http://www.kea.or.kr) KEA electronic brochure

<sup>68</sup> [www.kinpa.or.kr](http://www.kinpa.or.kr)

A broader level of regulatory evaluation is provided by the Korean Innovation Surveys, which are administered by the Science and Technology Policy Institute (STEPI) every two years and provide an important independent measure of appropriation of innovation through formal and informal mechanisms (WIPO report page 46). This review, however, does not distinguish between uses of utility patents versus full patents.

KIPO's own efficiency and effectiveness is measured through the in-house KIPO Examination Quality Control process, which samples examined cases twice-yearly and gives feedback to the examiner in charge.<sup>69</sup> The results of these analyses are available through the KIPO website. External feedback is sought from companies through a formal stakeholder liaison committee which has representative from KINPA. The committee meets twice yearly to provide feedback to KIPO on its operations.

### **Alignment amongst authorities**

The Korean Government established a Presidential Council on Intellectual Property in 2009, to coordinate government action on IP.<sup>70</sup> It has 13 government members and 19 civilian members, the latter appointed by the President. Names of civilian members do not appear to be public.

The main focus of the Council is the Strategic Plan for IP and associated action plans including their review and evaluation. Five committees of the Council are responsible for creation, protection, utilization, infrastructure of IP, and emerging IP. The Framework and its overriding legislation also requires local government and public sector research institutions to formulate policies for IP and actively utilize it, and cooperate with each other on IP creation and utilization.<sup>71</sup>

The Ministry of Trade Industry and Energy, responsible for industry policy more generally, is aiming to enhance entrepreneurship and identify new value-added industries. Working within this framework, KIPO has announced an action plan for an IP-based Creative Economy, as part of the Korean Government's domestic economic development strategy.<sup>72</sup>

### **Costs and benefits**

There is no doubt that the patent regulations cost companies, because it requires both skills and resources to lodge applications and see them through to being granted. However, the patent system also encourages companies to share information and is the internationally recognised system of IP protection. Thus, it would cost Korea more to opt out of the system, than to remain within it.

The costs of a patent system fall more heavily on SMEs, proportionately, because SMEs find it more difficult to afford both application and maintenance costs. The utility system alleviates some of these costs, but provides lower protection. However over the years the utility system in Korea has become more aligned with full patents, and this accounts for its reduced use since the law changes of 2006.

---

<sup>69</sup> [www.kipo.go.kr](http://www.kipo.go.kr)

<sup>70</sup> [www.ipkorea.go.kr](http://www.ipkorea.go.kr)

<sup>71</sup> Framework for Intellectual Property, Article 4

<sup>72</sup> KIPO, 2014: *op cit*, page 16

### **Flexibility and 21<sup>st</sup> century regulation**

The Framework for Intellectual Property (Article 8) requires review and implementation of a new IP strategy every 5 years. Each new plan is developed following advice from the Presidential Council.

IP harmonization is also regularly considered when the economy is negotiating trade agreements, particularly free trade agreements. Many of the changes to Korea's IP system can be traced to the influence of international harmonization and trade agreements (e.g. with Japan and the USA).

Potential conflicts with other government actions are avoided by provisions of the Framework for Intellectual Property, which specifically states that where other government regulations are amended, then they need to satisfy the objectives of the Framework.<sup>73</sup>

However there is also scope for minor amendments to patent laws if issues arise. KINPA plays a role here but possibly the more important mechanism is informal feedback from SMEs. It is possibly these feedback loops that have led KIPO to introduce a number of administrative changes to enable SMEs (and, as a result, companies of all sizes) to interact more easily with it. These include allowing companies to meet with examiners prior to submitting applications, and providing for collective examination of groups of patents related to a single product (e.g. for smartphone technology which includes IP for display systems, power, antennas, electronic hardware and software).<sup>74</sup> Such interactions provide KIPO with unrivalled direct access to SME customers and potential for enhanced feedback to government on the operation of patent regulations and the need for review.

KIPO also publishes excellent annual statistics, available for both industry and researchers to analyse. A number of public research institutes also collect data. The most important of these is the Korea Institute of Intellectual Property (KIIP)<sup>75</sup> and the Korean Small Business Institute (KOSBI).<sup>76</sup> KIIP aims to conduct pacesetting research in IP and international competitiveness and to collect and analyse IP trends. KOSBI explores issues facing SMEs and advises government agencies on policy implications. KOSBI also cooperates with similar organisations in other economies, e.g. Chinese Taipei's Industrial Technology Research Institute.

### ***The CURRENT SITUATION***

#### **Patenting in Korea**

Korean companies' marketing strategies have changed considerably with their increased use of the patent system. In 2002, Korean innovation survey showed that most companies favoured a 'first to market' strategy coupled with maintaining trade secrets. Only three years later, in 2004, companies in the same survey were reporting that their favoured mechanisms were patenting, registered designs, complex design and trademarks.<sup>77</sup>

---

<sup>73</sup> Framework for Intellectual Property Article 4.

<sup>74</sup> *Ibid* page 27

<sup>75</sup> [www.kiip.re.kr](http://www.kiip.re.kr)

<sup>76</sup> [www.kosbi.re.kr](http://www.kosbi.re.kr)

<sup>77</sup> Park, K, *op cit* page 47

Across Korea, the industries which use full patents most heavily are information technology, electronics, chemical and metals industries.<sup>78</sup> As might be expected, larger companies are the most active in the Korean patent system. In this it is no different to any other economy. However, with over 8,500 firms in Korea applying for patents in 2005, smaller firms are also heavy users of the patent system.

### The balance of utility models and full patents

The effort required to obtain a utility model patent or full patent in Korea today is almost the same as the effort needed for a full patent, because both need to be examined. There is anecdotal evidence that smaller companies favour utility model patents, but objective evidence is lacking. Larger companies continue to use both systems, particularly where some inventions which cannot pass the requirements for full patenting (Table 3-4).

**Table 3-4: Protection of “Electronic” Inventions, Top Ten Companies**

Company name	2012 – registered		2011 – registered		2010 – registered	
	Utility model	Full patent	Utility model	Full patent	Utility model	Full patent
LG Electronics	1	2,946	2	2,641	1	1,644
Samsung Electronics	61	2,564	2	2,010	1	1,689
Ja Hwa Electronics	5	408	4	348	1	212
Motorola Mobility	2	173	1	179	0	84
D&D Electronics	2	51	3	37	1	31
Unix Electronics	1	37	0	23	1	22
Dongbu Daewoo Electronics Corp.	0	17	0	132	0	120
Lien Chang Electronic Enterprise	3	3	0	3	0	0
Buwon Electronics	2	2	1	2	0	1
KDG Electronics	1	2	2	1	1	0
<b>Total</b>	<b>78</b>	<b>6,203</b>	<b>15</b>	<b>5,376</b>	<b>6</b>	<b>3,803</b>

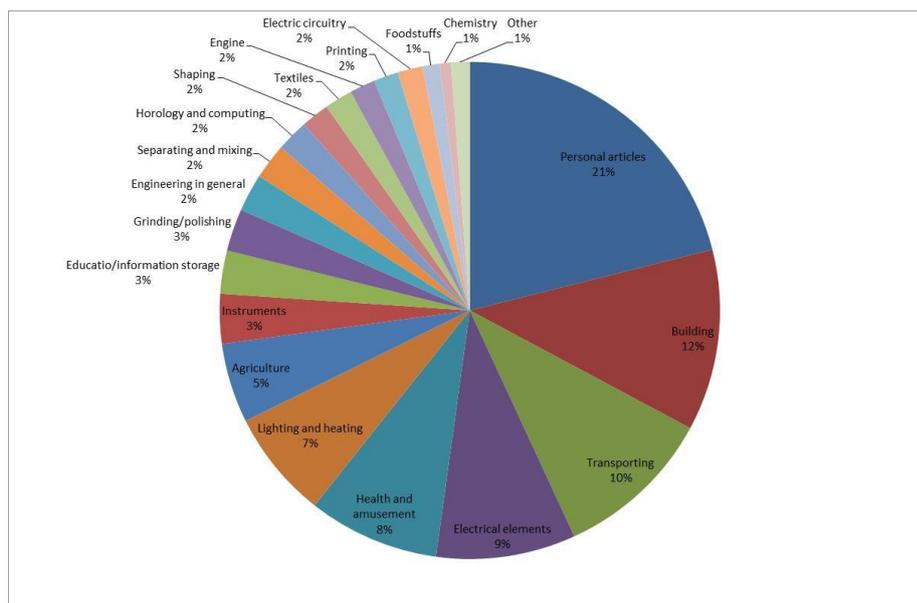
Source: KIPRIS database search (keyword = electronic\$), registered patents only, by registration year

However, there is evidence that as utility models patents are limited to the shape or structure of an article or a combination of articles, and are only valid for 10 years, the heaviest users of utility models are in sectors which rely on fast-moving trends. This is dominated by companies which manufacture personal articles, building components, transportation technologies and electrical technologies, many of which are likely to be SMEs. These accounted for over 50% of utility model applications in 2012 (Figure 3-6).

---

<sup>78</sup> Park, K, *op cit* page 49

**Figure 3-6: Technology focus of Utility Model Applications in Korea**



Source: Author’s analysis, based on 2012 data from KIPO

The consumer electronics industry in Korea also supplies component and sub-assemblies to companies such as Samsung. These companies are more likely to be SMEs and an examination of a limited number of their patents shows great variation in the use of utility versus full patents. It appears from the data (Table 3-5) that the choice of utility model or full patent relates more to the strength of the invention and the type of coverage required, rather than a trend for SMEs to favour utility models, at least in this industry.

**Table 3-5: Protection of Electronic Inventions, Samsung Suppliers<sup>79</sup>**

Supplier	2012		2011		2010		Other
	Utility model	Full patent	Utility model	Full patent	Utility model	Full patent	
Optronics (Chinese Taipei)	0	0	1	3	0	4	Many earlier full patents
Chunghwa Picture Tubes	0	0	0	0	0	0	Seven full patents in previous 3 years
Intops LED company	0	2	0	0	0	1	One utility patent in 2005
Interflex	0	4	0	8	0	8	Many earlier full patents
Sam-Young Electronics	0	2	1	2	1	0	Many earlier full patents
Flexcom	0	2	0	2	2	2	Many earlier full patents
Seshin Electric	0	4	0	1	0	0	No utility model patents

Source: KIPRIS database search for supplier name as applicants, registered patents only, by registration year.

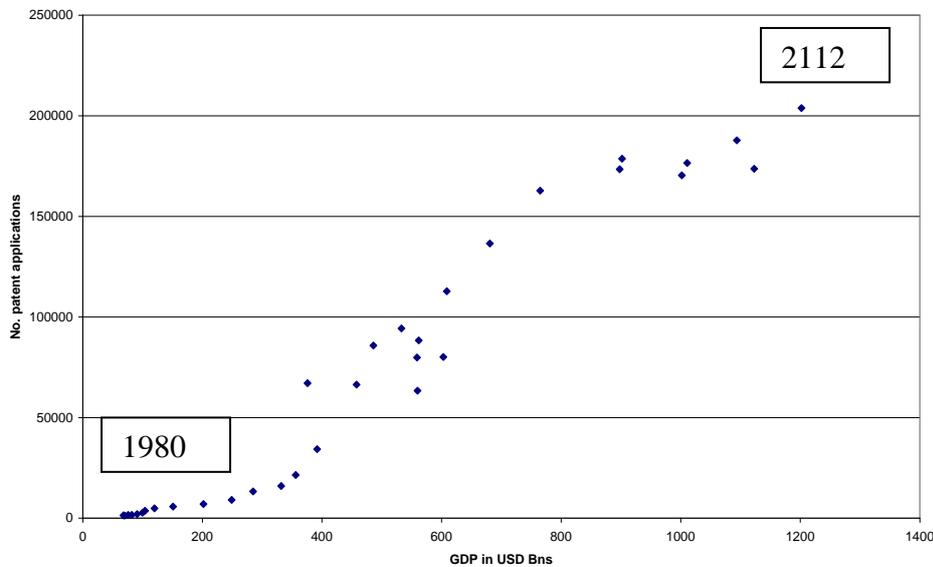
<sup>79</sup> Supplier applicant names from Han, J et al (2008): In the Belly of the Beast - Samsung Electronics’ Supply Chain and Workforce in South Korea –Electronics Industry in Asia, Research Institute for Alternative Workers’ Movements, South Korea, Research Paper no. 3; and [www.viglaceraland.vn/yenphongiz/Investment/ListofEnterprises/tabid/909/Default.aspx](http://www.viglaceraland.vn/yenphongiz/Investment/ListofEnterprises/tabid/909/Default.aspx)

Despite the fall in use of utility models as a proportion of total patent applications, KIPO received from 5,800 to 6,400 utility model applications in each of the last three years,<sup>80</sup> so companies which use utility models are still a significant customer base and users of the IP system.

### Types of innovation

The patent regulations in Korea have enabled companies and inventors to extend the geographic reach of their technical innovations and thus take advantage of opportunities offered by global trade. South Korea had one of the world's fastest growing economies from the 1960s to the 1990s and this has been linked closely to growth in patents (Figure 3-7). While these figures show a strong correlation, rather than a direct cause and effect, the OECD and others accept that patents play an important role in both innovation and economic performance, and that the patent system encourages technology diffusion and technology transactions between markets (either through direct licensing, or trade in goods and services).<sup>81</sup>

**Figure 3-7: Correlation between GDP and Patent Applications, Korea, 1980-2112**



Source: Patent data from WIPO and GDP data from [www.tradingeconomics.com](http://www.tradingeconomics.com)

From other academic studies, it appears that company organisational structures that have changed over the period, including the decline of the chaebols, have been a result of external economic pressures rather than any response to the evolving regulatory system.

Within government there appears to have been little institutional innovation in terms of coordination, however the establishment of SME training centres is an institutional response to the need for change. KIPO has also responded in management and human resource innovation, introducing a range of new approaches to support SMEs, in particular.

<sup>80</sup> KIPO (2013): Annual Report 2013, KIPO, 2014

<sup>81</sup> OECD: Patents and Innovation – Trends and Policy Challenges, OECD 2004

**Table 3-6: Summary of Impacts of Utility Patent Regulations on Innovation**

Type	Positive Effects	Negative Effects
Process	Inventors can protect their IP Use of PCT scheme can enable inventors to protect their IP in many jurisdictions	Favours larger companies, smaller companies can find it just as expensive to lodge utility model applications as full applications
Procedural	Significant changes in KIPO administrative management to support SMEs Higher standard for utility patents provides greater protection	Alignment of utility and full patent systems adds to SME costs
Personnel-related	Added skills in KIPO and inventor organisations, opportunities for patent attorney industry	Costs of training and qualifications
Structural	None indentified	Organisations may pay a higher price for new equipment due to costs of patenting absorbed by developer
Institutional	Establishment of IP training centres for SMEs by KIPO	Additional coordination costs for government

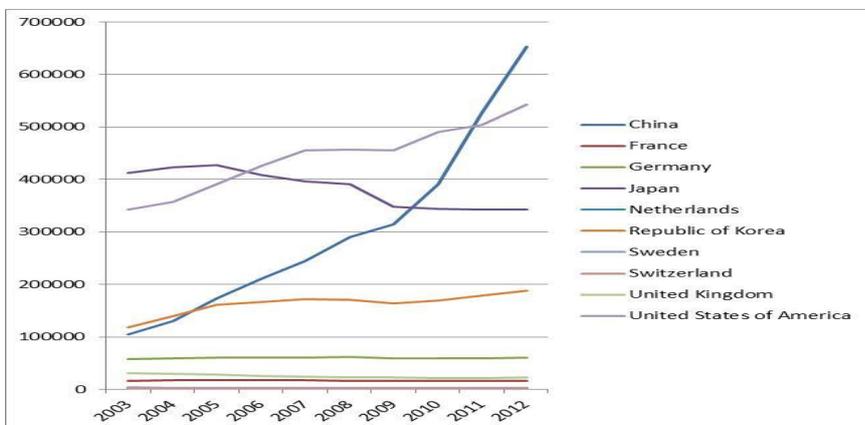
Source: Author’s analysis

**Korea compared to other economies**

As a result of aligning itself with international patenting standards and encouraging technical development, Korea is now ranked 5<sup>th</sup> in PCT applications globally. In 2012 Korean organisations and individuals led the world in resident patent applications per million population, beating Germany by a factor of three and the US by almost four times.<sup>82</sup>

In 2013, organisations in the USA lodged 27.9% of PCT applications (ranked first), Japan lodged 21.3% (ranked 2<sup>nd</sup>); China lodged 10.4% (ranked 3<sup>rd</sup>); and the Republic of Korea lodged 6%.<sup>83,84</sup> European activity, while strong, has stagnated over the last decade (Figure 3-8). PCT applications lodged through KIPO have increased by 37% in this period.

**Figure 3-8: Trends in PCT applications, 2003-2012, Top Ten Economies**



Source: WIPO statistical search for total patent applications (direct and PCT “national phase”), 2013

<sup>82</sup> KIPO (2013): Annual Report 2013, *op cit* page 19

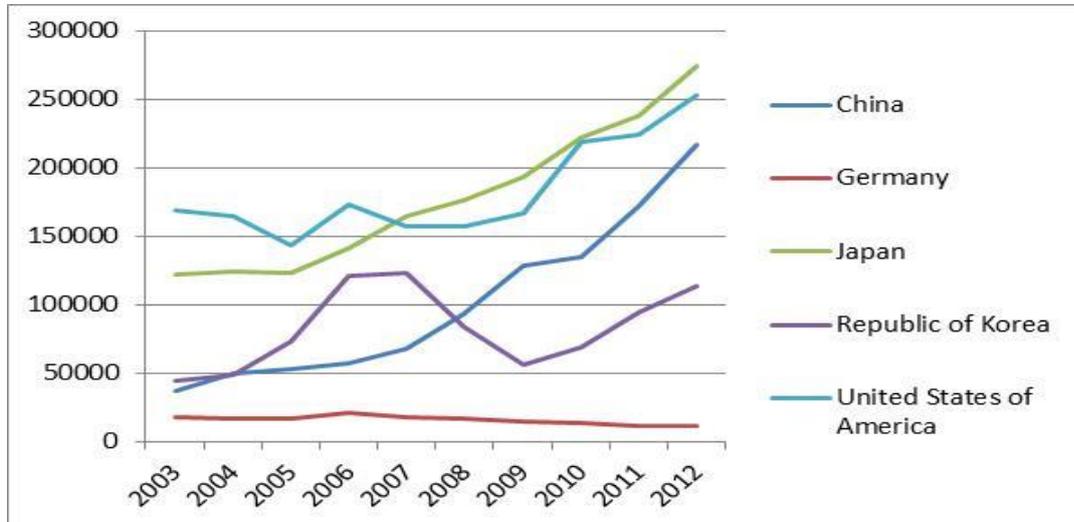
<sup>83</sup> [www.wipo.int/export/sites/www/ipstats/en/docs/infographics\\_systems\\_2013.pdf](http://www.wipo.int/export/sites/www/ipstats/en/docs/infographics_systems_2013.pdf) accessed May 2014

<sup>84</sup> WIPO International Filing Figures, 2013

[www.wipo.int/export/sites/www/ipstats/en/docs/infographics\\_systems\\_2013.pdf](http://www.wipo.int/export/sites/www/ipstats/en/docs/infographics_systems_2013.pdf)

Further, Korean direct and PCT national phase patents granted have increased by 61% over the same period and Korea was ranked 4<sup>th</sup> in the world in total patents granted in 2013, being beaten only by China, Germany and Japan (Figure 3-9).

**Figure 3-9: Total patents granted, Selected Economies, 2002-2012**



Source: WIPO search for total patents granted (direct and PCT national phase), top five economies (2013)

## ***POLICY IMPLICATIONS***

This Korean patent system case study has shown the importance of the patent regulatory system as an enabler of innovation in Korea, even though it may not be the main driver. The three areas that are of most relevance to policy makers are international harmonization, the need to match the patent regulatory system to the stage of economic development, and the need to support SMEs to enable them to take advantage of the regulatory system.

### **Importance of international harmonization**

This Korean case study has shown the value of international harmonization in patenting and also the value in ongoing review of patent laws so that they are suited to the level of technological development in the economy. In Korea there are a number of informal mechanisms which enable companies to liaise with KIPO and provide feedback on the practical operation of IP laws. It appears that these avenues are more accessible to larger companies than to SMEs; however the activities of academics and small business research institutes provide an avenue for SME's views to be collected and publicised.

### **Matching the regulatory system to technological development**

Korea's utility model patent system emerged at the time when the economy was not technologically advanced. Utility model patents were heavily used during Korea's early technological development because they enabled companies to gain protection for adaptations to technologies from outside Korea.

Once Korean companies developed to the point where they could do their own R&D and develop their own technologies, then the full patent system became more important to them. Hence, the use of utility model patents has declined as in overall importance relative to full patents. However, utility models are still important, particularly for smaller companies.

Academic studies show that this trend is being repeated in other developing economies, with utility patents being most useful for technologically poor economies.<sup>85</sup> As Korea develops further it might be expected that the ratio of utility model patents to full patents will decline further, however it is also unlikely that such patents will fall out of use, as individual companies, mainly SMEs, will still find them attractive.

There have been concerns that expanding international patenting will strengthen the market power of companies in developed economies and raise prices in developing economies.<sup>86</sup> However studies using data from 64 economies have shown that when developing economies increase their patent protection, then innovation by their domestic firms also increases.<sup>87</sup> However, the optimal IP protection regime will vary between economies depending on the level of technological development, the long term effect on the economic growth rate of the developing economies,<sup>88</sup> and whether an open or closed trade regime is adopted.<sup>89</sup>

These results suggest that the policy to strengthen patent protection is more appropriate for economies that have acquired a certain level of technological capability than those whose technologies are relatively undeveloped. Thus, the phase of technological development needs to be considered when designing a patent protection policy.<sup>90</sup>

### **Procedures to enhance contact with SMEs**

While Korea has made great progress and has an open and transparent system for consulting with stakeholders when legal changes are being considered, the formal system for obtaining industry views appears to focus on larger companies, through organisations such as KINPA.

KIPO, however, has developed a range of mechanisms to interact with SMEs. These are based around training and capacity building to first raise awareness and skills in IP, and then in enhanced services, at the time an SME seeks to use the IP system. This provides an avenue for interaction that is often missing in jurisdictions where the IP system remains aloof and does not see itself as providing an industry support function.

### **Conclusion**

Development of IP regulations in Korea has been driven by a need to harmonize domestic regulation so that companies can take advantage of international trade opportunities and have sufficient domestic capacity to compete with those entering the economy from overseas. While the system has remained relatively stable there have been many minor changes brought about by the needs of SMEs and other clients – these have led to continual and ongoing adjustments to the patent law, and its administration.

---

<sup>85</sup> Kim et al (2012), *op cit*, page 34

<sup>86</sup> Deardorff, A (1992): Welfare Effects of Global Patent Protection, *Economica* 59: 35-51

<sup>87</sup> Chen, Y and Puttitanun, T (2005): Intellectual Property Rights and Innovation in Developing Countries, *Jnl of Development Economics* 78:474-493

<sup>88</sup> Dinopolous, E and Sergstrom, P (2010): Intellectual Property Rights, Multinational Firms and Economic Growth, *Jnl of Development Economics* 92:13-27

<sup>89</sup> Gould, D and Gruben, W (1996): The Role of Intellectual Property Rights in Economic Growth, *Jnl of Development Economics* 48: 323-350

<sup>90</sup> Kim et al (2012): *op cit* page 34

In the main, the regulatory system is enabling for innovation, because of the strengths of the protections afforded (Table 3-7). There are also costs associated, but the overall impact is positive, with the main effect being on companies and other innovating organisations.

**Table 3-7: Summary of Korea IP Regulatory Analysis**

<b>Regulatory Analysis</b>		<b>Overall Impact on Innovation</b>
<i>Political and Administrative Viability</i>		
Transparency	Stakeholders' views reflected through the IP Council, KINPA and informal contact with SMEs; all regulations on KIPO site	Enabling for Korean inventors, possibly favours larger companies
Alignment	International harmonization requirements dominate. IP legislation requires alignment by other laws (IP laws dominant)	Enables companies to protect their own IP and expand internationally; adds to costs
<i>Economic Efficiency and Effectiveness</i>		
Costs and Benefits	Patent system promotes innovation broadly, and utility model system enables "incremental" innovators to gain protection  Publication of patents benefits all society  KIPO has progressively changed its administrative approaches to support SMEs;	Enabling for process (within company) and management (within KIPO) innovations  Alignment of utility and full patent approaches adds to costs for SMEs  Some other types of innovation protected by other parts of IP system
Scientific integrity	Not applicable – the regulations are based on historical precedents and norms	
Flexibility and Twenty-first Century Regulation	Regulations mainly technical; specific bans / permits. Formal review and regeneration of plans - no sunset clauses.  KIPO continually revises its administration of regulations in response to informal stakeholder input.  A formal and transparent evaluation strategy would assist stakeholders	Enabling for companies, within technical limits

## 4. MALAYSIAN PHARMACEUTICAL CLINICAL TRIALS

### **INTRODUCTION**

This case study examines the impact of regulation of clinical trials on innovation in Malaysia, particularly its emerging clinical trials capacity. The pharmaceutical regulatory system is an example of a social regulation that has been introduced to enhance public safety and public health, the latter through increasing access to new drugs to treat disease.

The case study briefly explains the evolution of the pharmaceutical industry, particularly the reasons for a recent shift towards running clinical trials in developing economies. The roles of global and regional harmonization in drug development are explained. The case study discusses the relevance of Malaysia's Country Health Plan and the Third Industrial Master Plan (IMP3), both of which are important in promoting clinical trials in the country. The study uses the APEC/OECD framework to review the development, promulgation and review of clinical trials regulations, focusing on capacity development in public healthcare facilities and SMEs. The study comments on Malaysia's emerging strengths in conducting clinical trials as a result of its regulatory and industry policies, and suggests lessons for other APEC economies.

### **THE NEED FOR PHARMACEUTICAL DEVELOPMENT**

#### **Global pharmaceutical markets**

Pharmaceuticals, or drugs, emerged as an industry approximately a century ago. Prior to that time, people used herbal or other folk remedies to treat symptoms of diseases or to try to cure them. Pharmaceutical manufacturing as a formal industry was boosted by the discovery of insulin and penicillin in the 1940s and development of standardized manufacturing techniques.

The pharmaceutical markets worldwide in 2012 amount to more than USD 900 billion. The USA has most of this market, with Europe coming second (Table 4-1). Globally, it is estimated that 4,300 companies are involved in drug innovation.<sup>91</sup>

**Table 4-1: Value of Global Pharmaceutical Markets in 2012**

<b>Region</b>	<b>Value (USD billions)</b>	<b>% of Total</b>	<b>% Growth</b>
USA	348.7	37.8	-1%
Europe (EU and non-EU)	221.8	24.0	-0.8%
Asia, Africa and Australia	168.3	18.2	12.8%
Japan	112.1	12.2	0%
Latin America	72.5	7.8	10.9%
<b>Totals</b>	<b>923.4</b>	<b>100</b>	

Source: IMS Health Market Prognosis 2013; drawn from data on percentage market share and growth rates 2012-2017.

---

<sup>91</sup> Munos, B: Lessons from 60 years of Pharmaceutical Innovation. Nature Reviews – Drug Discovery Volume 8 December 2009 pp 959-967

Despite most sales being in developed economies, demand in Asia, Latin America and Africa is growing quickly, with forecasts of annual increases of 11%-14% up to 2017.<sup>92</sup> Over the same period, demand in North America will peak at 3.7% p.a. growth and demand in Europe will peak at 2.6% p.a. growth. One of the reasons for growing demand in developing economies is the enhanced availability of drugs, as people get access to drugs where there has been no access before (Table 4-2).

**Table 4-2: Pharmaceutical Sales in APEC Region Economies, 2011**

Region	Value (USD billions)	Expenditure Per capita (USD)
Australia	13.268	587
Brunei Darussalam	N/A	N/A
Canada	26.057	759
Chile	3.068	178
People's Republic of China	66.863	50
Hong Kong, China	1.23	173
Indonesia	6.044	27.40
Japan	127.377	1007
Republic of Korea	14.796	306
Malaysia	1.814	63
Mexico	12.978	113
New Zealand	1.065	241
Papua New Guinea	N/A	N/A
Peru	1.418	48
Philippines	2.911	31
Russia	20.653	145
Singapore	0.716	138
Chinese Taipei	4.594	198
Thailand	4.407	198
USA	337.1	1077
Viet Nam	2.425	27

Source: International Federation of Pharmaceutical Manufacturers & Associations (2012): The Pharmaceutical Industry and Global Health; drawn from Annex 3. N/A = not available

### Steps in the development of new drugs

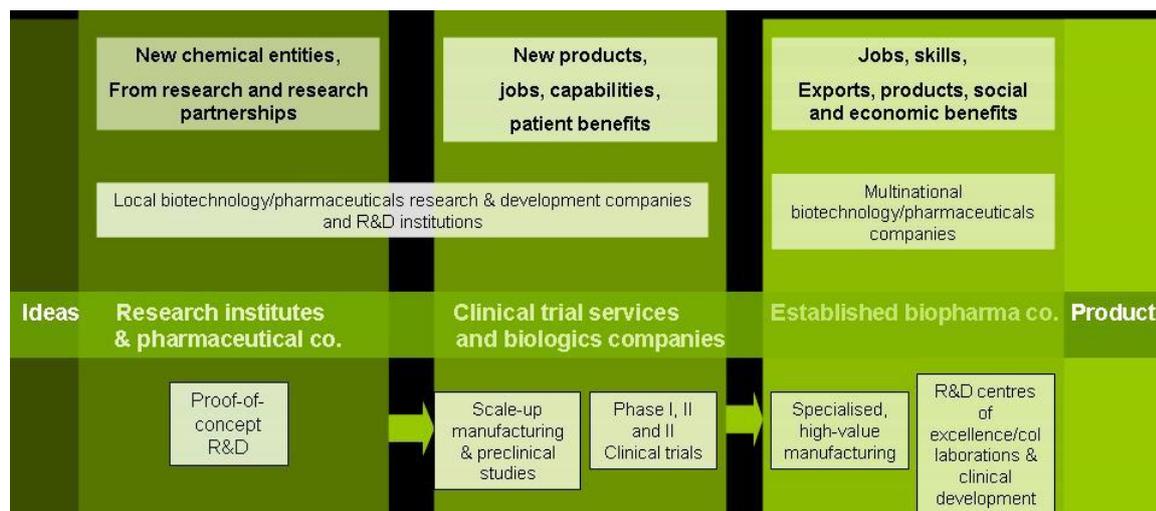
Drug development programs take from 7 to 12 years. It is an expensive process and only the largest companies can afford to pay to bring a new drug right through to market. Worldwide, only 260 companies have been responsible for the ~1200 new drugs (termed “new molecular entities (NMEs)”) that have been introduced in the last 60 years.<sup>93</sup>

The development of a new drug takes place in a set of discrete phases, moving from an initial compound with some chemical activity in the laboratory (a chemical lead), through several steps to a product that can be tested in humans. Stages are summarised in Figure 4-1.

<sup>92</sup> IMS Health (2013): *op cit*

<sup>93</sup> Munos (2009) *op cit*

Figure 4-1: Stages in development of a new drug



Source: Adapted from Pharmaceuticals Industry Strategy Report, Commonwealth of Australia 2009

The increased complexity and cost of drug development over recent decades has led, since the 1980s, to fragmentation of the supply chain. Successful drug innovation needs skills in R&D, clinical development, manufacturing and marketing and companies now seek to identify and partner with those organisations which can provide such skills from wherever in the world they are located.<sup>94</sup>

Now, large companies are more likely to obtain new chemical entities under license from smaller biotechnology companies and R&D institutions. They will also use service companies (Clinical Research Organisations or CROs) to conduct formal preclinical and/or clinical trials. The drug companies themselves sponsor (pay for) the trials and then market the final product, once approved. They may also manufacture it or this process may be subcontracted to a major contract manufacturer.

The whole process is heavily reliant on the intellectual property protection system, the operation of which is summarised in the IP case study.<sup>95</sup>

### Trends in clinical trials

Clinical trials are becoming more complex due to a number of factors<sup>96,97</sup>

- the need for more study participants in order to meet the demands of Good Clinical Practice and regulatory requirements
- the increasing difficulty in recruiting clinical trial participants (includes difficulty in identifying suitable trial participants, finding people not already being treated for the disease being studied and difficulty in obtaining representative population samples);

<sup>94</sup> Greis, N, Dibner, M and Bean, A: *External Partnering as a Response to Innovation Barriers and Global Competition in Biotechnology*, Research Policy 24:609-630 (1995).

<sup>95</sup> See the IP case study for a brief discussion of the costs and benefits of the IP system, at page 1

<sup>96</sup> Dickson and Gagnon (2009) op cit

<sup>97</sup> Lovato, L et al: Recruitment for controlled clinical trials: Literature summary and annotated bibliography, Controlled Clinical Trials 18(4): 328-352, August 1997

- the complexity of diseases for which new drugs are being developed; and
- the increased likelihood of adverse drug reactions if people have multiple chronic diseases.

These factors, plus increased demand for good quality data by regulators, have increased the cost of bringing a drug to market. The average cost of bringing each drug to market ranges from USD 800 million to USD 1,318 million.<sup>98</sup> The process is also taking longer, due in part to greater regulatory requirements.<sup>99</sup>

In response to increased costs and time frames, pharmaceutical companies have been looking for cheaper locations to run their trials and also try to run trials in multiple locations at the same time (“multi-centre trials”). Each trial is led by a Lead Investigator with the required technical and clinical skills. Since 2002, the number of active FDA-regulated Investigators based outside the USA but sponsored by US pharmaceutical firms has grown by 15% p.a., and is an indicator of the move by such firms to running trials in other locations.<sup>100</sup>

Many developing economies have responded to this increased demand by building their clinical trial capacities: sites in Asia expanded from 0% to 5% of global trial sites from 2002 to 2007.<sup>101</sup> By 2007, APEC member economies accounted for between 11% and 74% of clinical trial sites in developing regions 2007 (Table 4-3). However, while their involvement in clinical trials is expanding, many APEC economies still have relatively few clinical trials sites as a percentage of total population.

**Table 4-3: Summary of Top 50 Economies’ Clinical Trial Sites, 2007**

<b>Global Region</b>	<b>No. APEC trial sites</b>	<b>APEC economies participating</b>	<b>Non-APEC trial sites</b>	<b>Total trial sites</b>	<b>APEC as % of Region Totals</b>
Africa	N/A		553	553	0
Asia	2,088	Hong Kong, China; Chinese Taipei; the Philippines; Korea; Singapore	757	2,845	73.4%
Eastern Europe	1,084	Russia	4,494	5,578	19.4%
Latin America	304	Chile, Peru	2,480	2,784	10.9%
Middle East	N/A		642	642	0
North America	39,313	USA, Canada		36,281	100%
Oceania	3,271	Australia, Japan, N. Zealand		3,271	100%
Western Europe	N/A		18,806	18,806	0
<b>Total</b>	<b>46,060</b>		<b>27,732</b>	<b>73,792</b>	<b>62.4%</b>

Source: derived from Thiers et al (2007)

<sup>98</sup> *ibid*

<sup>99</sup> Dickson, M and Gagnon, JP (2009): The Cost of New Drug Discovery and Development, *Discovery Medicine*, 20 June 2009, [www.discoverymedicine.com/Michael-Dickson/2009/06/20/the-cost-of-new-drug-discovery-and-development/](http://www.discoverymedicine.com/Michael-Dickson/2009/06/20/the-cost-of-new-drug-discovery-and-development/)

<sup>100</sup> Seth W. Glickman, John G. McHutchison, Eric D. Peterson, Charles B. Cairns, Robert A. Harrington, Robert M. Califf, and Kevin A. Schulman: Ethical and Scientific Implications of the Globalization of Clinical Research, *N Engl Jnl Med* 2009; 360:816-823, February 19, 2009

<sup>101</sup> Thiers et al (2007) op cit page 4

## REGULATION AND DRUG DEVELOPMENT

### Drug development regulatory framework

The regulation of drug development, broadly speaking, is based on the need for public safety. There have been many cases over the last 20 years of people dying after taking contaminated or counterfeit drugs, particularly in developing economies where the regulatory system may be less well structured, or not enforced effectively.<sup>102</sup>

Today's formal drug approval processes stem from systems developed first in the USA by the US Food and Drug Administration (FDA) which has had responsibility for testing food and drugs in the US since 1906,<sup>103</sup> and which developed the current testing system in 1938. The aim, as with all public safety regulations, is to balance the benefits and risks of new drugs and to ensure that people can make informed decisions before taking them.

There are five major steps in drug development, with the emphasis being on meeting technical regulatory standards and an extensive system of permits affecting sponsors, participants, host sites and clinicians (Table 4-4). Given the social nature of clinical trials regulations, the latter is to be expected as this is the main means by which risk is managed prior to the trial.

**Table 4-4: Approaches to Drug Development Regulation**

<b>Bans</b>	<b>Technical Standard</b>	<b>Planning Standards</b>	<b>Pricing and levies</b>	<b>Permits</b>
Types of trials may be limited to certain diseases; bans on movement of tissue samples	Need to demonstrate safety and efficacy in three phases	Trial sites must comply with hospital/medical planning standards	Usually on cost recovery basis	Import permits for trial drugs; permits to commence trials; skill requirements in trial administration; ethics approval

Source: Author's analysis

Step one is that a drug must first be proved safe in animals (or equivalent), a process called preclinical trials. Preclinical trials are also used to work out the best dose for a new drug, and to look for potential unexpected side effects of any new chemical entities. After this, the drug can be tested in healthy people, in Phase I trials.

In Phase II trials, the drug is tested on a small number of people which have the relevant disease. If Phase II trials are successful, the drug moves to Phase III, when a large group of people with the target disease are tested. Such trials may be conducted in many economies at once – for example in 2013, pharmaceutical companies worldwide ran Phase III trials in an average of 6.3 economies.<sup>104</sup> If the drug succeeds in all these trials, then manufacturers can apply to have it approved in each market in which they wish to sell it.

<sup>102</sup> Ibid page 11

<sup>103</sup> FDA history at [www.fda.gov/aboutfda/whatwedo/history/default.htm](http://www.fda.gov/aboutfda/whatwedo/history/default.htm)

<sup>104</sup> DeGregorio, T: 2013 Clinical Trials Scoreboard – Infographic Year in Review, Citeline (2014)

In addition to an extensive approvals process, many economies have implemented post-marketing data reporting (Phase IV) which aim to alert regulatory authorities if there are unexpected side effects or cross-interaction with other drugs.

### **Global harmonization of approval systems for new drugs**

One of the main global regulatory frameworks for the development of new drugs is the International Conference on Harmonization of Technical Requirement for Registration of Human-Use Pharmaceuticals (ICH). This was initiated in 1990 by the European Union, Japan, and the United States<sup>105</sup> and followed an earlier initiative by the World Health Organization (WHO) and the Council for International Organizations of Medical Sciences, which issued International Guidelines for Biomedical Research Involving Human Subjects.<sup>106</sup>

Following the formation of ICH, the WHO then encouraged further regional harmonization initiatives, including through APEC, ASEAN, and the South African Development Community.

ICH aimed to harmonize the interpretation and application of technical guidelines and requirements for drug registration, in order to reduce duplicate testing and reporting during drug development. Prior to harmonization, each economy had its own requirements for testing and data submissions. Following harmonization, companies can now submit a Common Technical Dossier (CTD), which is accepted by drug regulatory agencies in those economies. This has facilitated collection of common data; consistency in the ordering and presentation of data; and electronic data submissions.

ICH also established an Expert Working Group on Good Clinical Practice (GCP) to provide unified standards for submission of data to regulatory authorities in different economies and to protect the safety and welfare of humans during clinical trials. These initiatives were in response to public concerns over safety of new drugs, increased costs of bringing drugs to market, and improved trial methods, among other things.<sup>107</sup>

ICH issued guidelines in 1996<sup>108</sup> and between 1997 and 2001 these were adopted in Singapore, China, Malaysia, Thailand, Indonesia, Australia, Canada, the USA and New Zealand.<sup>109</sup>

ICH's Expert Working Group on Consideration of Ethnic Factors also considered how to balance variations in drug effects between different races, to help reduce requirements for detailed local studies to assess potential ethnic differences.<sup>110</sup> The Working Group agreed (in 1998) that additional studies performed in new regions would provide data on efficacy, safety, dosage and dose regimens, so that foreign clinical data could be extrapolated to that

---

<sup>105</sup> Molzon, J The Value and Benefits of ICH to Drug Regulatory Authorities - Advancing Harmonization for Better Health, ICH Secretariat: ICH 20<sup>th</sup> anniversary report, ICH, 2010

<sup>106</sup> Vijayanathan, A and Nawawi, O: The importance of Good Clinical Practice guidelines and its role in clinical trials, 2008, Biomed Imaging Interv J. 2008 Jan-Mar; 4(1): e5.

<sup>107</sup> *Ibid*, Table 2

<sup>108</sup> ICH Expert Working Group: ICH Harmonised Tripartite Guideline for Good Clinical Practice E6(r1), 10 June 1996

<sup>109</sup> Vijayanathan and Nawawi (2008) *op cit*

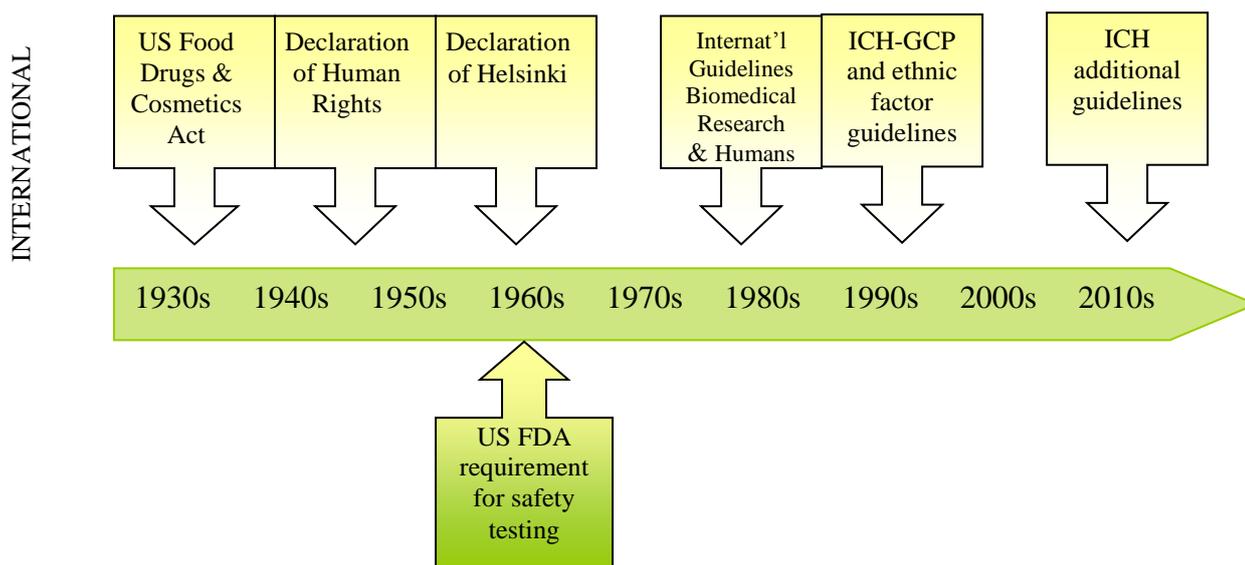
<sup>110</sup> Olliaro, P, Vijayan, R, Inbasegaran, K, Choy, C and Looareesuwan, S: Drug Studies in Developing Countries, Bulletin of the World Health Organization 79(9), 894-895, 2001

region.<sup>111</sup> Some economies, however (e.g. China) still require Phase III trials to be conducted locally before a new drug will be approved for sale.

By 2010, ICH had issued quality guidelines on drug stability, impurities, quality, specifications, Good Manufacturing Practice, pharmaceutical development, safety guidelines, clinical safety, clinical study reports, ethnic factors, good clinical practice, clinical trials, terminology and technical documentation.

Steps in development of internationally harmonized drug development regulations are summarised in Figure 4-2.

**Figure 4-2: International Harmonization of Drug Development Regulations**



Source: authors' research

### Global harmonization of intellectual property protection for drug developers

The second important agreement which has harmonized regulations internationally is the Trade-related Aspects of Intellectual Property Rights (TRIPS) Agreement. This allows for the protection of intellectual property in international trade.

Part of the TRIPS Agreement helps economies enhance access by their citizens to new drugs. It provides some protection for the data that companies are required to lodge with regulators from an economy, in order to seek approval for a drug.<sup>112</sup>

### PIC/S

The Pharmaceutical Inspection Convention<sup>113</sup> commenced in 1970 and in 1995 the Pharmaceutical Inspection Co-operation Scheme commenced as an agreement between

<sup>111</sup> Tominaga, T: ICH and Domestic Regulations – Excellence Through Harmonization (2010), ICH Secretariat: ICH 20<sup>th</sup> anniversary report, ICH, 2010

<sup>112</sup> Correa, C: Protection Of Data Submitted For The Registration of pharmaceuticals - Implementing the standards of the TRIPS Agreement, published by South Centre in collaboration with the Department of Essential Drugs and Medicines Policy of the World Health Organization, 2002

<sup>113</sup> The Convention for the Mutual Recognition of Inspections in Respect of the Manufacture of Pharmaceutical Products

domestic health authorities. The two agreements are together termed PIC/S. PIC/S provides for mutual recognition of inspections conducted by domestic agencies and harmonization of requirements for Good Manufacturing Practice – both relevant to pharmaceutical manufacturing. Under PIC/S domestic agencies exchange information. Malaysia was accepted into PIC/S in 2002.<sup>114</sup>

### **Other global harmonization initiatives**

There are two other important harmonization initiatives that are relevant to development of clinical trials regulations in Malaysia. Neither was initiated by governments, and hence are not global regulatory initiatives, but they have been since encoded in the laws of many economies, including Malaysia.

### **Publication of clinical trial results**

As clinical trials are sponsored by private companies, concern emerged during the 1990s that results of less-successful, or unsuccessful, trials were being suppressed. The International Committee of Medical Journal Editors, a non-government group, announced in 2004 that all trials must be registered on a publicly accessible register before recruitment of the first participant, before these journals would accept the trial's results for publication.<sup>115</sup>

As publication is an important step in gaining credibility for the effect of a new drug, reaction was swift. The WHO endorsed the move later in 2004. As a result of these initiatives, between 2004 and 2008 the number of clinical trials registered on public databases increased 6-fold, from 3,000 to 19,000.<sup>116</sup>

While the independent (privately run) trials registers remain, many economies have now introduced domestic registers. Within APEC these include Australia, China, Republic of Korea, Japan, Thailand and Malaysia.<sup>117</sup> Malaysia's trial register was established in 1978, and can be accessed by clinical trial applicants and search online.

### **Declaration of Helsinki**

The World Medical Association, an association of domestic medical organisations and individual physicians,<sup>118</sup> agreed on the Declaration of Helsinki in 1964. This declaration covers ethical principles for obtaining agreement of human subjects in clinical trials, as well as matters relating to privacy, the conduct of ethics committees, the design of research protocols and the treatment of vulnerable groups and individuals.<sup>119</sup> It has since been amended 9 times, the most recent being in 2008 and 2013.

### **Regional harmonization**

Since 1979 the ASEAN Pharmaceuticals Project has resulted in harmonization of guidelines related to drug regulation including the ASEAN Good Manufacturing Practice Guidelines

---

<sup>114</sup> National Pharmaceutical Control Bureau: Annual Report 2012, published 2013

<sup>115</sup> International Committee of Medical Journal Editors (ICMJE). Clinical Trial Registration: A statement from the International Committee of Medical Journal Editors. [www.icmje.org/clin\\_trial.pdf](http://www.icmje.org/clin_trial.pdf)

<sup>116</sup> Ghersi, D and Pang, T: From Mexico to Mali: four years in the history of clinical trial registration, *Journal of Evidence-Based Medicine* pp1-7, 2009

<sup>117</sup> WHO International Clinical Trials Registry Platform

<sup>118</sup> [www.wma.net](http://www.wma.net)

<sup>119</sup> WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects

(for approved product manufacture) and the ASEAN Operational Manual on Drug Evaluation and Control.<sup>120</sup>

ASEAN also has a Pharmaceuticals Product Working Group which has worked on harmonization of guidelines for technical procedures and testing, including development of common technical documents, in operation since 2004.<sup>121</sup> The aim is to harmonize ASEAN pharmaceuticals regulations to complement and facilitate the aims of the ASEAN Free Trade Area particularly, and to eliminate technical barriers to trade posed by regulations without compromising drug quality, efficacy, and safety.<sup>122</sup>

## **REGULATORY AND POLICY FRAMEWORKS IN MALAYSIA**

### **Malaysian Country Health Plan**

Malaysia's main regulatory agency under which clinical trials are controlled is the Ministry of Health, which is responsible for the current Malaysian Country Health Plan 2011-2015.<sup>123</sup> The Health Plan focuses on five areas – population health, personal health, research and innovation, human capital development and technical and other support programs.

Health planning in Malaysia started in 1956, but systematic monitoring and evaluation of the outcomes and impacts of Malaysia's successive health plans did not commence until the 8<sup>th</sup> plan. Outcome-based evaluation commenced in the 9<sup>th</sup> plan. Hence, the 10<sup>th</sup> (current) Health Plan sets out clear outcomes, underneath which are a set of domestic programs, each with key results areas and strategies.<sup>124</sup>

The Ministry of Health wants to ensure patient safety and high standards of care. Clinical trials enable patients to gain access to new treatments and hence help increase standards of care. In the Health Plan, the government acknowledges the difficulty in achieving greater involvement in clinical trials, because of overwork by specialists, difficulties in encouraging hospitals to adopt the latest in treatments, and understaffing of the department of Health's section for approving new drugs.<sup>125</sup>

### **Third Industrial Master Plan 2006-2020 (IMP3)**

While the Health Plan provides the underpinning regulatory framework, IMP3 2006 – 2020 sets specific industry development targets, partly in response to intense foreign competition and trade liberalisation. Malaysia now wants to develop creative and skilled human capital and identify new sources of economic growth.<sup>126,127</sup>

IMP3 is focussed on manufacturing because of its contribution to GDP and its potential for creating more skilled jobs.<sup>128</sup> The Plan outlines a strategy to increase “high-end”

<sup>120</sup> Ratanawijitrasin, S: Drug Regulation and Incentives for Innovation – The Case of ASEAN, 2006

<sup>121</sup> [www.asean.org/communities/asean-economic-community/item/accsq-pharmaceutical-product-working-group](http://www.asean.org/communities/asean-economic-community/item/accsq-pharmaceutical-product-working-group)

<sup>122</sup> Javroongrit, Y: Regional Update – ASEAN PPWG, presented to the ICH-Global Cooperation Group Meeting, Fukuoka, Japan, 5 June 2012

<sup>123</sup> Ministry of Health Malaysia: Country Health Plan – 10<sup>th</sup> Malaysia Plan 2011-2015

<sup>124</sup> *Ibid* page 42

<sup>125</sup> *Ibid* page 19

<sup>126</sup> Government of Malaysia: Malaysian Industrial Master Plan, 2006, Chapter 1

<sup>127</sup> Ohno, K: Industrial Master Plans – International Comparisons of Costs and Structure, National Graduate Institute for Policy Studies, 16 November 2009.

<sup>128</sup> *Ibid* Table 1.2 page 6

manufacturing, promote inward investment, expand the range of support services for industry and strengthen institutional support for human resource development and R&D.<sup>129</sup>

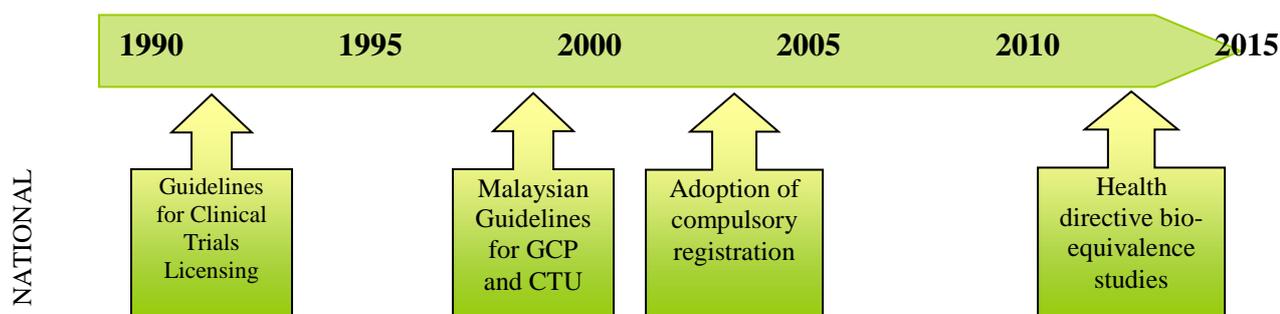
The Healthcare National Key Economic Area (NKEA) is part of IMP3 and has established a number of Entry Point Projects (EPPs) with specific aims and objectives. EPP2 aims to “create a supportive ecosystem to grow clinical research.” Specific objectives of EPP2 include increasing clinical trials from 150 now<sup>130</sup> to 1,000 trials by 2020. This target will be achieved by establishing more clinical research centres, increasing the number of GCP-certified investigators, and reducing the time taken for regulatory approvals.<sup>131</sup>

The compliance of Malaysia with ICH’s international guidelines for GCP, and its membership of PIC/S, are seen as major selling points to encourage more trials in Malaysia by sponsors from other economies.

### **CLINICAL TRIAL REGULATION AND APPROVAL**

Since 1999 the National Pharmaceutical Control Bureau (NPCB), established in 1978 to test pharmaceutical products imported to Malaysia,<sup>132</sup> has administered the Guidelines for Application of Clinical Trials, first published in 1999 and now in their 5<sup>th</sup> edition (Figure 4-3). The current edition extends trial compliance requirements to herbal medicines and requires trial applicants to declare if their test materials are from bovine or porcine sources – the latter is a Malaysia-specific requirement requested by its Muslim population.

**Figure 4-3: Malaysian Regulations to Extend Clinical Trials Capacity**



Source: Malaysian government publications

The other recent relevant regulation is the 2012 Ministry of Health Directive regarding bio-equivalence studies. This now requires companies which wish to sell a generic drug in Malaysia to conduct clinical trials studies to demonstrate that the generic version of the drug is equivalent to the original patented version. This regulation was introduced in response to public concern about the efficacy of generic drugs.

Within the NPCB, the Center for Investigational New Products assesses and approves applications to conduct clinical trials; inspects clinical trial sites and ensures compliance with Good Clinical Practice; monitors safety during trials; certifies preclinical facilities for

<sup>129</sup> *Ibid*, page 282

<sup>130</sup> NCCR Bulletin 1, 2011

<sup>131</sup> Healthcare NKEA Fact Sheet, Ministry of Health

<sup>132</sup> <http://portal.bpfk.gov.my/index.cfm?menuid=4>

compliance with Good Laboratory Practice (a similar international standard, for early stage testing); and ensure that ethics committees are operating properly. The Center also administers the GCP Accreditation Workshop and provides independent advice to the Medical Research and Ethics Committee.

### **Gaining approval to run a clinical trial**

Any drug to be trialled is nearly always imported by the sponsor, and hence the main method of controlling trials is through import licences issued by the NPCB's Center for Investigational New Products.<sup>133</sup>

Applicants must follow the procedures set out in the Guidelines for the Application of Clinical Trial Import License (CTIL) and Clinical Trial Exemption (CTX). These were first promulgated in 1999 and the current edition was released in 2009.<sup>134</sup> These Guidelines provide not only the application content and process but also procedures for reporting of adverse events during the trial (e.g. unexpected patient reactions), data requirements, chains of responsibility, labelling requirements, fees and product accountability and disposal. The third edition of these Guidelines also encompasses amendments from the 2008 Declaration of Helsinki.

A National Medical Research Register<sup>135</sup> number is required for submission of a CTIL application, but the process itself is manual rather than online.

NPCB has 30 working days to respond to new, completed applications, unless the application is for a trial involving stem cells, biotechnology products or herbal products, when they have 45 days. If the application is incomplete then the organisation “stops the clock” until the correct information is provided by the applicant.

### **Ethics approvals for clinical trial plans**

Applications for clinical trials must include ethics approvals from the relevant ethics committee. The ethics committee approves methods for selection of patients, obtaining their informed consent, the use of placebos (products which are administered to patients as part of the scientific protocol, but which are not expected to have any therapeutic effect) and other issues.

The Ministry of Health's Medical Research and Ethics Committee, established in 2002 is responsible for managing ethics approvals for clinical trials to be held on Ministry of Health sites, which includes public healthcare facilities.<sup>136</sup> It may also act as an ethics committee for non-Ministry of Health sites.

The Malaysian Medical Council also promotes high standards of medical ethics and practice in clinicians. The Council operates under the auspices of the Malaysian Medical Act 1971.<sup>137</sup>

---

<sup>133</sup> Other specifics of pharmaceutical approval systems world wide mean that once the sponsor has chosen a manufacturer, it must only use that manufacturer for its trial drugs and final (approved) drugs; hence the sponsor must export the trial drug from its manufacturing plant to its trial locations, wherever they may be.

<sup>134</sup> National Pharmaceutical Control Bureau: Guidelines for the Application of Clinical Trial Import License (CTIL) and Clinical Trial Exemption in Malaysia, 2009 (5<sup>th</sup> edition).

<sup>135</sup> [www.nmrr.gov.my](http://www.nmrr.gov.my)

<sup>136</sup> Ministry of Health Clinical Trials in Malaysia – presentation to conference in Chinese Taipei in 2008, at 8 [www.jrb.org.tw/DB/File/Download/970409\\_ClinicalTrialinMalaysiaTaipei\\_8April2008.pdf](http://www.jrb.org.tw/DB/File/Download/970409_ClinicalTrialinMalaysiaTaipei_8April2008.pdf)

<sup>137</sup> [www.mmc.gov.my/v1/](http://www.mmc.gov.my/v1/)

### **Public registration of clinical trials**

The application to conduct a clinical trial is submitted through the National Medical Research Register, an online portal administered by the Secretariat of the National Institutes of Health. Anyone can search the public portal to see research approved by the medical research ethics committee.

Malaysian trials sponsored by firms overseas (in practice, the vast majority) are also registered on public databases such as [www.clinicaltrials.gov](http://www.clinicaltrials.gov). However over time it might be expected that, as Malaysian biotech firms develop their own new chemical entities, that the number of Malaysian sites that can be gleaned from these public databases diverges from the true number of trials occurring in the economy.

### **Export of clinical trials samples**

Malaysia, unlike some other Asian economies, allows samples taken from clinical trial patients to be exported. This means that, for example, blood samples from patients in Malaysia can be sent back to the sponsor's laboratories (e.g. in Europe or Asia) so that all samples are tested according to the same protocol. Such an approach removes a source of variation which may be questioned at the time that the final drug applies for approval to be sold.

Export licences for trial samples, including human tissues and blood samples, are provided by the Disease Control Division of the Ministry of Health.

### **Drug approval following successful trials**

Documents on pre-clinical, pharmacology, toxicology, clinical pharmacology and clinical studies must be provided to the Drug Control Authority before a drug is approved for sale. In line with common practice other economies, samples of product, samples for testing, working standards, labeling proposals, and copies of material to be inserted inside packaging are standard requirements.

The Drug Control Authority also conducts market surveillance on all drugs on the market, including generic drugs.

## ***ENCOURAGING CLINICAL TRIALS***

### **Institutional arrangements**

When the government of Malaysia established the regulatory framework for clinical trials in 1999, leading Malaysian research institutions and public healthcare facilities responded to the new opportunities they saw in offering their facilities for clinical trials.

The Malaysian government established the Clinical Research Centre (CRC), as one of seven research units under the National Institutes of Health, in August 2000. The CRC reports directly to the Deputy Director General of Health (P&ST) and functions as the clinical research arm of the Ministry of Health. The CRC aims to become a leading clinical research institution in Asia and to improve patients' health outcomes through ethical and quality clinical research.<sup>138</sup> The CRC has 27 branches in major Ministry of Health Hospitals and also manages a Clinical Trial Unit (CTU), which helps government clinicians to establish ethical

---

<sup>138</sup> <http://www.crc.gov.my/vision-mission-function/>

clinical trial protocols, plan and manage research projects and publish the results.<sup>139</sup> The CRC also runs courses training clinicians in GCP in each State of Malaysia.

In 2011 the government launched Clinical Research Malaysia (CRM) under the Healthcare NKEA.<sup>140</sup> CRM is a non-profit site management organisation whose role is to attract clinical trials to Malaysia by facilitating access to the economy's network of clinical research centres, which includes 341 public healthcare facilities and hundreds of clinical trial sites plus universities nationwide.

### **The NPCB'S Development and Review of Regulations**

The Malaysian government has a formal system of management and ongoing review of the effect of its regulatory and industry development targets under its 2020 plans.

The main organisation responsible for ongoing monitoring and review of clinical trial regulations is the National Committee for Clinical Research (NCCR), which is chaired by the Director General of Health. It meets twice yearly and includes representatives from the pharmaceutical industry (through the Pharmaceutical Association of Malaya (PhAMA) and the National Pharmaceutical Society and the Malaysian Association of Pharmaceutical Industries, the latter of which includes CROs), Malaysian CROs, university clinical research centres (e.g. University of Malaya) and other sub-groups within the agency.<sup>141</sup> Each representative group (e.g. PhAMA) is responsible for gathering the inputs and comments from their own members during discussion of proposed changes for regulations.

Clinical Research Malaysia also meets regularly with the clinical research industry and holds a range of forums which aim to both inform and seek industry input into domestic regulatory and policy developments.

### **Transparency**

All of Malaysia's regulations for clinical research are available on government websites. The NCCR website<sup>142</sup> provides the Guidelines for Clinical Research, guidelines for use of human biological tissues for research, ethical review of clinical research using humans, applications of CTIL and CTX, and guidelines for GCP inspections. This site also links to various international guidelines which are used as the basis for the Malaysian local documents. This information is all in English and is hence accessible to international trial sponsors.

The Ministry of Health also publishes the NCCR bulletin, which disseminates information on changes to clinical research policies and guidelines. Since 2006 the CRC has also run an annual National Conference for Clinical Research, at which clinicians, CROs and sponsors "share experiences on research and practice and exchange ideas."<sup>143</sup>

The Clinical Research Centre website also provides access to updates, circulars and guidelines. This duplicates some of the information available through NCCR but also ensure that such information is easily available wherever sponsors/CROs enter the system.

---

<sup>139</sup> Annual Report Ministry of Health Malaysia, 2012, page 219

<sup>140</sup> NCCR Bulletin 1, 2011

<sup>141</sup> [www.nccr.gov.my/](http://www.nccr.gov.my/)

<sup>142</sup> [www.nccr.gov.my/index.cfm?menuid=17](http://www.nccr.gov.my/index.cfm?menuid=17)

<sup>143</sup> [www.nccrconference.com.my/fwbPagePublic.jsp?fwbPageId=pIndex](http://www.nccrconference.com.my/fwbPagePublic.jsp?fwbPageId=pIndex)

In the end, however, it is up to trial sponsors, CROs, and the general public to look for information on recent changes. There does not appear to be an email distribution list to notify stakeholders of changes. However, ample information is available online and NPCB is responsive to specific questions about current regulations – this is important because many trials are run concurrently over centres in different economies, and uniformity of approach in each centre is necessary to meet the demands of regulatory agencies at the time of approval. Where Malaysia diverges from global norms, trial sponsors may move the trial to another location, thus depriving citizens of access to the trial.

### **Alignment amongst authorities**

The NCCR, which is a domestic body governing clinical research in Malaysia, and whose secretariat is run by the NPCB, is responsible for ensuring alignment of clinical trials regulations with other health regulations. The involvement of external stakeholders in NCCR ensures that industry views are taken into account and that inconsistencies, as perceived by these stakeholders, can be addressed.

There are ample cross-measures in place to ensure that the views and perspectives of relevant institutions are incorporated into decisions on clinical trials regulations and industry development, e.g. NPCB is an independent adviser to the Medical and Research Ethics Committee.

PEMANDU (Performance Management and Delivery Unit), within the Prime Minister's Department, is responsible for overseeing implementation and assessing progress of the Economic Transformation Programme and the Government Transformation Programme.<sup>144</sup> Clinical Research Malaysia provides clinical trials statistics quarterly to PEMANDU, thus enabling the latter to track progress against EPP2 goals. Clinical Research Malaysia is also responsible for the marketing activity which aims to promote and market Malaysia as a preferred location for clinical trials. As it is now a corporatized body, it can manage trial budget and hire staff necessary to support clinicians in public hospital to conduct clinical trials.

### **Costs and benefits**

Analysis of costs and benefits of clinical trials regulations on the economy is informal. This is because global harmonization is the overriding driver for the regulations themselves. IMP3, set by the government, sets the clinical trials targets. There are short term and long term measures for overall benefits: numbers of trials in the short term, and overall population health in the longer term.

According to experts interviewed for this study, NCCR recognises that local industry may incur significant costs in complying with the clinical trial guidelines, and that these costs will be proportionately higher when local CROs are small. However, the longer term benefit to the Malaysian population is considered outweigh these short term costs.

### **Scientific integrity**

Malaysia's alignment with international standards for GCP, among other things, ensures that the scientific integrity of regulation is maintained.

---

<sup>144</sup> [www.pemandu.gov.my/](http://www.pemandu.gov.my/)

Within government there is a lot of effort going into developing databases that will provide information for evidence-based policy. In addition, development of health information systems will streamline the process of patient recruitment. It is necessary for health authorities to work on concert with Malaysia's Personal Data Protection Privacy Act 2010, which came into operation in 2013,<sup>145</sup> when planning patient data sharing.

### **Flexibility and 21<sup>st</sup> century regulation**

The GCP guidelines are process based rather than performance based, a necessary step to maintain global harmonization. However within Malaysia's structured planning system clear performance targets have been set, together with the strategies by which these are going to be met.

In relation to clinical trials regulations, the entire Ministry of Health is open to contact from the general public and industry, with the email addresses of key officials available on relevant websites. The NCCR is therefore regularly informed and is accessible if issues arise. NCCR will issue amended guidelines from time to time, in response to such issues or as part of maintenance of ongoing harmonization e.g. in relation to National Institutes of Health requirements.<sup>146</sup> These are available to investigators through the NMRR website ([www.nmrr.gov.my](http://www.nmrr.gov.my)).

## **THE CURRENT SITUATION**

### **GCP has laid the groundwork**

In deciding to comply with global GCP standards in 1999 Malaysia took the first step towards enabling its citizens to benefit from emerging drug treatments for serious diseases. However, at the time, the government recognised that externally harmonizing Malaysia's GCP framework was not enough and it introduced internal regulations to require clinicians participating in trials to meet the GCP requirements. Now, around 350 clinicians are trained each year in the GCP framework, enabling them to conduct trials for global sponsors.<sup>147</sup>

### **The complementary role of industry policy**

These steps, while necessary for clinical trials to grow, were not sufficient. Malaysia, like most advanced economies, does not force its clinicians to do research, nor enrol their patients in drug trials.

Only those organisations which saw opportunities in increasing trials, such as the University of Malaya's Clinical Investigation Centre, actively grew their trials capacity as soon as Malaysia adopted GCP in 1999.

Local capacity has grown more substantially since adoption of IMP3 – e.g. Questra Clinical Research Sdn Bhd was founded in 2011, and the Adventist Hospital in Penang set up its Adventist Clinical Research Centre in 2012.<sup>148</sup> Annual reports on achievements against

---

<sup>145</sup> Chi, M: *Data Protection Act Gazetted, Effective Today*, MalayMailOnline, 15 November 2013 [www.themalaymailonline.com/malaysia/article/data-protection-act-gazetted-effective-today](http://www.themalaymailonline.com/malaysia/article/data-protection-act-gazetted-effective-today)

<sup>146</sup> NIH Guidelines on Conducting Clinical Research in the Ministry of Health – Bil.9/2007, ref KKM/NIHSEC/03/0301-01 September 2007

<sup>147</sup> Seerangam, S: Paediatric Clinical Trials In Malaysia, NPBC, Ministry of Health, 2010

<sup>148</sup> [www.pah.com.my/services/clinical\\_research/](http://www.pah.com.my/services/clinical_research/)

NKEA targets show that policy is very focused on capacity building in scientific and clinical management, working with international sponsors and CROs, and enhancing administrative responsiveness (e.g. medical ethics approvals).<sup>149</sup>

Though not discussed in detail here, there it should be noted that there is also overlap between EPP2 and two other industry development initiatives. There is another NKEA in food and agriculture, where early stage trials of nutraceuticals and value-added food products (including high value herbal products, which are now covered by the GCP guidelines in Malaysia) will also be supported by an increase in clinical training and capacity across the research system and in industry.<sup>150</sup> This has also been encouraged through grants to overseas universities to conduct research into agricultural-based health products.<sup>151</sup>

A related EPP (EPP3) within the healthcare NKEA aims to increase exports of pharmaceutical products (covering generic drugs, biologic drugs, vaccines and over-the-counter drugs). In 2012 the export target was RM549m and this was actually exceeded, with exports reaching RM562m.<sup>152</sup> Under this EPP Malaysia is also encouraging foreign pharmaceutical firms to set up manufacturing facilities and has succeeded in attracting Indian company Ranbaxy and Australian company AFT Pharmaceuticals, among others.

### **Impact on innovation**

The Malaysian pharmaceutical market is growing rapidly, in the order of 10%-12% p.a., and spending on healthcare has doubled compared to 10 years ago.<sup>153</sup> This is partly due to a rise in drug imports, as well as tax incentives that encourage companies to establish manufacturing facilities in the country.

Changes to clinical trials regulations, coupled with the influence of recent industry policy, support these changes as the Malaysia population gains access to new treatments through the trials programs. The regulatory system has created additional costs for government, trial sponsors and service providers, however the Malaysian Government would argue that the benefits in enhancing domestic skills and access by patients to new treatments override these.

Within industry the main impact has been on personnel-related innovations whereas in government there has been substantial managerial and institutional innovation (Table 4-5).

---

<sup>149</sup> PEMANDU (2013): *op cit* Annual Report

<sup>150</sup> PEMANDU (2013): *op cit*, page 228 and related sections

<sup>151</sup> PEMANDU: Economic Transformation Program Annual Report 2013, Page 110

<sup>152</sup> Healthcare chapter, Economic Transformation Programme Annual Report 2013

<sup>153</sup> Gross, A: Overview of the Pharmaceutical Market in Malaysia (2013), Pharmaphorum, [www.pharmaphorum.com](http://www.pharmaphorum.com)

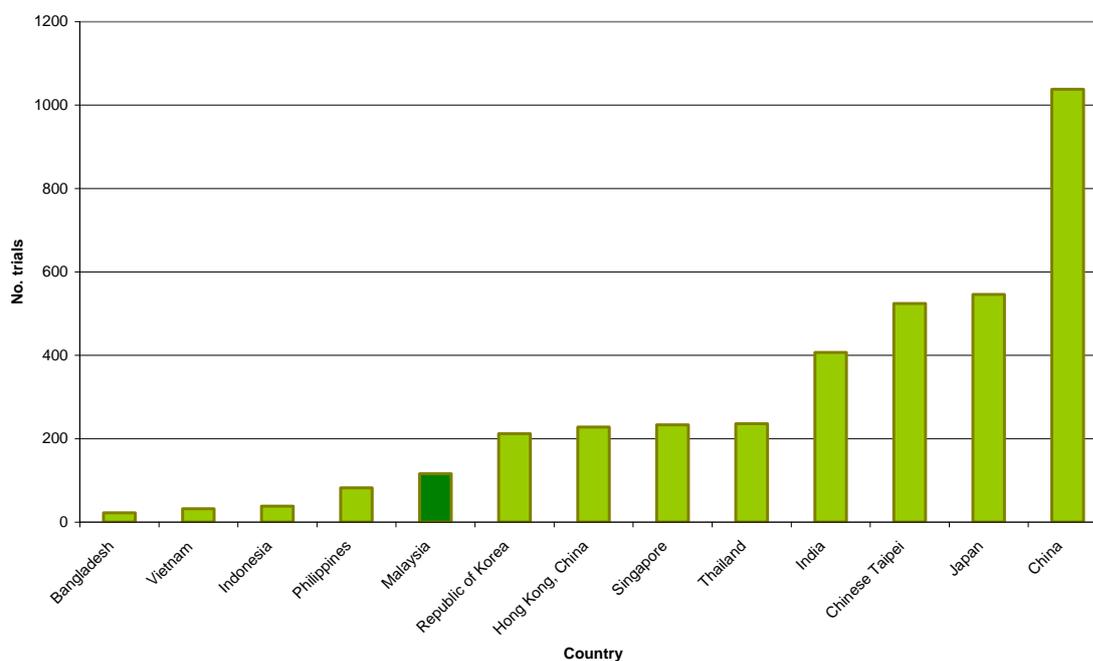
**Table 4-5: Summary of Impacts of Clinical Trial Regulations on Innovation**

Type	Positive Effects	Negative Effects
Process	New drug development (mainly by overseas sponsors) and availability for patients in Malaysia	
Procedural	Adoption of ICH GCP standards raises skill level, has associated society benefits	Associated organisational costs
Personnel-related	Capacity building in public healthcare facilities and service companies	Costs of training and maintenance of registration
Structural	New equipment and facilities established	Access to services by patients may be limited by location of population versus accredited facilities
Institutional	New institutions or relationships between institutions, emergence of SMEs as CROs, NCCR and associated Malaysian government organisations	Additional coordination costs for government

Source: Author's analysis

### Malaysia compared to other Asian economies

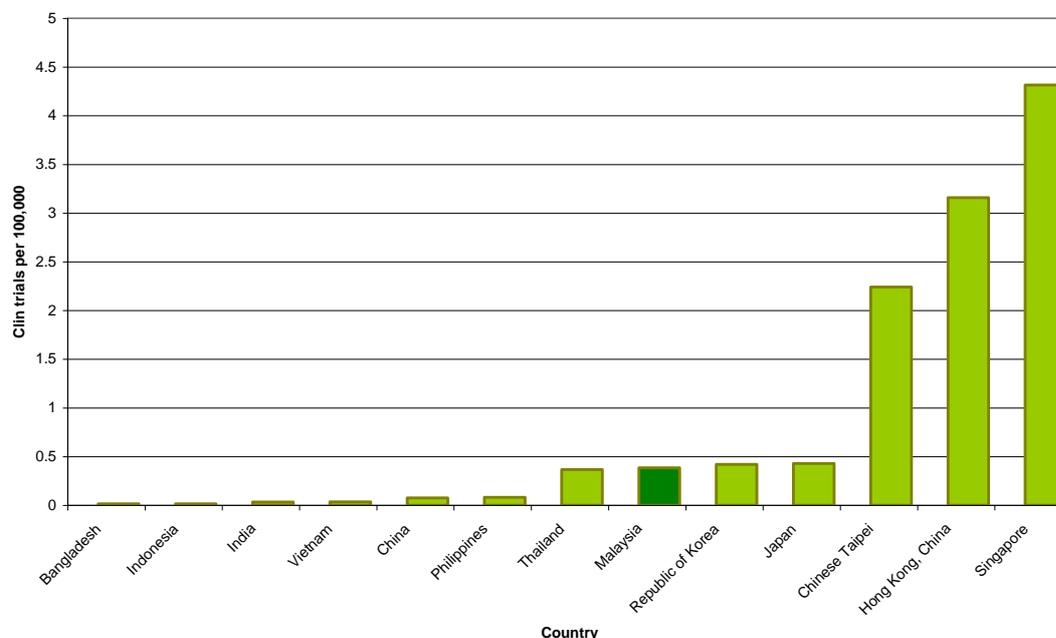
Malaysia is currently ranked 9<sup>th</sup> in Asia in the number of clinical trials commenced in 2012 (Figure 4-4). It has about half the number of trials started in South Korea; Hong Kong, China; Singapore; and Thailand, and one tenth of those commenced in China in that year.

**Figure 4-4: Number of trials in Asian economies, 2012**

Source: Derived from clinical trial data, Phases I-III, Pan Pacific Clinical Research Association, [www.pacra.org](http://www.pacra.org). PACRA data are more limited than Malaysian data because the former is sourced from [www.clinicaltrials.org](http://www.clinicaltrials.org)

On a per capita basis, however, Malaysia is ranked 6<sup>th</sup> (Figure 4-5). This moves it ahead of Thailand, India and China, all of which have much larger populations.

**Figure 4-5: Clinical Trials Rate per 100,000, Asia**



Source: Derived from clinical trial data, Phases I-III, Pan Pacific Clinical Research Association, [www.pacra.org](http://www.pacra.org)

Malaysia's compliance with GCP and its willingness to allow tissue samples to be exported distinguishes it from neighbouring economies such as Indonesia. Indonesia has also adopted the ICH GCP guidelines and is part of the ASEAN Pharmaceutical Products Working Group. However, unlike Malaysia, it only provides for patent protection of pharmaceuticals if they are manufactured domestically and it has previously been criticised for weak law enforcement, which has also led to a large scale problem of drug counterfeiting.<sup>154</sup>

In relation to clinical trials, Indonesia does not allow export of tissues and sample from trials conducted in the economy, because of concerns that overseas companies could use such sample to develop "profitable pharmaceuticals without remunerations for Indonesia."<sup>155</sup> Indonesia also has a less well developed system for monitoring trials, training in GCP and providing ethical approvals in a reasonable time.<sup>156</sup> As a result, clinical trials in Indonesia fall well behind those in Malaysia on a per capita basis and have fallen since 2008 when the Indonesian government implemented regulations to "protect Indonesian people from abusive and exploitative implementation of clinical trials."<sup>157</sup>

<sup>154</sup> Ratanawijitrasin, S (op cit) 2006. See also Background Document on Counterfeit Medicines in Asia., WHPA Regional Workshop on Counterfeit Medical Products, Taipei, June 2011

<sup>155</sup> Grant, R (2007): US, Indonesia Spar Over Virus Samples, [www.the-scientist.com](http://www.the-scientist.com), 28 November 2007

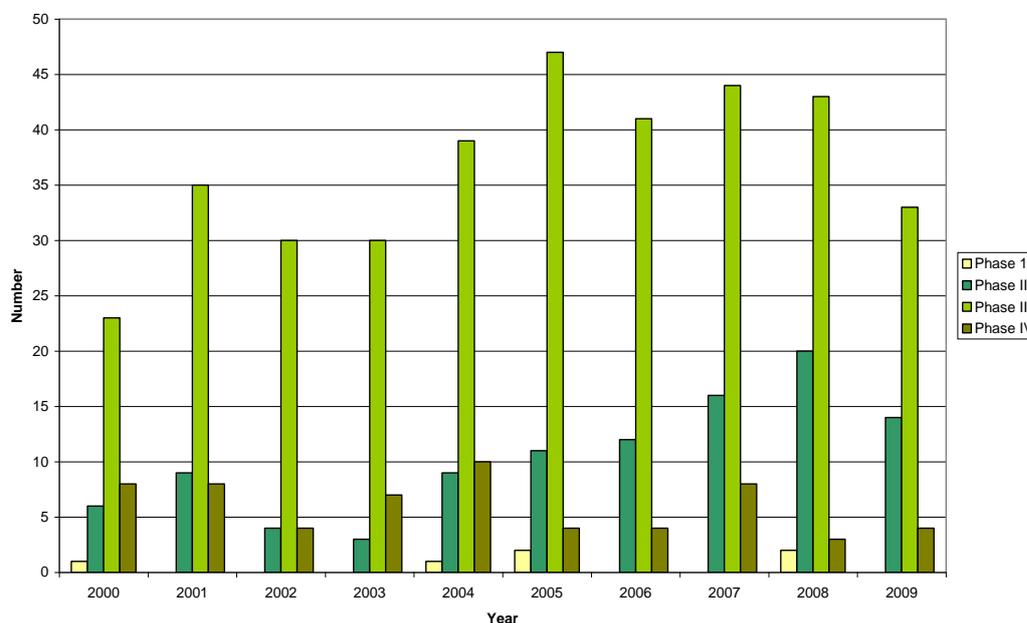
<sup>156</sup> Setiabudy, R: Clinical Research in Academia – a Viewpoint from Indonesia, presentation to the 9<sup>th</sup> Kitasato University- Harvard School of Public Health Symposium, Tokyo, 11&12 September 2009

<sup>157</sup> Purwadianto, A: *Bioethics Issues in Clinical Trials and its Challenges in Indonesia*, Presentation to European Group on Ethics in Science and Technology, Bureau of European Policy Advisers, 2013

### Changes in trial phases over time

Initially, the main growth in Malaysia was in Phase III trials (Figure 4-6), as sponsors were attracted by the large patient pool and low costs compared to conducting these trials in developed economies. In Phase III trials the dosage has already been determined and the key requirement is for compliance with GCP, as the tissue and blood samples are sent to the overseas sponsor for processing.

**Figure 4-6: Growth of Clinical Trials in Malaysia**

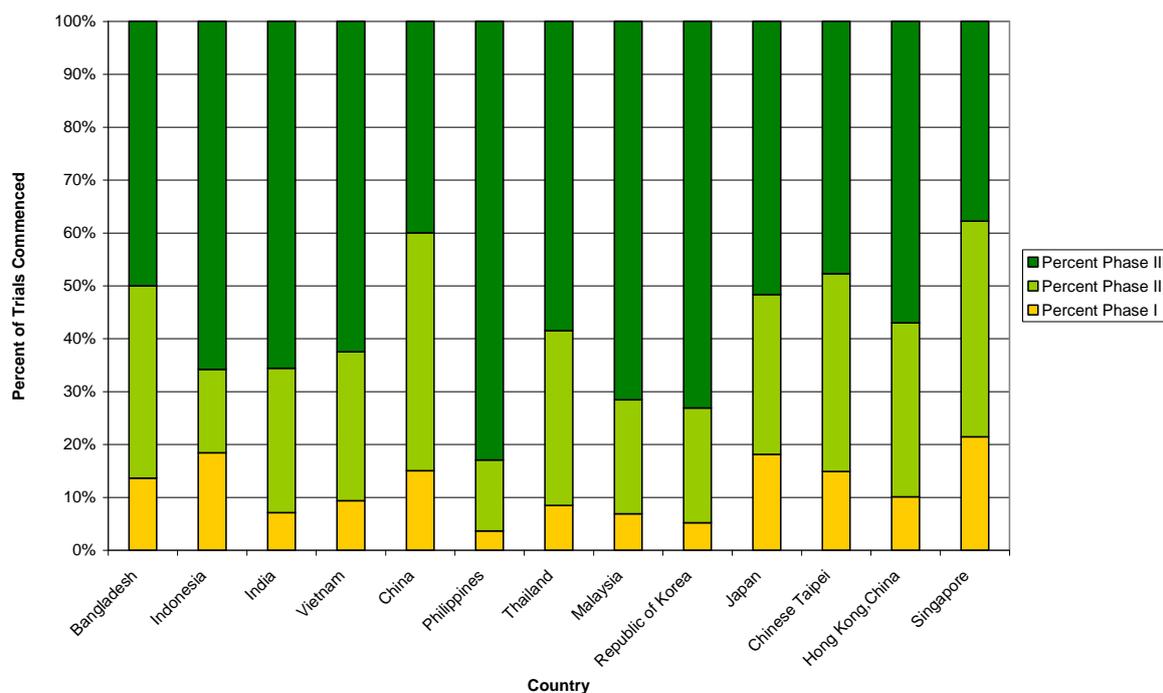


Source: Seerangham (2010) and CRC annual reports

However if Malaysia is to meet its self-imposed target of 1000 trials by 2020, it is going to have to increase its earlier phase trials.

Phase II trials started to grow significantly in 2004 (Figure 4-6 above) but both Phase I and Phase II trials still need to expand even further to meet the proportions of early stage trials conducted by leading Asian economies (Figure 4-7). Phase I and II trials in Malaysia, for example, account for less than 30% of the total, whereas they account for at least 42% of the total number of trials in Hong Kong China, Singapore, India, China and Chinese Taipei.

Figure 4-7: Trials commenced 2012, by Phase



Source: Derived from clinical trial data, Phases I-III, Pan Pacific Clinical Research Association, [www.pacra.org](http://www.pacra.org)

Such trials are an important source of foreign direct investment because different skills are needed for earlier stages of the clinical trials process. This is going to require further investment by Malaysia in R&D capacity including capacity building for pharmacists, biochemists and clinicians. The NPCB recognises that to expand current clinical trial numbers, Malaysian clinicians need to be able to manage Phase I and Phase II trials. NPCB is currently training its staff in Japan to evaluate Phase I and Phase II trial applications from sponsor companies and CROs.

### **POLICY IMPLICATIONS**

The case study of clinical trials development in Malaysia has reinforced the importance of a strong regulatory system, which is actively enforced, to ensure public safety and also to enable the economy to participate in what is a global industry. However important factors that have supported innovation under this regulatory regime include domestic capacity building and recent active support from industry policy. Comparisons between Malaysia and Indonesia also show that nuances in the development and enforcement of regulations can have major effects on the impact of a regulation on innovation.

### **Regulatory system is necessary but not sufficient to support innovation**

This cases study shows the importance of international harmonization in providing the basis for a regulatory system that enables an economy to participate in a global industry. However it also shows that the regulatory system, at least in relation to clinical trials, is not sufficient to induce innovation – regulations must first be effectively enforced, and then must be complemented by targeted industry policy which addresses not only domestic capacity but appropriate inward investment, induced by focused marketing and development of underpinning administrative and data systems.

In Malaysia's case the underpinning regulations not only include GCP Guidelines which are aligned with a global regulatory system, but other supporting legislation such as the Medical Act (for registering medical practitioners) and the Malaysia's Personal Data Protection Privacy Act (for controlling patient data).

### **Enforcement must be a focus**

In developing economies, testing and approval resources may be limited and regulatory agencies may lack the human resources need to run robust administrative regimes.<sup>158</sup> As we have seen from Indonesia, divergence from compliance with international frameworks can work against a desire to enhance capacity in developing sector. So, while international harmonization may not directly induce innovation, its absence can work against innovation and domestic capacity building.

In terms of policy, a globally-harmonized regulatory system remains an underpinning requirement. It must be strictly enforced to ensure compliance with international standards and supplemented with targeted industry policy to achieve the capacity-requirements for ongoing participation.

Both Malaysia and Indonesia aim to increase the number of clinical trials in their economies. Both are signatories to the relevant international and regional conventions. However, the less well developed enforcement regime in Indonesia, coupled with bans on movement of human tissue samples across borders, appear to be limiting Indonesia's capacity to take advantage of the global search for new trial sites. This shows that subtleties in the underlying regulation, and its enforcement or operations, can lead to major effects in the impact of that regulation on innovation. It is early days in the emergence of many economies as clinical trials locations, but policy makers must pay attention to the operation of the regulations as a whole, when considering reasons for observed trends.

### **Capacity building and training go hand in hand with regulation**

Malaysia has identified that for its next phase of development it needs to host Phase I and Phase II stage trials. Academic studies have found that the main problems in conducting such trials in Asia include ethical compliance, particularly where the patient population may be poorly educated; training of clinicians in GCP; and skill levels within regulatory agencies.<sup>159</sup> Regulation is not enough to overcome these difficulties – what is needed is training, capacity building and education of both clinicians, service organisations and patients to ensure that developing economies can participate in early stage trials and thus enhance their health prospects.

### **Support from industry policy is required for innovation**

Finally, the case study has shown that the boost to industry innovation occurred when industry policy was harnessed to build the number of clinical trials in Malaysia. Growth in domestic capacity was slow until only recently, because while capacity had been built, it was up to clinicians to decide whether to participate in trials. This was clearly insufficient to achieve progress and hence it is the industry policy target coupled with a targeted marketing

---

<sup>158</sup> USP Advisory Panel for the WHO Commission on Intellectual Property Rights, Innovation and Public Health, 16 November 2005

<sup>159</sup> Louisa, M et al: Current Status of Phase I Clinical Trials in Asia – an Academic Perspective, *Acta Medica Indonesia – the Indonesian Jnl of Internal Medicine*, 44(1), January 2012 pp 71-77

campaign (through CRM) and emergence of domestic private sector capacity that has begun to increase the number of trials taking place domestically.

Policy initiatives are also relevant in areas that are not normally the purview of the health ministry, under which clinical trials initiatives is occurring. It appears that other NKEAs in Malaysia also have the potential to affect achievement of the clinical trials EPP and government agencies would do well to consider the overlaps in effort (e.g. capacity building and marketing) in order to contribute to the successful achievement of several other EPPs.

### ***Conclusion***

Development of clinical trials regulations in Malaysia have been driven by a need to harmonize domestic regulation to enable the population as a whole to benefit from trials conducted by (mainly) overseas sponsors. It has only been effective because of strict enforcement and associated capacity building for clinicians. Changes to the system were initially driven by international trends; however the recent surge in activity has been due to associated industry policy initiatives which have specifically focussed on innovation.

In the main, the impact of the regulatory system is enabling for innovation, because it has opened the economy to new medical treatments and drugs for existing and emerging diseases (Table 4-6). Costs are minimal because trial sponsors fund the trials, hence the clinical trial regulations also generate foreign direct investment. The Malaysian government has introduced substantial institutional innovations. Companies and other service providers have increased their technical capacity as part of their compliance with the regulations.

**Table 4-6: Summary of Malaysia Clinical Trials Regulatory Analysis**

<b>Regulatory Analysis</b>		<b>Predominant impact on Innovation</b>
<i>Political and Administrative Viability</i>		
Transparency	Stakeholders' views reflected through formal structures such as NCCR. All regulations available on government sites.	Enabling for domestic and overseas trial sponsors and operators
Alignment	International harmonization requirements dominate. Coordination mechanisms established through NCCR and PEMANDU	Relationships forged between R&D institutions and sponsors. New institutional arrangements established
<i>Economic Efficiency and Effectiveness</i>		
Costs and Benefits	Clinical trials system has a cost but overall benefit is to society and the economy's industrial capacity.	Enabling for process, personnel-related, procedural, structural and institutional innovations  Compliance costs may reduce incentives for individual clinicians and public sector institutions
Scientific integrity	Regulations are based on internationally accepted scientifically-based steps	Development of technical skills
Flexibility and Twenty-first Century Regulation	Regulations mainly technical and permit-based, with some bans and planning requirements. No sunset clauses  NCCR provides avenue for continual review and response to stakeholders.  Master Plan structure provides formal framework for review	Enabling for companies, within technical limits

## 5. URBAN WATER SUPPLY AND MANAGEMENT

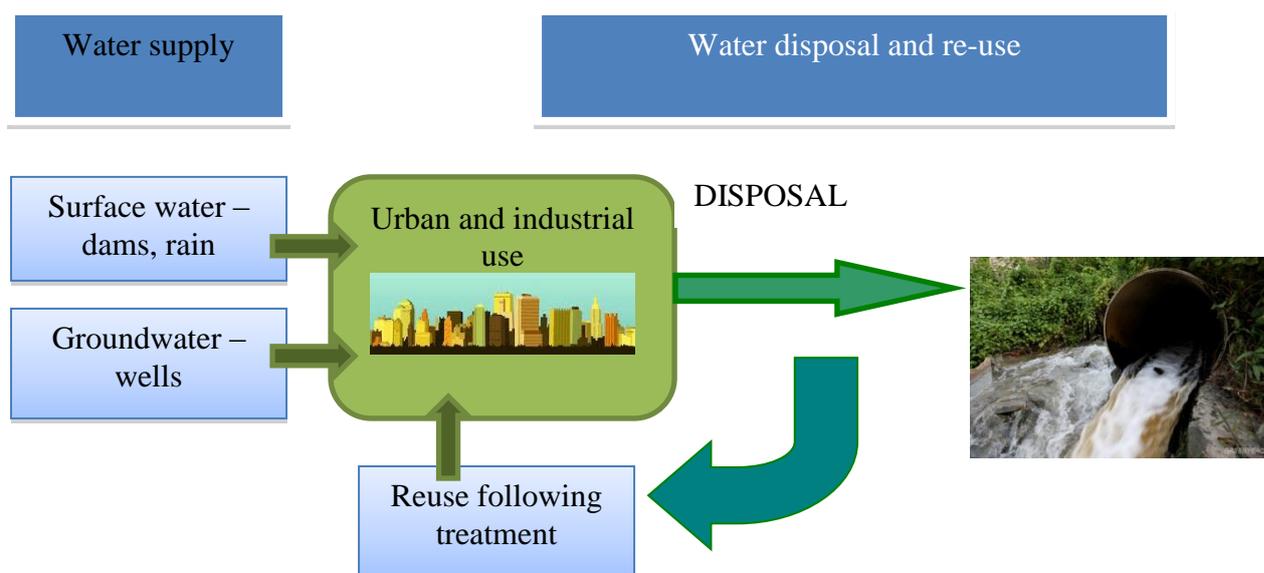
### INTRODUCTION

Access to and use of water for humans, crops and industries is of concern to governments worldwide. Water management problems can be grouped into three areas, all of which have attracted the attention of regulators: water scarcity, management of water supply, and management of water pollution.

Water scarcity or insecurity threatens development. Around 1.2 billion people live in areas of absolute scarcity and a further 500 million people are approaching this level.<sup>160</sup> Water scarcity has been a major preoccupation in drier APEC economies such as Australia, parts of China, Mexico and the west coast of the USA, and in those economies, including Singapore, where geographical boundaries limit or threaten access to fresh water.<sup>161</sup> Water scarcity is also an issue in regions where the water supply varies throughout the year and/or is contaminated.

Water scarcity, water supply and management of water pollution are interlinked (Figure 5-1). Thus, this case study focuses on the combined issues of water scarcity (access to water) and management of water disposal and re-use, the latter emphasized because of major changes over the last 20 years in disposal and re-use policies, particularly in developed economies.

Figure 5-1: Generic Approaches to Water Supply and Disposal



Source – derived from Morris, British Geological Survey 2001, author's amendments

Note – groundwater sources are not covered in case study as they are not relevant to either Melbourne (Australia) or Singapore in the examples discussed

<sup>160</sup> United Nations Department of Economic and Social Affairs – Water for Life Website [www.un.org/waterforlifedecade/scarcity.shtml](http://www.un.org/waterforlifedecade/scarcity.shtml) accessed May 2014

<sup>161</sup> UNEP Vital Water Scarcity Index [www.unep.org/dewa/vitalwater/article77.html](http://www.unep.org/dewa/vitalwater/article77.html)

The case study covers two economies, Australia and Singapore. Both face water scarcity – Australia because of absolute lack of rainfall and inability to effectively capture rain that falls, and Singapore from its limited land area and reliance on imported water for much of its history. Both have addressed water scarcity by developing, among other things measures to reduce use and encourage re-use of water.

The case study commences with an overview of the approaches taken globally to water regulation and management. The case study then reviews the emerging area of water-sensitive urban design (WSUD), developed in Australia following many years of research and re-evaluation of water policy in urban settings. The case study focuses on the state of Victoria which, like most of Australia, has a complex 3-level governance system. Victoria has approached the regulatory challenge through an innovative use of planning regulations at the local level. The second half of the case study discusses how Singapore has integrated water use and re-used at the local level, through a more traditional utility-based approach.

In Australia, planning is administered locally, with some overriding state and domestic policies influencing local regulations. In Singapore, planning is managed at the central level. The two cases therefore provide some interesting comparisons on the impact of different governance systems on regulatory development and implementation.

The case study finishes with a short section comparing the two economies, and some policy lessons for broader application.

**Regulations and Water Management**

**Water regulations**

Regulations have long been used as a mechanism to address water scarcity and limit pollution. Approaches include bans, standards, levies and permits, many of which also have social objectives, primarily maintenance of human health (Table 5-1). In most jurisdictions, health ministries will set technical standards and define banned and permitted materials for drinking water, and environmental protection ministries will set technical standards and defined banned and permitted materials for waste water (entering the environment as storm water or disposed to local rivers). However, planning standards, a recent and innovative use of regulations for water management, are our focus here.

**Table 5-1: Approaches to Water Regulation**

<b>Bans</b>	<b>Technical Standard</b>	<b>Planning Standards</b>	<b>Pricing and levies</b>	<b>Permits</b>
Disposal of certain items e.g. persistent organic pollutants	Maximum target levels for contaminants such as bacteria	Requirements for on-site waste water remediation	On a cost recovery or fully costed basis, including levies to remediate pollution	Permits to dispose of particular chemicals or to take water from rivers

Source: Author’s analysis

**Trade regulations and free trade agreements**

Trade regulations can have a significant impact on approaches to water and waste water management, because trade can affect an economy’s access to innovation and new technologies.

Recent trade innovations stem from the Uruguay Round of Multilateral Trade Negotiations (1993-94), which established a Committee on Trade and the Environment to identify the relationship between trade measures and environmental measures, in order to promote sustainable development.<sup>162</sup> As a result of the Uruguay Round, several APEC economies announced commitments to liberalise trade in environmental services. Later on, in 2012, APEC committed to reduce tariffs on a list of 54 environmental goods by 2015.<sup>163</sup> The list includes machinery used to purify and filter water to reduce contamination in waste water for waste treatment or recycling.

In 2007 APEC, member economies also launched an action agenda to promote environmental goods and services, reduce trade barriers for such good and services, and to pursue clean and sustainable development. APEC's previous work had noted that barriers to trade, technical regulations, IP rights and subsidies could all be used to restrict the movement of goods and services between economies, and hence their ability to respond effectively to new technical standards.<sup>164</sup> APEC's Work Program on Environmental Goods and Services (EGS) is designed to ensure that APEC economies can meet environmental goals at the lowest cost, and by using the latest technologies. The aim is to also enhance prospects for creation of "green" jobs.<sup>165</sup>

More recently, the TransPacific Partnership Agreement has emerged as a regional initiative to establish a free trade area in the Asia Pacific. While the Agreement is yet to be finalized, there are claims that the trade liberalization that results will provide increased access by service providers which can introduce more environmentally friendly production processes, particularly if the TPPA reduces barriers to services trade.<sup>166</sup>

## **INNOVATION AND Water MANAGEMENT**

### **Changes in water management technologies**

A number of studies have identified major drivers of change in adoption of new water management technologies over the past 20 years. These drivers, summarised, include stricter environmental regulation, consumer and community pressure, changing business attitudes to environmental compliance, public policy and investment focus on water, large scale investment in infrastructure under new standards, and technological developments.<sup>167</sup>

---

<sup>162</sup> Trade Negotiations Committee of WTO: Decision on Trade and Environment, Uruguay Round Ministerial Decisions and Declarations, 15 December 1993 and 14 April 1994. [www.wto.org/english/docs\\_e/legal\\_e/56-dtenv.pdf](http://www.wto.org/english/docs_e/legal_e/56-dtenv.pdf)

<sup>163</sup> APEC Leaders' Declarations Annex C [www.apec.org/Meeting-Papers/Leaders-Declarations/2012/2012\\_aelm/2012\\_aelm\\_annexC.aspx](http://www.apec.org/Meeting-Papers/Leaders-Declarations/2012/2012_aelm/2012_aelm_annexC.aspx)

<sup>164</sup> APEC Policy Support Unit Study on Good Regulatory Practices for Goods and Services Necessary or Desirable for Climate Change Mitigation and Adaptation, October 2009

<sup>165</sup> APEC EGS: Annex C- Trade And Investment In Environmental Goods And Services, 12 November 2011, <http://egs.apec.org/more-articles/285--annex-c-trade-and-investment-in-environmental-goods-and-services->

<sup>166</sup> Meltzer, J: The Trans-Pacific Partnership Agreement, the environment and climate change, in , Trade Liberalisation and International Co-operation: A Legal Analysis of the Trans-Pacific Partnership Agreement, Edward Elgar, 2014.

<sup>167</sup> Perkins, P: The Environment Management Services Industry, Paper prepared for the 2006 Australian State of the Environment Committee, Department of Environment and Heritage, Canberra.

Technological developments and innovation have been crucial in supporting implementation of new standards (regulations) in prevention and remediation of pollution. The regulatory aim is to reduce the volume of the contaminant going to landfill, to increase resource recovery of for re-use or use in other products, and to maximize the recovery of fresh(er) water, for reuse or for disposal into common effluent systems.<sup>168</sup>

As a result of industry resistance or social structures, or to speed adoption, Governments may introduce other supporting (non-regulatory) policy instruments to support change in response to new regulation, including education, networks of suppliers, R&D incentives and subsidies. These must be fine-tuned to the circumstances in which technical change processes occur and tip the balance.<sup>169</sup>

### **Water-sensitive urban design**

As noted above the focus of this case study is water-sensitive urban design (WSUD), which is a planning and water management philosophy that attempts to achieve

“the integrated design of the urban water cycle, incorporating water supply, wastewater, storm water and groundwater management, urban design and environmental protection. It represents a fundamental shift in the way water and related environmental resources and water infrastructure are considered in the planning and design of cities and towns, at all scales and densities.”<sup>170</sup>

At a practical level, water-sensitive urban design means that local water supply and waste water management authorities, between them, aim to reduce the use of potable water, maximised re-use of water, reduce the discharge of wastewater beyond the boundaries of the site in which it is generated, minimise pollution levels in storm water before it is discharged (e.g. to lakes, rivers, ocean) and protect the integrity of groundwater (Figure 5-2).

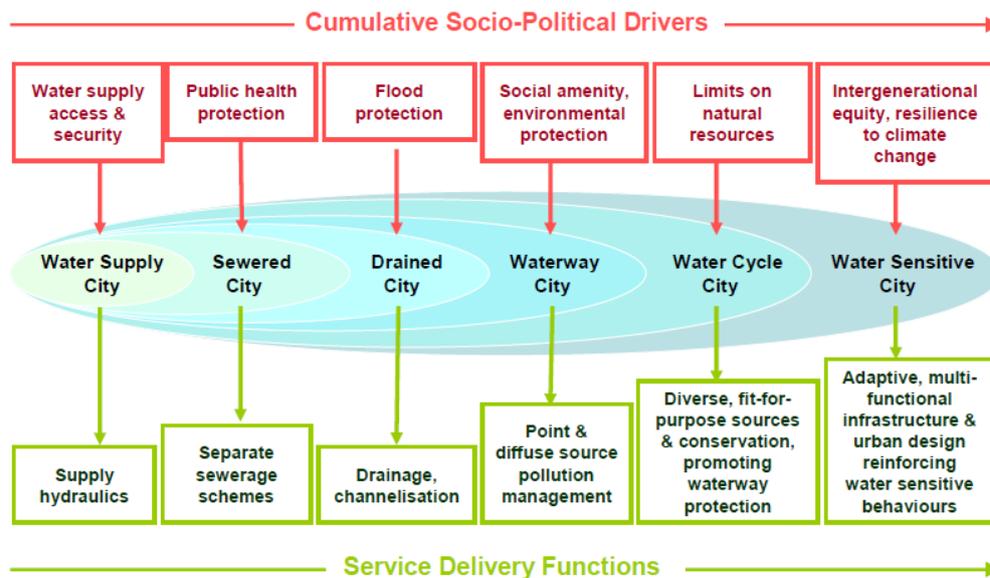
---

<sup>168</sup>Visvanathan, C and Asano, T: The Potential For Industrial Wastewater Reuse, 2000

<sup>169</sup> Kemp, R: Technology and Environmental Policy—Innovation effects of past policies and suggestions for improvement, 2000

<sup>170</sup> Joint Steering Committee for Water Sensitive Cities, July 2009

Figure 5-2: Urban Water Management Frameworks



Source: Brown, et al: Transitioning to Water Sensitive Cities – Historical Current and Future Transition Strategies, presentation to 11<sup>th</sup> International Conference on Urban Drainage, Edinburgh, 2008

At the technical level, innovations that support water-sensitive urban design can include:<sup>171</sup>

- engineering (asset) approaches, such as on-site storm water and industrial or domestic water retention and cleaning systems (otherwise known as grey water management systems) to purify waste water and enable its use elsewhere on the site, or prior to discharge
- environmental approaches, such as development of urban wetlands, swales and other vegetation to slow movement of waste water discharged on-site; and
- product-based approaches such as on-site water storage tanks (for water supply and to minimise waste-water discharge), and appliances or installed equipment which enabled reduced use of potable water.

Such systems may be developed at an “on-site” scale (individual lots) and owned/operated by the lot owner; at a cluster or development scale (servicing several dwelling or a whole development) and operated by some common ownership model; or at a distributed system (large) scale, operated by water utilities.<sup>172</sup>

Surveys have examined potential barriers to introduction of new water management approaches and have found that the main issues are public health outcomes (potential disease, for example, resulting from re-use of grey water), regulation and approvals procedures, capital costs and maintenance costs. Uptake of third pipe technologies was also prevented by

<sup>171</sup> Hussey, K and Kay, E (2014): *The opportunities and challenges of implementing ‘water sensitive urban design’: lessons from stormwater management in Victoria, Australia*, in press

<sup>172</sup> Cook, S, Tjajandraatmadja, G, Hom A and Sharma, A (2009): Definition of Decentralised Systems in the South-East Queensland Context, Urban Water Security research Alliance Technical Report 12

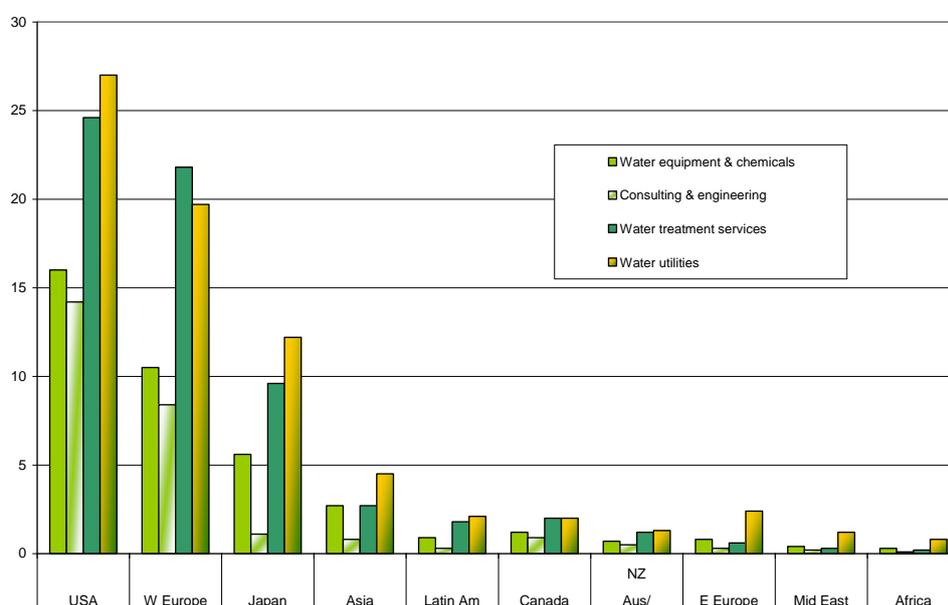
access to property and water re-use schemes also had barriers around community perceptions.<sup>173</sup>

### Services and water-sensitive urban design

Water-sensitive urban design aims change water use through site and landscape changes. The main professions involved in implementing WSUD are engineers, planners, environmental scientists and landscape architects. They rely not only on engineering and design solutions but equipment and other services that enable them to achieve their aims.

The demand for on-site product integration and bespoke solutions in response to local topology, geography and climate has led to emergence of environmental services industries. These dominate the environment-related industries in more developed economies (Figure 5-3). While statistics are hard to come by, more recent analyses have noted that markets for environmental equipment are declining while those for environmental services are increasing in China and Korea, and that Asia is emerging as the focus of clean technology new investment.<sup>174</sup> In all cases, local knowledge is important and hence opportunities are arising for local/domestic firms, often SMEs, either alone or in partnership with larger multinational firms that can provide multidisciplinary services.

Figure 5-3: Balance of Equipment and Services in Water Management, by Region



Source: Derived from Environmental Business International, 1996

The need for large scale heavy-engineered infrastructure in past water supply and disposal systems has also led to management by a central government authority (a public utility). This

<sup>173</sup> Brown, R., Farrelly, M. and Keath, N. (2007) Summary Report: Perceptions of Institutional Drivers and Barriers to Sustainable Urban Water Management in Australia. Report No. 07/06, National Urban Water Governance Program, Monash University, December 2007, ISBN: 978-0-9804298-2-4

<sup>174</sup> The Energy and Resources Institute: *Promoting Environmental Services Sector in Asia – Resource and Energy Efficiency Services*, Background paper for “International Conference on Green Industry in Asia”, Technical session – promoting energy and environmental services, 9-11 September 2009, Manila

has been the case in both Australia and Singapore, although they have taken different approaches to achieve this aim.

Water-sensitive urban design, however, demands a decentralized approach, because (parts of) supply and disposal may be managed on site. It also demands flexible institutional arrangements that can cope with climate uncertainty and variability; and monitor, evaluate and review policies and regulations.<sup>175</sup> In many economies, administrative and planning aspects of land use, flood mitigation, water quality management, urban development, and environmental protection are managed separately.

## **APPROACHES TO WATER MANAGEMENT IN AUSTRALIA**

### **History of water management**

Australia is a dry continent and water supply oscillates between low during droughts, and high (and uncontrolled) during floods. The population is concentrated on the coasts and the economy has always relied on extensive use of dams to supply drinking water for towns and regions.

Australia is a federation with three layers of government; however there are five levels of water management (national, cross-border, within-State, regional and local), because major riverine systems cross state boundaries and several local council areas may rely on water from a single river or catchment.

The National Water Initiative (signed in 2004) is the only national level water agreement. It was based on science which commenced in the 1990s, when the Australian government funded the Cooperative Research Centre (CRC) for Catchment Hydrology as a multi-disciplinary, multi-organisational research hub. The CRC was a joint venture between public sector research institutions and industry players, in this case including a major Victorian water utility, Melbourne Water. The CRC researched catchment hydrology, soil physics, vegetation dynamics, flooding and river hydraulics, irrigation and drainage. The central goal was production of IT-based decision support systems to predict the movement of water, particulates, and solutes from land to rivers (including urban runoff), linking the impact of climate variability, vegetation, soil, and water management together in an integrated package.<sup>176</sup> It was re-funded for a further 7 years in 1999.

As a result of the work completed, it was realized that cities could not remain as consumers of water collected in distant water catchments, but had to be part of the catchment itself. In 1994, building on this work, Australia State governments began releasing guidelines for the emerging field of Water-sensitive Urban Design (WSUD). This occurred first in the State of Western Australia in 1994 and in the State of Victoria in 1999. The work culminated in the National Water Initiative (NWI), a national strategy agreed by the Australian Government and all State governments in 2004. NWI spans water management issues and the adoption of best practice including the use of WSUD.<sup>177</sup>

---

<sup>175</sup> Brown et al (2007) *op cit*

<sup>176</sup> CRC for Catchment Hydrology web archive [www.secheresse.info/spip.php?article142](http://www.secheresse.info/spip.php?article142)

<sup>177</sup> Council of Australian Governments: Intergovernmental agreement on a national water initiative, 2009

## Development of water regulations in Australia

The primary driver for water regulation in Australia is absolute scarcity of water caused by the dry and unpredictable climate. Until recently, water has not been priced at its full value and, according to the Productivity Commission, there is no effective market for urban water because governments make their investments in supply with only limited knowledge of the value that users place on the resource.<sup>178</sup> Even where charging regimes recover operating costs, there is no reflection of the value of water in times of shortage.

According to experts interviewed for this case study, recent influences on water management policy in Victoria include a record-breaking drought (2002 to 2010), the realization that large scale desalination plants were not a feasible option because of public opposition, pollution loads in adjacent Port Phillip Bay, and an increased understanding that current methods of water management would destroy urban amenity.

### Regulations managing demand for water

Water demand management strategies are the responsibility of the water corporations. By way of example, Melbourne Water, City West Water, South East Water and Yarra Valley Water, which are responsible for supplying water to Metropolitan Melbourne, have developed a Water Supply and Demand Strategy which is a 50 years strategy to balance the supply and demand for water in Melbourne by residents, businesses and the environment. The final document, covers between now and 2055,<sup>179</sup> focuses on strategies to reduce demand and increase re-use, without introducing more regulations apart from existing Water Saving Rules, in place since the end of 2011. The focus is primarily on public education and behaviour change, as well as identifying new sources of water.

The local water supply and management strategies are strongly evidence-based and use existing cost data to support the argument for change. The resulting costs and benefits of each program in the strategy are exhaustively examined, e.g. a proposal to increase the use of local water sources by increasing local use of rainwater, storm water and recycled water is supported by an analysis of potential costs and direct benefits.<sup>180</sup>

### Regulations reducing pollution

The Victorian Environment Protection Authority is responsible for administering regulations to reduce water pollution. The regulations are based on a risk framework which encourages lower risk activities (reduce) first, followed by higher risk activities (re-using and recycling) (Figure 5-4). Re-use is encouraged for both domestic and industry users, in the latter case for cooling, washing, irrigation etc.<sup>181</sup> The EPA's Compliance and Enforcement Policy<sup>182</sup> sets out the framework for its administration of the pollution regulations.

---

<sup>178</sup> Productivity Commission (2008): Towards Urban Water Reform – A Discussion Paper, Productivity Commission Research Paper, Commonwealth of Australia 2008

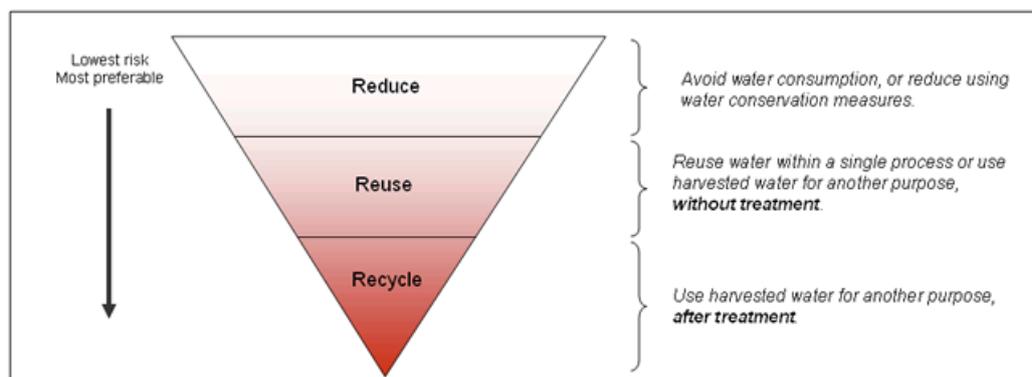
<sup>179</sup> Lovering, J (2006): Water Supply-Demand Strategy for Melbourne 2006 - 2055

<sup>180</sup> *Ibid* page 38

<sup>181</sup> Victorian EPA: Industrial Water Re-use Guidelines, Publication Number IWRG632, 30 June 2009, 13pp.

<sup>182</sup> Victorian EPA: Compliance and Enforcement Policy, Publication Number IWRG1388, 28 June 2011

Figure 5-4: Victorian Government Water Conservation Hierarchy



Source: <http://www.epa.vic.gov.au>

### Planning provisions

The main avenue through which WSUD is implemented is through the Victorian Planning Provisions, which encourage better planning outcomes by minimising damage to properties and inconvenience to residents from urban runoff; ensuring that the street operates adequately during major storm events and provides for public safety; and minimising increases in storm water run-off and protect the environmental values and physical characteristics of receiving waters from degradation by urban run-off.<sup>183</sup>

The main storm water management clause of the EPA's Victorian Planning Provisions dates from 2006 and is known as "Clause 56". Clause 56 applies to land in specific residential zones within the State and only to residential subdivisions which create at least three vacant lots. The clause sets out standards that such subdivisions must aim to achieve, including integrated water management, integrated urban landscaping, use of re-used and recycled water, urban runoff standards and drinking water supply.<sup>184</sup>

The overriding WSUD principles that underpin Clause 56 are based on the neighbourhood focus of Melbourne's development plan.<sup>185</sup> Its objectives support and promote walking, cycling, public transport, the neighbourhood street network, integrated water management and subdivision construction site management.

Clause 56 does not apply to industrial, commercial and infill developments, to residential developments which already have an existing dwelling, nor to developments on land owned by the central government.<sup>186</sup> Thus while it is a step forward, its lack of universal coverage leads to inconsistencies which are creating difficulties with implementation, as will be discussed below.

<sup>183</sup> Hussey, K and Kay, E: The opportunities and challenges of implementing 'water sensitive urban design': lessons from stormwater management in Victoria, Australia, in press (2014)

<sup>184</sup> Department of Transport, Planning and Local Infrastructure: Victorian Planning Provisions Practice Note - Using the residential subdivision provisions of Clause 56 – Residential subdivision, 2006

<sup>185</sup> Department of Infrastructure: Melbourne 2030– Planning for Sustainable Growth, October 2002

<sup>186</sup> Hussey and Kay (2014) *op cit*

## APEC Regulatory Analysis

### Transparency

The Victorian government has an extensive set of documents on its websites, including all the policy statements, outcomes of reviews, consultation drafts, legislation, explanatory notes provided by professional organisations, and practice notes for industry professionals. Strategic plans for its major agencies, e.g. the EPA, include commitments to developing and enforcing regulation transparently, to promote the sharing of information and learnings. Further, compliance of duty-holders and EPA's regulatory actions will be explained and open to public scrutiny. Enforcement actions will be made public, to build the credibility of EPA's regulatory approach and processes.<sup>187</sup>

### Alignment amongst authorities

It will have become apparent that many Victorian government agencies, plus private water supply corporations, are responsible for water supply and management in Victoria. The Essential Services Commission of Victoria sets prices for regulated water services as a result of plans submitted by each of the water supply corporations.<sup>188</sup>

Successful implementation of any provisions requires coordination among a range of authorities, principally the environment, planning and water ministries at State level, and local Councils and regional authorities at regional level. The difficulties this poses to integrated water management in the Australian context are well-recognised, with the existing system being described as “a complex and entrenched web of institutional and regulatory arrangements that very distinctly see the administrative and planning aspects of land use, flood mitigation, water quality management, urban development, and environmental protection managed separately (Brown 2008), with numerous and different actors involved but kept separate by very different regulatory regimes.”<sup>189</sup>

According to experts interviewed for this case study, local Councils are responsible for whole of water cycle management, but many of their plans omit particular economic areas for which they do not have responsibility e.g. under current building regulations some residential subdivisions can be planned without taking water management into account, and local Councils do not have planning control over Federal government facilities within their Local Government Areas.

The decentralization of water supply and management authorities increases the risk that regulations be applied differentially across various regions of the State. Uniformity in approach has been induced the Department of Environment and Primary Industries, which requires each water supply authority to follow uniform water demand strategy guidelines.<sup>190</sup>

The State government has promoted engagement across the agencies that are responsible for water management through a concerted program of consultation and public guidelines which are intended to influence funding agencies, local government agencies and water utilities.

---

<sup>187</sup> Environment Protection Agency Victoria (2011) *op cit* page 4

<sup>188</sup> Melbourne Water: Melbourne Water 2013 Water Plan

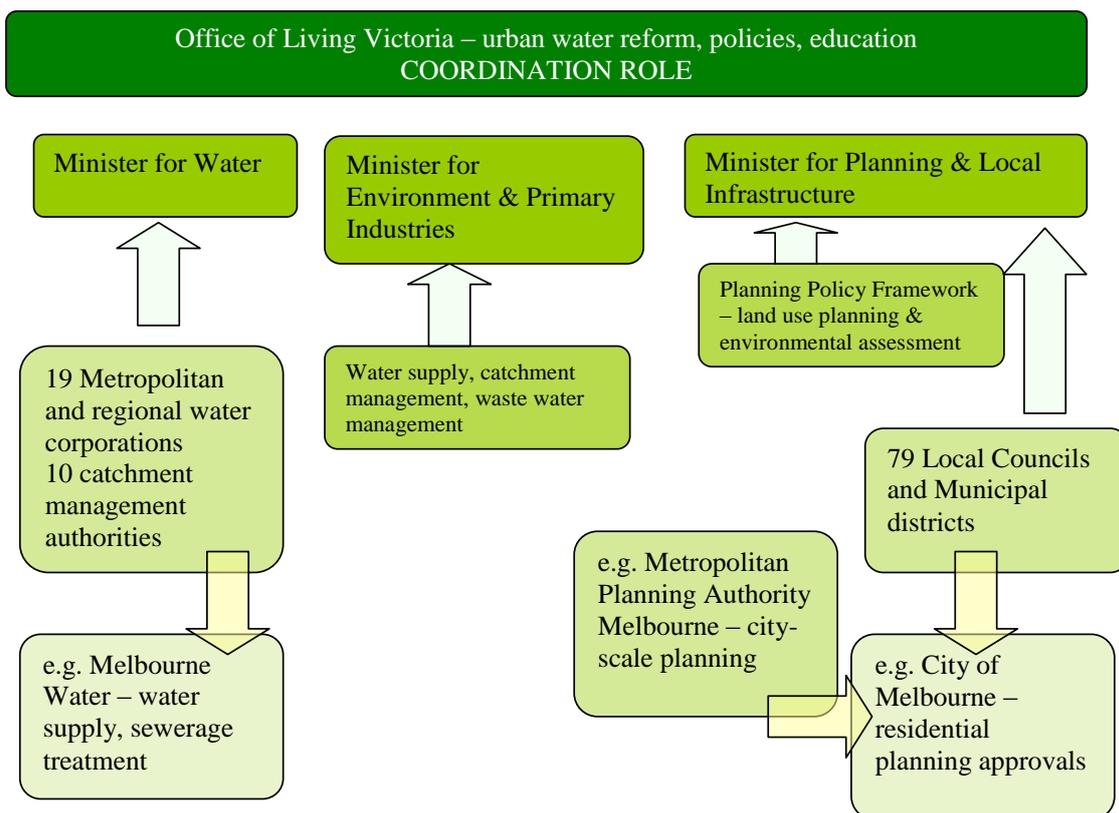
<sup>189</sup> Hussey and Kay (2014), *op cit* page 1

<sup>190</sup> Department of sustainability and Environment: Guidelines for the Development of a Water Demand Strategy – Overview, August 2011

For example, the Melbourne's Water Future strategy engaged key players in government, primarily the Department of Finance and Treasury, in aligning urban planning with water planning and coupling it with economic incentives including pricing.<sup>191</sup> It took 3 years to develop, with an initial roadmap followed by a reform package, a government response, a new organisation (Office of Living Victoria – OLV), a consultation draft and finally the Melbourne's Water Future Final Strategy.<sup>192</sup>

OLV was established to promote and coordinate the different Ministries (Figure 5-5), and act as a change agent for government, the water industry and the community to support the new approach to managing water supply, re-use and disposal. Part of OLV's remit was to develop (or commission) a Regulatory Impact Statement on the effect of the new regulations on the existing building industry regarding implementation of building controls to improve water performance of new buildings.<sup>193</sup>

**Figure 5-5: Victorian government Ministries with Urban Water Responsibilities**



Source: Government documents and expert interviews

Towards the end of the case study research, the Victorian government announced that it had abolished OLV as an independent entity and had brought it under the control of the Department of Environment and Primary Industries. It was reported at the time that despite the changes, OLV's urban water work program would continue as normal.<sup>194</sup>

<sup>191</sup> Victorian State Government (2013): Melbourne's Water Future – A Fresh Approach to Urban Water.

<sup>192</sup> Harbidge, S: Living Victoria – Establishing the value proposition, Water Sensitive Cities CRC, 2014

<sup>193</sup> The Living Melbourne, Living Victoria Implementation Plan, Government Response, 2012 (est)

<sup>194</sup> Doutré, C: Office of Living Victoria abolished as a stand alone entity, now under Department of Environment and Primary Industries Control, Weekly Times Now, 20 July 2014

### Costs and benefits

WSUD in Victoria is expected to be widely beneficial to the broader environment and will protect social and economic values by reducing floods, improving local visual amenity, protecting wildlife habitats and reducing pollution.<sup>195</sup> The overall government theme is *Sustainable Neighbourhoods*,<sup>196</sup> including the enhancing the health of local residents by improving local amenities.

Each local council has its own guidelines for how to measure the potential benefits and costs of a WSUD project. These draw their technical specifications from overarching guidelines issued by water suppliers. Each project must consider full life cycle costs, taking into account capital expenditure, installation, operation, life span and decommissioning costs.<sup>197</sup>

EPA documents claim that WSUD lowers capital and construction costs; however, according to those interviewed for this study, there is concern among the building and construction industry about the impact on the purchase price of a house in a new subdivision where WSUD is mandated, compared to another area where it is not – a direct effect of gaps in coverage of the regulations.

Those interviewed for the study also reported it is difficult to engage with the construction and development industry on the potentially innovative aspects of WSUD. The water industry is conservative and focused on safety, partly due to previous well-publicised and highly damaging negative health impacts of water contamination in New South Wales, which led to complete re-organisation of the water supply system in that State.<sup>198</sup> As a result the industry is keen to use what is known rather than what is new. Some innovation occurs by SMEs rather than with the larger companies, but it is site specific and there is no evident link with industry policy at the State level.

Major players acknowledge that engaging with the community on the costs and benefits of WSUD is a challenge, because it also requires a major change in the way people understand where their water comes from and goes to and who pays for it.

### Scientific integrity

WSUD as an approach is strongly based in scientific research (see page 62). Tangible outputs from the years of government-funded research include:

- A domestic hydrological modelling platform for urban water (e-Water Source<sup>199</sup>), which can help planners develop water supply scenarios, consider the impacts of both centralized and decentralized water supply infrastructure, evaluate demand and model environmental impacts.
- A toolkit for online access to water modeling (eWater Toolkit<sup>200</sup>), a web-based distribution point for hydrological, ecological and catchment management models,

---

<sup>195</sup> Victorian EPA (2005): Water Sensitive Urban Design, Publication 989

<sup>196</sup> Hussey, K and Kay, E: The opportunities and challenges of implementing ‘water sensitive urban design’: lessons from stormwater management in Victoria, Australia, in press (2014)

<sup>197</sup> Melbourne Water: City of Melbourne WSUD Guidelines – Applying the Model WSUD Guidelines, an Initiative of the Inner Melbourne Action Plan, 165pp (2006, est.)

<sup>198</sup> McLellan, P QC: Sydney Water Inquiry Fifth Report, Final Report Volume 2, December 1998

<sup>199</sup> [www.ewater.com.au/products/ewater-source/for-urban/](http://www.ewater.com.au/products/ewater-source/for-urban/) accessed May 2014

<sup>200</sup> [www.ewater.com.au/products/ewater-toolkit/](http://www.ewater.com.au/products/ewater-toolkit/) accessed May 2014

databases and other resources useful to those involved in land and water management or R&D.

- A model for urban storm water improvement conceptualization (MUSIC<sup>201</sup>), which is a modeling tool for urban storm water systems.

These outputs have been essential in developing the ability of engineers, landscape planners and local Councils to plan and model the impacts of particular local approaches and designs. The tools have also become the standard through which industry can demonstrate its compliance with water-sensitive urban design. The translation of this research into practical tools has also had economic impacts - the eWater Toolkit, for example, is now used in over 120 economies.

### **Flexibility and twenty-first century regulation**

While WSUD has been in place for a number of years, the “what does success look like” conversation in Victoria is still ongoing, particularly as it relates to broader community and health benefits anticipated from introducing WSUD.

Melbourne Water, as supplier to a number of Melbourne Councils, has implemented a program of raising awareness and capacity building (via pilot projects with local councils) since 2006. It is now setting implementation targets for WSUD and its role in storm water management.<sup>202</sup> Such targets are still based on technical standards and are contained in guidelines which include evaluation and communication so that performance can be tracked and evaluated.

The often slow nature of residential development means that performance measures are still being developed. It appears that its application in pre-planning and application phases of building development are now well-defined and measurable, particularly given the availability of modeling tools such as those above. Ongoing longitudinal analysis of storm water and rivers in Victoria is required in order to establish whether WSUD has contributed to longer term environmental remediation, however the EPA, which is responsible for such monitoring, has no long term measurement scheme in place at the scale that would be required to inform local Councils of the effectiveness of the approach.<sup>203</sup> Academic studies of implementation in another State, Queensland, are using sophisticated event monitoring stations to measure inflow and outflow from WSUD systems.<sup>204</sup>

The EPA itself is moving from predetermined technical content standards set by the EPA to an end-point based approach which provides for novel technical solutions to reach the same endpoint. The current EPA Five Year Plan, for example, aims to set standards and expectations for all activities based on good science and consideration of community aspirations.”<sup>205</sup>

---

<sup>201</sup> [www.ewater.com.au/products/ewater-toolkit/urban-tools/music/](http://www.ewater.com.au/products/ewater-toolkit/urban-tools/music/) accessed May 2014

<sup>202</sup> Urrutiaguer, M, Edwards, P and Chandler, C: The Evolution of a WSUD Capacity Building Program: The Role of Implementation Targets, Novatech 2010, 7<sup>th</sup> International Conference on

<sup>203</sup> Hussey and Kay (2014) *op cit*

<sup>204</sup> Parker, N: Assessing the effectiveness of water sensitive urban design in Southeast Queensland, PhD thesis, Queensland University of Technology, 2010

<sup>205</sup> Environment Protection Authority (Victoria): 5 Year Plan 2011-2016, published September 2011, page 17

In line with most Government practices throughout Australia, the Victorian government regularly reviews the impact of specific programs in order to determine whether the outcomes sought by the policy have actually been achieved.<sup>206</sup> Rather than use sunset clauses in regulatory areas, government agencies will be required to implement a formal evaluation program that provides an opportunity to measure the effectiveness of past regulations and make amendments to these as required. Regulatory Impact Statements must be prepared for any new or amended regulation.<sup>207</sup>

As part of the planning for establishment of OLV, during 2013 the Victorian government reviewed the Water Act 1989 and the Water Industry Act 1994. The government was advised by an expert panel with legal and water industry experience. This panel developed new legislation which aimed to reduce duplication between the two Acts, simplify existing arrangements around water resource management, and incorporate the Living Victoria whole of water cycle management approach.<sup>208</sup> The government then provided opportunity for public comment on an “exposure draft” of the new legislation early in 2014 and also held public forums around the State. In addition, several background and explanatory papers were produced to aid in the public interpretation of the new legislation.<sup>209</sup>

The resulting proposed Water Bill 2014, which aims to streamline the framework for water management in the State, will not come into force until 2016 at the earliest, but it aims to clarify the definition of “environmental water”, consolidate water management arrangements within government, manage water on a “whole of cycle” basis, clarify rights to ownership and management of storm water and enhance enforcement regimes.<sup>210</sup> The proposed Water Act also sets out criteria for evidence that must be collected by decision-makers prior to determining applications for water entitlements, including considering environment protection. Risk management, particularly risks to water resources, is also a focus of the new legislation.

Stakeholder input from over 40 government agencies and utilities has been sought for the OLV’s Metro Framework, which is still under development. The Metro Framework will initially guide the development of regional water cycle plans in metropolitan Melbourne and will involve OLV, the Metropolitan Planning Authority, Melbourne Water, relevant water corporations, planning authorities, local councils and other organisations such as VicRoads, Parks Victoria, major regional institutions such as universities and relevant business and community organisations.<sup>211</sup>

While the aim is to set objective performance standards and to implement WSUD as widely as possible, the patchy nature of the geographic application of Clause 56 and the overriding complexity of the regulatory system and its players mean that there have been significant gaps in application. According to recent research, awareness of Clause 56 is high, but there is little support for its application to private subdivisions (because of added costs and

---

<sup>206</sup> Victorian Department of Treasury and Finance [www.dtf.vic.gov.au](http://www.dtf.vic.gov.au) accessed July 2014

<sup>207</sup> E.g. see [www.depi.vic.gov.au/about-us/legislation/regulatory-reform](http://www.depi.vic.gov.au/about-us/legislation/regulatory-reform) on the DEPI site (accessed July 2014)

<sup>208</sup> Clearwater newsletter: Victorian Water Law Review – open for public comment until 14 February 2014, 4 February 2014

<sup>209</sup> De Sousa, D: Main Elements of the Water Bill Exposure Draft, Maddocks Lawyers, Update of Water Law Reform in Victoria, January 2014, [www.ecomms.maddocks.com.au](http://www.ecomms.maddocks.com.au) accessed July 2014

<sup>210</sup> [www.livingvictoria.vic.gov.au/water-law-review](http://www.livingvictoria.vic.gov.au/water-law-review) accessed July 2014

<sup>211</sup> [www.livingvictoria.vic.gov.au/priorities](http://www.livingvictoria.vic.gov.au/priorities)

concerns about selectively disadvantaging developers caught in its scope).<sup>212</sup> Further, while some Councils have enthusiastically embraced WSUD, others are still unclear as to where it applies within their local government area – this points to a need for ongoing and continued education of those required to implement the program – planning officers in local Councils.<sup>213</sup>

### **Innovation incentives in water management**

While WSUD regulations are clearly based on science in Victoria, it does not follow that innovation will occur and create associated economic benefit. Indeed, industry development and innovation appear to be a minor consideration in the introduction of WSUD in Victoria. According to experts interviewed for this study, there are few limited links between regulators and industry policy agencies in the government. The main innovation focus has been on skill development within local Councils, through the establishment of pilot projects prior to the setting of key performance indicators for WSUD.<sup>214</sup>

The other key innovation has been the emergence of the Centre for Water Sensitive Cities as an institutional innovation. This Centre is the “descendant” of the original Co-operative Research Centre established in 1990s. Given the clear role of research and development in the emergence and demonstration of WSUD as a concept, it is puzzling that the potential for ongoing innovation is not a focus. The Centre itself however has forged an international reputation and experts from there have played a major role in up-skilling Singapore for its own entry into WSUD (next section).

It is clear that the scientifically-ground framework of WSUD has promoted innovation in Victoria in local councils and builders/developers who are required to comply with Clause 56. Most of the industry innovations have been in the delivery of services (landscape planning, engineering). However the main innovations have been at government level where a raft of coordinating mechanisms have been established, partly in response to the complex three-tiered government system, but also apparently because of maintenance of existing demarcations in responsibility between water providers and planners.

## **Policy implications**

### **WSUD has led to major changes in water management**

The change in planning regulations and move to WSUD is having a major impact on the way that water is managed in Victoria. The “old ways” of one water utility or local council making decisions in isolation have gone and it is now necessary for those organisations to consult with a raft of other people and organisations before making a decision. This in turn forces greater scrutiny of underlying data and assumptions, and hence is reinforcing an already-existing requirement for transparency, and greater underlying scientific validity in regulatory formation, review and enforcement.

### **Education is essential step in implementing new regulations**

WSUD regulations cannot be implemented successfully without extensive educational campaigns for planners (in government), the community and builders/engineers. Academic

---

<sup>212</sup> Hussey and Kay (2014) *op cit*

<sup>213</sup> *ibid*

<sup>214</sup> Brown et al (2009) *op cit*

studies of its implementation in Victoria have noted the need to educate players at all stages of the planning process – pre-approval, planning and implementation – because of varying skill levels and thorough process management across local councils.<sup>215</sup> It should also be noted that the US Center for Disease Control identifies education about public health issues as one of the ten essential roles of public health services<sup>216</sup> – relevant to water regulation because of the link between clean water and good public health.

It should be noted that, while public education has been the focus of stakeholder engagement in relation to saving water, the public is not the target of education for WSUD initiatives. Rather, the focus is on professionals who interpret planning laws for the public (as clients) or residential developers..

### **Institutional frameworks need to be clear in order to support implementation**

Academic studies and experts interviewed for the project have also highlighted ambiguity in application as a significant barrier to successful implementation in the Victorian situation.<sup>217</sup> Complex regulatory structures, the dispersed responsibilities for implementation across local Councils, and the inherent gaps in coverage of Clause 56 to different types of building developments have caused conflicts and have inhibited adoption.

The Victorian government needs to adopt WSUD to meet its objectives for water re-use. Initially, OLV was established to overcome the inherent difficulties created by the current institutional framework. It is therefore unfortunate that this organisation has now been abolished. As an independent body it had the potential to effectively coordinate across the diverse governance frameworks that operate in Australia, particularly across two levels of government (state and local). It remains to be seen whether it can operate effectively within the Department of Environment and Primary Industries, and whether its previous focus will be lost and/or dispersed as issues relevant to its parent department come to dominate.

### **Performance measures need to apply to all planning stages**

Extensive scientific validation occurred prior to the development of WSUD, and evidence-based instruments have enabled Councils to evaluate proposals at the planning stage. However the apparent absence of agreed performance measures for the end phase of WSUD – where water exits a site and enters local rivers– means that the Victorian Government will have difficulty in justifying one of its major claimed benefits of WSUD – that of environmental improvement. In addition, there are no agreed benefit measures for broader social and health issues. The need to evaluate and measure such benefits is on the government's mind, but the difficulty arises because of the need to be able to transparently attributed observed benefits, e.g. reduced personal stress, to the introduction of the regulation. This is not an easy task. Nevertheless it needs to be done if financial agencies are to be convinced of the benefits of WSUD compared to its costs.

---

<sup>215</sup> Hussey and Kay (2014) *op cit*

<sup>216</sup> The Public Health System and the 10 Essential Public Health Services

<http://www.cdc.gov/nphpsp/essentialservices.html>

<sup>217</sup> *ibid*

## Conclusions for Australia

Development of water regulations in Australia was driven initially by water scarcity, risk management and potential costs of traditional solutions, particularly in times of increased rainfall variability.

The regulatory framework is complicated by the multi-layer governance system and the perpetuation of different organisations (some of which may yet be privatised).<sup>218</sup> There remain gaps in regulatory application of Clause 56 that cause price pressures and developers are therefore reluctant to adopt them. Table 5-2 summarises the findings of the regulatory analysis for Australia – despite the strong scientific basis and high transparency, the impact of institutional change dominates, with associated high costs of implementation.

**Table 5-2: Summary of Australian Water Regulatory Analysis**

Regulatory Analysis		Overall Impact on Innovation
<i>Political and Administrative Viability</i>		
Transparency	Government commitment to transparency; however difficulties in finding/understanding scope regulations due to incomplete application of Clause 56	Enabling for professions and community
Alignment	Establishment of new coordinating agency to cross existing boundaries	Institutional innovation (OLV – now abolished); cost of added coordination requirements across the system
<i>Economic Efficiency and Effectiveness</i>		
Costs and Benefits	Targets and benefits clear at technical level, still developing at community level	Enabling for process innovations but more costly. Provides some opportunity for new industries
Scientific integrity	Strongly science-based with ongoing objective measurement and continuous improvement	Enabling for both government and industry; may add to costs
Flexibility and Twenty-first Century Regulation	Performance-based, but lacks ability to measure ultimate impact of WSUD. Ongoing review and input process well established; No sunset clauses	Development of process and structural innovations essential to implement effectively

## APPROACHES TO WATER MANAGEMENT IN SINGAPORE

### History of water management

Singapore achieved independence in 1965. While approximately 2,340 mm of rain falls each year, it lacked the land needed to capture and store this water for its population. At the time of independence, average water consumption was 75L per person per day and it had only three reservoirs which drew from only 11% of its land area.

As a city-State, Singapore's government has control over all aspects of water supply and management. In the 1960s it started to apply standard technical approaches to expand conventional water resources and to explore unconventional sources (the latter including water re-use and desalination).

<sup>218</sup> Aussie Water Sell-off Hinges on National Regulator, 15(1): January 2014, Global Water Intelligence. Other articles refer to earlier proposals in 1993

In 1971 the Concept Plan for urban development and in 1972 the Water Master Plan were adopted. The Concept Plan is a strategic land use and transportation plan to ensure optimal land use to meet economic, residential and recreational needs.<sup>219</sup> The Master Plan aimed to increase water capture and supply through expanding existing reservoirs, building new reservoirs and by collecting water from densely populated new towns.<sup>220</sup> These plans relied on more or less traditional engineering, including extension of the sewerage system to ensure all used water was collected and treated. Appropriate land zoning, including keeping potentially polluting industries out of catchment areas, was an important feature of the system.

A Sewerage (Used Water) Master Plan was conceived in the late 1960s. It divided Singapore into 6 used water catchment zones each served by centralized water reclamation plant which complied with international standards. Storm water was channeled into rivers and reservoirs rather than the sewerage system. The development of this system included use of “trenchless technology” innovations which reduced costs to government and also reduced inconvenience to the public of installing the sewerage system.

Singapore first started exploring desalination in the 1970s but at that time it was not technically feasible. It again explored desalination in the mid 1980s but was again deterred, this time because of costs.<sup>221</sup>

In 1991 a new Concept Plan aimed to enhance the role of water in the urban environment and the Public Utilities Board (PUB – Singapore’s water utility) began to consider alternative sources, as technical developments meant that these were now economically feasible.

In parallel, the government started to consider improving recycling water so that it could be re-used. A demonstration plant was built in 2000, using a mix of traditional and new technologies, and by 2002 was shown to be safe. Desalination was implemented in 2005<sup>222</sup>). A program of public education commenced, including branding of recycled water as NEWater. Public acceptance of recycled water for industrial use was also helped by establishment of an independent expert panel, globally sourced, which audited the tests and procedures PUB used to verify the safety of NEWater.

At the same time wastewater treatment plants were re-named “water reclamation plants”, and wastewater was rebranded as “used water”. The public education campaign included development of a NEWater Visitor’s Centre, which is visited by every school child in Singapore. The media was also engaged to explain the concept to the populace.

Singapore now uses the terminology of “National Taps” to talk about its water – the Four National Taps supply water from local catchments, imports, NEWater and its desalination plant. By 2011 the local catchments had been extended to 17 reservoirs which drew from 67% of the land area, and up to 30% of the water supply was recycled.<sup>223</sup>

---

<sup>219</sup> Singapore’s First Concept Plan is Completed, 1971 – Singapore Online Historical Resources Guide, [www.nlb.gov.sg](http://www.nlb.gov.sg)

<sup>220</sup> Tortajada et al (2013) page 19

<sup>221</sup> *Ibid*, page 21

<sup>222</sup> PUB: Desalinated Water – the 4<sup>th</sup> National Tap, brochure, 8 October 2013

<sup>223</sup> Tortajada, C, Joshi, Y and Biswas, A: *The Singapore Water Story – Sustainable Development in an Urban City State*, Routledge, 286pp., 2013

## Development of water regulations in Singapore

There are two agencies responsible for water regulation in Singapore – the Public Utilities Board (PUB) and the National Environment Agency (NEA). The Singapore Green Plan, first issued in 1992 and updated most recently in 2012, sets out targets for environmental sustainability. The current plan (2012) is based around 6 focus areas, one of which is water.<sup>224</sup> It is under the control of the Ministry of the Environment and Water Resources.

The NEA is responsible for regulating discharge of water into the sea, whereas PUB regulates water entering the storm water system.

### Regulations managing demand for water

PUB is responsible for water supply under the Public Utilities Act, and hence is responsible for managing demand as well as managing initiatives which encourage re-use of water and which control disposal of water into sewers (the latter under the Sewerage and Drainage Act PUB).

PUB moderates demand for water by pricing, mandatory control measures (e.g. fitting of water saving devices)<sup>225</sup> and facilitation. For example, the Sanitary Appliances Fee (SAF) and Waterborne Fee (WBF), introduced by PUB in the 1970s, are levied to offset the cost of treating used water and for operating and maintaining the used water network.<sup>226</sup> The SAF is a fixed component based on the number of sanitary fittings in each premises. The WBF is charged based on the volume of water supplied to premises, regardless of the location and how the water is used or discharged.<sup>227</sup> In 1991 PUB also introduced the Water Conservation Tax, which aims to discourage excessive water consumption.<sup>228</sup>

Water is now priced to recover the full costs of production and prices contain a component to reflect the cost of developing additional water sources.<sup>229</sup> The Water Conservation Tax applies from the first drop of water used.<sup>230</sup> The public has been educated about the need for water conservation through a number of government campaigns including the Save Water Campaigns (1995, 1996 and 1998), the Water Efficient Homes Program (2003) and the 10 Litre Challenge (2006).<sup>231</sup>

### Regulations reducing pollution

Singapore's initiatives to reduce water pollution and enhance water recycling have been supported by NEA pollution regulations since the early-1970s. These regulations combine bans, permits, technical and planning standards to achieve the desired change. In the late 1990s existing water and air pollution regulations were consolidated to create the Environment Pollution Act of 2000.<sup>232</sup>

<sup>224</sup> Singapore Green Plan, Ministry of Environment and Water Resources website [www.mewr.gov.sg](http://www.mewr.gov.sg), accessed Sept 2014

<sup>225</sup> Xie, 2003 *op cit* page 4

<sup>226</sup> Xie (2006) *op cit* page 6

<sup>227</sup> [www.pub.gov.sg/general/Pages/WaterTariff.aspx](http://www.pub.gov.sg/general/Pages/WaterTariff.aspx) accessed May 2014

<sup>228</sup> Tortajada C and Joshi, Y: Water Demand Management in Singapore – Involving the Public, Water Resource Management Jnl, 2013, vol 27, 2013

<sup>229</sup> [www.pub.gov.sg](http://www.pub.gov.sg), page on water pricing in Singapore <http://www.pub.gov.sg/general/Pages/WaterTariff.aspx>

<sup>230</sup> Soon, TY et al: *Clean, Green and Blue – Singapore's Journey Towards Environmental and Water Sustainability*, Ministry of Environment and Water Resources Singapore, 2009

<sup>231</sup> Tortajada et al (2013) page 95 Figure 4.1

<sup>232</sup> PUB and Centre for Liveable Cities (2012): Water – From Scarce Resource to National Asset, Appendix D

Regulations are enforced strictly and penalties are applied for breach. The NEA's Code of Practice on Pollution Control<sup>233</sup> now specifies that trade effluent must be treated to reach allowable limits before being discharged into a public watercourse. There are also strict guidelines to prevent dilution of production effluent by potable, rain or industrial water. Singapore is rigorous in levying fines on those companies which fail to comply with these regulations.<sup>234</sup>

The enforcement of these regulations has been so successful that it enabled Singapore to open up water catchments to uses other than housing from the late 1990s.<sup>235</sup>

### **Planning regulations**

The Singapore Land Authority Act provides the legal basis for managing water resources and land together, through the Urban Redevelopment Authority and similar agencies. However PUB takes the lead responsibility<sup>236</sup> and it is able to influence the adoption of water saving and recycling methods for formulating a framework for implementation of WSUD in Singapore. Its involvement in town planning also extends to requirements for drainage easements, drainage standards, delivery of reticulated recycled water, storm water management and infrastructure funding.

### **APEC regulatory analysis**

#### **Transparency**

All of Singapore's water regulations are easily accessible through the Singapore Standards e-shop, linked to the SPRING Singapore website – SPRING is the government agency responsible for supporting industry growth (it is not involved in regulation).

PUB works closely with relevant industry associations and professional bodies as required e.g. the Institution of Engineers, to ensure that professional services meet appropriate standards, understand the regulations and can implement them. This working relationship also provides an avenue for consultation between PUB and industry. All the PUB initiatives are supported by extensive written guidelines.

Community engagement has always been part of PUB's approach. According to experts interviewed for this study, about two-thirds of the population now lives in water catchment areas, and the water falling on their properties as rain is going to return as their drinking water source. It is therefore important that they realise their actions affect the cleanliness of the water catchment.

One of the strengths of PUB's community engagement is its ability to encapsulate its message into easily remembered slogans and tag lines (e.g. ABC – Active, Beautiful, Clean – Waters). Weeks such as the "Clean and Green Week" reinforce the message. Education campaigns generally precede regulatory changes (which are then enforced).<sup>237</sup>

---

<sup>233</sup> [http://www.nea.gov.sg/cms/pcd/coppc\\_2002.pdf](http://www.nea.gov.sg/cms/pcd/coppc_2002.pdf)

<sup>234</sup> Xie, J: Dealing with Water Scarcity in Singapore – Institutions, Strategies and Enforcement, Environment and Social Sector Unit, World Bank Analytical and Advisory Assistance Service, background paper July 2006

<sup>235</sup> PUB and Centre for Liveable Cities (2012) *op cit* page 44

<sup>236</sup> Xie, 2003 *op cit* page 6

<sup>237</sup> Xie, J (2006) *op cit* page 7

### Alignment amongst authorities

The splitting of responsibility between PUB as the public water utility and the National Environment Agency (NEA) as the organisation responsible for pollution management is typical of the approach taken in most economies where water supply and water disposal have been perceived as two different activities.

PUB's overall regulatory role in recycling water means that it has little requirement for liaison and alignment with other authorities.

### Costs and benefits

The costs of Singapore's water initiatives have been high but the broader health costs brought about by poor sanitation in the 1960s – lack of proper sewage disposal and poor quality drinking water in the 1960s created water pollution and poor health.<sup>238</sup> Initiatives to improve water supply and sewerage treatment had rapid health benefits, including a reduction in typhoid deaths from 142 in 1980 to 33 in 1989.<sup>239</sup> By 1992, water pollution had been reduced to levels considered acceptable by the World Health Organisation.<sup>240</sup>

Since this time the main driver has been a perceived need for water independence coupled with, more recently, a desire to improve the population's social and physical health. When dealing with both broad types of regulation – demand management and disposal management – Singapore has taken a broad, society-level approach to measuring the benefits, supplementing a strict direct benefit/cost analysis.

### Scientific Integrity

According to experts interviewed for this study, the adoption of WSUD principles in Singapore follows original work on WSUD completed in Australia in the 1990s. According to experts consulted for the project, scientific integrity has been maintained through a focus on objective technical and planning standards coupled with an emphasis on R&D to develop, demonstrate and implement new technical approaches.

### Flexibility and 21<sup>st</sup> century regulation

Singapore's water regulatory system is clearly performance-based as the planning and technical standards on which it is based specify certain objectives and it is up to the land developers or industries to develop or install appropriate equipment to achieve those aims. Nevertheless the way in which the population is being engaged to help achieve the broader objective of reducing water use and maintaining clean catchments is always changing.

The government has implemented programs to enhance the public understanding and uptake of WSUD, as their involvement is crucial to success. In 2006 the government introduced the ABC Water Program – Active, Beautiful Clean Waters. This is part of Singapore's current aim, to “transform itself into a city of Gardens and Water.”<sup>241</sup> The 2007 ABC Waters Master Plan has identified 100 local projects where WSUD principles could enhance the integration of water with the environment. Of these, 23 have been completed.

---

<sup>238</sup> Heng, L: The Judiciary and Environmental Governance in Singapore, *Jnl of Court Innovation*, 2010

<sup>239</sup> *Ibid*, page 46 – check reference

<sup>240</sup> *Ibid* page 71 – check reference

<sup>241</sup> PUB Singapore: Active Beautiful Clean Waters Design Guidelines

According to experts interviewed for this study, ABC Waters Design Guidelines serve as a reference for developers and industry professionals to plan, design and incorporate innovative waterscapes into their developments through the use of ABC Waters design features. Additional codes of professional practice provide more detailed guidance e.g. the Code of Practice for Surface Water Drainage, the Drainage Handbook on Managing Urban Runoff, the Code of Practice on Environmental Health and Engineering procedures for ABC Waters Design Features. The ABC Design Guidelines also include technical performance objectives.

### **Innovation incentives in water management**

Industry development has always been part of PUB's strategy in developing alternative water supplies and providing for water recycling. Given that this was a new area, PUB originally drew expertise from around the world to deliver the initial plans and projects that proved the concept.

A joint PUB-Institution of Engineers Certification Scheme was introduced to help property developers in Singapore to meet guidelines and propose suitable ABC projects and is an example of an innovation incentive targeting the private sector. The skills of the existing engineering and landscape design industry have grown as a result. PUB also offers a joint training program with the Singapore Institute of Architects and the Singapore Institute of Landscape Architects.

Singapore has now emerged as a centre for water R&D and styles itself as a "global hydrohub".<sup>242</sup> This has occurred since Singapore formed the National Research Foundation as part of the Prime Minister's office in 2006.<sup>243</sup> This policy initiative has been accompanied by substantial funding. NRF's Environment and Water Industry (EWI) Programme Office, which is chaired by PUB and also includes the Economic Development Board and International Enterprise Singapore, currently has S\$470m to promote water R&D and to foster leading edge technologies that will help Singapore solve its own problems and create an internationally competitive industry.<sup>244</sup>

These initiatives have attracted several large water companies to Singapore, and the local industry has doubled to 100 companies.<sup>245</sup> Singapore expects the contribution of this industry to grow from S\$0.5 billion in 2003 to S\$1.7 billion in 2015.<sup>246</sup>

### **Policy implications**

#### **Regulation has led to major reduction in risk**

Introduction of WSUD, coupled with a strong regulatory system to prevent pollution and reduce demand, appears to have been an effective policy approach to reducing water supply risk in Singapore. By 2060 PUB plans to triple the current recycling capacity so that recycled

---

<sup>242</sup> Environmental and Water Industry Programme Office: Tap Into Singapore's Pool of Resources – Building a Global HydroHub, brochure, no date

<sup>243</sup> [www.nrf.gov.sg](http://www.nrf.gov.sg)

<sup>244</sup> [www.ewi.sg](http://www.ewi.sg)

<sup>245</sup> PUB press release 28 August 2014 Singapore's water industry poised to continue its growth momentum <http://www.pub.gov.sg/mpublications/Pages/PressReleases.aspx?ItemId=421>

<sup>246</sup> Environment and Water Management industry overview, [www.edb.gov.sg](http://www.edb.gov.sg) accessed July 2014

water accounts for 55% of supply. It also wants to reduce use of water per person from the 153L daily use in 2001, to 140L per day, by 2030.<sup>247</sup>

### **Regulation has used a range of approaches but these must be integrated**

Singapore has achieved these developments through a mix of regulation (and enforcement), education, technological development and partnerships.

The approach taken by Singapore shows that all possible approaches – bans, technical standards, pricing, planning standards and permits – can be used to manage supply, demand and re-use, but that these must be integrated to be effective. Rigorous enforcement has been central to achieving targets with industry. Active education and engagement programs have engaged the local community. The Government has then seen the opportunities provided by technical change and capacity building to enhance industry development.

### **Consultation and public education have been major contributors to success**

The standout feature, however, has been the approach taken with the public. This is the reason for Singapore's considerable success. This approach has been described as public-private-people<sup>248</sup> because of the importance of the latter in the success of individual projects. Singapore has announced its intentions to continue to use this guiding principle to ensure continued shared ownership of water coupled with ongoing innovation.<sup>249</sup>

### **Conclusion for Singapore**

Development of water regulations in Singapore were driven initially by water scarcity and risk management and later by technical developments which have enabled the integration of planning standards with water regulations.

As a result the regulatory framework and innovation operate hand in hand, with the government recognising the potential for new regulations not only to induce local innovation, but to provide an opportunity for industry expansion (Table 5-3). The result has been innovation across the economy with new industries emerging as well as new institutional arrangements which support further innovation.

**Table 5-3: Summary of Singapore Water Regulatory Analysis**

<b>Regulatory Analysis</b>		<b>Impact on Innovation</b>
<i>Political and Administrative Viability</i>		
Transparency	Close working relationship with professional bodies and major education programs to engage public and industry as partners; all regulations on SPRING/PUB/NEA sites	Enabling for professional development
Alignment	Coordination with other Ministries in working groups	Introduces water innovation to other agencies
<i>Economic Efficiency and Effectiveness</i>		
Costs and Benefits	Benefits measured on 100 year time scale through water self-sufficiency	Enabling for process, personnel-related, structural

<sup>247</sup> [www.pub.gov.sg/water/newater/Pages/default.aspx](http://www.pub.gov.sg/water/newater/Pages/default.aspx) accessed May 2014

<sup>248</sup> Xie, J (2006): *op cit* page 9. For more general discussion see also Ng, T et al (2013): A public private people partnerships (P4) process framework for infrastructure development in Hong Kong, *Cities*, 31:370-381, April 2013

<sup>249</sup> PUB (2013): From the First Drop – PUB Annual Report 2012/13

		innovations
Scientific integrity	Strongly science-based with ongoing objective measurement and continuous improvement	Enabling for both government and industry
Flexibility and Twenty-first Century Regulation	Performance-based but combine all approaches for maximum effect No sunset clauses New initiatives aimed at engaging public-private-people partnerships	Enabling for institutional innovations

Source: Author’s analysis

**COMPARING SINGAPORE AND AUSTRALIA**

Australia led the world in development of WSUD using planning regulations. Singapore has implemented a range of regulations which create the same effect, using water regulations. However, the journey has perhaps been easier in Singapore than in Australia, because of a more streamlined governance structure in the former economy.

In Singapore PUB, as the primary agency responsible for WSUD policies, has been able to take the lead and form a coherent set of regulations and can implement a defined set of training and engagement programs to enhance enforcement.

In Australia, the complexities of responsibilities at State and local government led to the establishment of an independent agency to oversee regulatory enforcement, however the regulations itself remain fragmentary. These local gaps in WSUD regulations have slowed implementation. The impact of abolishing the OLV, as coordinating agency, remains to be seen.

In both economies, however, there are common positive and negative effects on innovation, which are summarised in Table 5-4.

**Table 5-4: Impact of Water Regulations on Innovation in Victoria (Australia) & Singapore**

Type	Positive Effects	Negative Effects
Process	Some new product development, innovations in goods (site-based equipment) and services (landscape level engineering and environmental design)	Costs of protection required for IP (goods); need for site specific solutions limits economies of scale
Procedural	Adoption of WSUD raises skill levels, has associated societal and environmental benefits.	Associated organisational costs
Personnel-related	Capacity building in engineering companies and SMEs, local authorities Emergence of new industry capability in SMEs	Large costs associated with additional training, pilot projects (Victoria) and public awareness campaigns (Singapore)
Structural	New equipment and facilities at local level	Potential loss of economies of scale for both equipment and its monitoring/upkeep
Institutional	Establishment of OLV as coordinating agency in Victoria (since abolished); Institutional innovation in Singapore is focussed on government-public sector R&D initiatives and emergence of SME service capability, neither of which are strongly evident in Victoria	Additional coordination costs for government, large costs associated with additional consultation and public engagement

Source: Author's analysis

## 6. CONCLUSIONS

### *CONCLUSIONS*

There are some common conclusions that can be drawn from these case studies.

The first conclusion is that leadership has been important in both initiating regulatory change and in creating an associated impact on innovation and economic development. In both Korea and Malaysia the initial decisions on regulatory harmonization were taken by their leaders in response to global regulatory trends (in the 1960's and 1990's respectively). In Australia and Singapore, regulatory changes have been initiated by governments in response to access to resources and in both economies the regulatory changes have been part of a response to larger issues of long term resource constraints.

The second conclusion is that, having initiated the regulatory change, policy makers need to consider the impacts on innovation of their regulations and identify the common links with industry policy in order to enable regulatory change to enhance innovation and economic growth. The changes to industry policy required to bring about such change also require strong leadership and a focus on the desired objectives of industry development.

Korea launched its IP harmonization program in association with trade policy in the 1960s, but it was only explicitly linked with industry development recently. Its National IP Strategy now contains the dual aims of regulatory harmonization with enhancement of IP creation and protection and ultimate economic benefit. This strategy, plus the broader (non-regulatory) impacts of economic restructuring since the 1960s, has helped to lift the Republic of Korea to one of the world's greatest patenting nations.

Similarly, Malaysia adopted international clinical trials standards over 15 years ago, and took steps to increase capacity by its clinicians. However, it has been only in the last five years, after the government set a specific objective for industry development, that the regulations have had a major effect on innovation through effective linking to industry development policy. It has only been possible for Malaysia to determine the impacts of this initiative by the concurrent establishment of a rigorous and accurate reporting system, using data drawn from its regulatory approvals processes.

Finally in Singapore the government has also harnessed its adoption of WSUD to leverage industry development. This effect is not obvious in Australia, which preceded Singapore in introducing WSUD, but which has failed to couple it with effective industry development.

The third major lesson from the case studies is that regulation is a process rather than an event. In all cases where a regulation has been effectively introduced, governments have made major efforts to educate those which are affected by the regulation both directly and indirectly. These education campaigns can be an effective mechanism to engage users and the broader population in the reasons for the regulation, and reduce conflict at the point where penalties can be applied. This is seen most strongly in Singapore, which has a formal process for education and community engagement, but it is also seen in Malaysia in its recent campaigns to explain clinical trials to the general public, and in Australia with the

introduction of pilot programs for WSUD in Victorian Councils. Both Singapore and Malaysia are educating the public, whereas Australia is educating professionals.

This lesson also tells us that the impact of regulations needs to be considered beforehand. A common current approach (in Australia at least) is to develop a Regulatory Impact Statement, which examines the potential impact of a new regulation on the relevant industry, the community and government.

The fourth major lesson from the case studies is that institutional structures need to engage all relevant parties but can take many forms. Korea, for example, has an IP Council where both government and industry advise on IP reform and industry development and Malaysia has effectively coordinated its clinical trials regulations through NCCR and its related industry development through PEMANDU and CRM. Singapore, through the dominant role of PUB, has avoided the need to establish new governance arrangements for WSUD but it has focused its industry-relevant WSUD developments through the NSF. Finally Australia has established the OLV to coordinate and educate the disparate organisations that are responsible for implementing WSUD at two levels of government.

The fifth and final lesson from the case studies is all case studies show some compliance to best practice regulation but that none meet all the criteria on the OECD-APEC criteria (Table 6-1).

**Table 6-1: Summary of Application of OECD-APEC Framework to the Case Studies**

<b>OECD-APEC criterion</b>	<b>Korea</b>	<b>Malaysia</b>	<b>Singapore and Australia</b>
Transparency	All available on internet except industry members of IP Council not named	All available on internet and structured process for stakeholder input	All available on internet; complexities of Australian governance can confuse those to which regulations apply
Alignment	International harmonization requirements dominate; IP legislation requires alignment with by other laws	International harmonization requirements dominate; established coordination mechanisms	Local coordination dominates in both Singapore and Australia. In Australia multiple layers of government have required establishment of new coordinating agency. In Singapore single agency simplifies alignment
Costs and Benefits	Costs of utility patents similar to full patents; benefits of utility patents highest in specific industry sectors; SME training efforts by KIPO adds administrative costs but benefits SMEs	Direct compliance costs high but broader societal benefits	Targets and measures focus on technical levels. Ability to measure impact on society level limited by lack of frameworks and distribution of measuring equipment
Scientific integrity	No, historical basis driven by harmonization	Yes, based on internationally accepted science but harmonization also the primary driver	Strong scientific basis in both economies
Flexibility and 21st century regulation	Mainly technical, no sunset clauses. Complies with continuous review requirement but in response to informal	Combination of technical and permit-based, complies with continual review requirement through informal mechanisms and through Master Plan	Technical performance-based in both economies but measurement framework measuring ultimate impact not fully developed. No sunset

	inputs	process	clauses. New initiatives in Singapore harness public-private-people partnerships
--	--------	---------	--

Source: Drawn from the case studies

All case studies could demonstrate compliance with the transparency requirements and all had taken steps to achieve alignment with other regulations, with some requiring new institutional structures to support this. Compliance costs increased in all cases but the arguments have been put that societal and/or environmental benefits are greater in all cases.

The greatest divergence from the APEC ideal framework is in scientific integrity, with the IP case study showing the importance of historical influence in decisions to implement some regulatory regimes. In both the clinical trials and water case studies, however reliance on science was strong and pre-dated the regulatory frameworks implemented.

The cases also showed that sunset clauses are the exception rather than the rule, but that there are review processes in place in all economies, with Malaysia probably the most formal, followed by Australia, then Korea and Singapore.

### **RECOMMENDATIONS**

Recommendation for policy makers arising from the case studies are as follows:

- 1. Policy makers need to consider the potential effect of new regulations on innovation and economic development, and actively monitor their impacts.**

As can be seen from all three case studies there is potential for regulation to affect innovation, both positively and negatively, and hence overall economic growth. Hence, policymakers need to consider potential impacts of regulation on innovation and establish systems to be able to measure such impacts, and make changes to the regulation or its administration should the overall impact be negative.

Establishment of monitoring measures is best done at the time of implementing the regulation, so that indicators can be objective and statistics can be collected from when the new regulation is implemented. In Malaysia, for example, statistics collected by the national regulator are forming the basis of reports to the Prime Minister's Department/ on progress in meeting the goals set for increasing clinical trials under IMP3.

- 2. Where a regulation has the potential to promote innovation, industry policy needs to be harnessed to initiate industry change.**

It can be seen from the Korean case study that regulation can have no impact on innovation until some other event happens to initiate change in industry. This was also the case in Malaysia, where international regulatory harmonization had limited impact until the economy's leaders decided to promote capacity development in clinical trials – from this point, economic capacity started to increase, enabled by the regulatory framework.

- 3. New or amended regulations should be preceded by industry and public consultation and the impact on both needs to be continually monitored so that**

**administration can be adjusted to support compliance and industry development.**

In Singapore, public and industry education campaigns have preceded the introduction of new water regulations so that there is general acceptance when the new law is finally enforced. While Korea has implemented regulatory changes without substantial public and industry consultation, KIPO is monitoring the impact of such changes on SMEs and is amending its patent law administration to minimise negative effects and costs for SMEs.

**4. Policymakers need to implement formal review processes to help SMEs to provide input to regulatory evaluations.**

As can be seen from the Korean case study, regulatory review systems can be skewed towards larger companies which have the capacity to interact at senior levels of government. This issue is better addressed in Malaysia, where formal committees provide clear avenues for industry input and include provision for smaller players to provide comment.

**5. End-point impact measures need to be identified during regulatory development (possibly through inclusion in formal Regulatory Impact Statements) so broader impacts on society and the environment can be effectively measured.**

In Australia a Regulatory Impact Statement has become part of standard government practice when considering new regulations. Their purpose is to provide evidence of the key steps taken during the development of a proposal, including consultation with key stakeholders, and assess the costs and benefits different options under consideration. Development of a regulatory impact statement prior to introduction of new regulations enables governments to not only consider longer term impacts but also provides a framework for identification of impact measures that can help agencies measure such impacts in both the short and long term.

**6. Policy makers need to avoid or manage regulatory gaps in order to enhance both understanding and compliance.**

The Australian case study provides an excellent example of how gaps in regulatory coverage can cause confusion amongst those that are being asked to implement it or comply with it. The Victorian government originally addressed this through establishment of the Office of Living Victoria; however OLV's recent abolition calls into question the capacity for the current responsible agency, the Department of Environment and Primary Industries, to manage engagement with its key target audience, who are urban planners. In the other three case studies the national operation of the regulations minimizes these gaps.

The overlap with APEC's trade agenda also needs to be considered – harmonization is made more difficult when there are gaps in the regulatory framework.

**7. Policy makers must actively enforce regulations to ensure compliance and to enhance capacity**

The case studies show the impact of effective enforcement of regulation, in particular in the comparison between Indonesia's and Malaysia's approach to clinical trial regulation. In the latter case strong enforcement has enhanced economic capacity to conduct clinical trials. Similarly, in Singapore, enforcement of new water re-use regulations provided the impetus for enhanced capacity in both research institutions and industry and the eventual creation of significant industrial capacity in the Singaporean economy.

**8. Relevant APEC Committees, Working Groups and Fora should work together to address the impact of regulations so that the impact of regulations on specific industries can be better understood.**

While focus of these case studies has been OECD-APEC Good Regulatory Practices Criteria, the studies are relevant to a number of APEC Working Groups. There is potential for these working groups to work together to consider the issues raised here, possibly led by the APEC Economic Committee (EC). Of particular importance is the potential for this committee to coordinate with the work at other APEC sub-fora such as the Small and Medium Enterprises Working Group, the Life Sciences Innovation Forum, the Intellectual Property Rights Experts Group and the Policy Partnership on Science, Technology and Innovation.

### ***AREAS FOR FURTHER RESEARCH***

This set of case studies has extended our understanding of the impact of regulation on innovation. It has shown that in some cases (Singapore and Australia) that different approaches can be used to achieve the same ends. It has also highlighted the potential opportunities for industry development when regulatory change is actively linked with industry policy.

Case studies provide the opportunity to obtain qualitative data to measure social and public impacts. However it is difficult identify key influences because of the operation of multiple variables in any case study. The impact of multiple variables can be limited by, for example, completing case studies in a single sector. This has been done in the Singapore/Australia case with water regulations; but there is also the Malaysia/Indonesia comparison in clinical trials, which has not been explored in depth because of budgetary constraints.

The conceptual frameworks outlined at the beginning of the work could also be used to compare and contrast different approaches. For example, it may be possible to identify examples of all five innovation types in a single sector. This issue can be considered by APEC in its forward work agenda