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Anti-counterfeiting health products Seminar. Building International Cooperation to Protect Patients

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Anti-counterfeiting health products Combat
A perspective from a small Latin American developing country

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I - The counterfeit of health products in the framework of the national policies on innovation, industrial development and public health

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The counterfeit affects the pharmaceutical innovation proccesses and the access of population to medicines

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New medicines are focused
in general on diseases of great
incidence in human health
Their prices are generally high
because they refer to top technologies

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The counterfeit of new medicines not only damage public health, but the innovative enterprises and also the public policies oriented to science, technology and industrial development.

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The negative consecuences in the innovation proccesses are very important in the developing countries,that focus their growth strategies in technology development and invest strongly in R&D

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The transformation of pharmaceutical generic industries in innovation focused ones demand strong private and public funding specially in small developing countries

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The innovation in pharmaceutical sector needs great investment and comprises long and complex proccesses, from which only few of the tested options become successful products

The big international pharmaceutical corporations lead an important part of the research oriented to generate new medical products

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From TRIPS agreement, is taking place a transformation of an important number of pharmaceutical industries from developing countries into innovative ones

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Generic local pharmaceutical industry has sometimes the technological background to make possible the transformation into an innovative one

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Such processes are usually part of the national policies designed in developing countries to promote innovation and industrial development

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In general, those policies involve an important transfer of public investment in terms of technical assistance, incentives and financing

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A long term development perspective, imply to pay attention to the industrial sectors considered the keys of those strategies

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Those policies are also oriented to attract private funding for the selected sectors by means of public incentives

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That is why the achievement of those projects and strategies, like the private and public investments
applied to them, become an important public interest matter to be protected

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That public priority include the protection of private investment applied to innovative or R&D projects in the, due the high risk they usually involve

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Once is defined that the development must be based on technological innovation, the protection of inventions became one of the tools to promote private investment, applied to the creation, use and dissemination of new technologies

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Public polices oriented to foster innovation in the pharmaceutical sector of the developing countries, help also to build capability to assure the internal supply of medicines, and furthermore that necessary for export

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In the field of local pharmaceutical innovation, there is an special interest in apply part of the R&D efforts on local diseases, on which international companies
do not pay enough attention

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The development of local pharmaceutical industries,innovative or generic ones,helps moreover to the supply of medicines at lower costs, and at the same time, is a way of maintaining the budget of the public health under control

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Then, it appears to be an important interelation (at least in the developing countries) among: innovation, technological development, the building of industrial capabilities, the access to medicines and their prices, and the Intellectual Property

One proof of the importance of those matters and their interconexion, is that all of them have been considered in the TRIPS agreement, the negotiations to its conclusion, the results of the Doha round, the resolution of TRIPS Council issued on December 2007, and the discussions that are taking place nowadays in that Council.

In terms of public health, the offer of generic medicines of quality would improve the competition, the supply and the lower prices of them, at the same time that favour, as said, the development of the industrial capabilities of those countries

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But that assertion does not contradict the other that consider the Intellectual Property Rights, and specially the patents, as an important tool to be used by the policies of innovation and industrial development

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To keep the balance, and looking not to affect the supply and prices of medicines, the free competition, the innovation process and the growth of the local pharmaceutical industry; the monopoly coming from the patents and other IP rights need to be limited to avoid some excesses

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The counterfeiting activities damage the policies for the supply of medicines, and at the same time the competition in the pharmaceutical market, likewise the innovative and the generic based companies

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In similar way, the counterfeit damage the IP rightholders specially those on trademarks and patents

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The counterfeit of medicines becomes in that sense a problem for the national strategies for industrial and technological development

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That negative phenomenon produce a negative effects on the balance among different players, harming their agreements and alliances

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II – The anti-counterfeiting Combat, Drafting an Strategy

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The axis of that possible anti-counterfeiting strategy would be focused more in the demand than in the supply

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The best scenario would be that of a reduced market due to a minimal demand for the counterfeit products

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That hypothetical scenario would meet in special the following characteristics:

A) One health system that would be able to cover the whole population, to assure the access to medicines of good quality, to take care of the most important diseases, and that gives priority to education and prevention

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B) A regulation and control system proper, efficient and respected, that covers the whole chain that goes from production to delivery and selling of medical products; assuring their security,effectiveness and quality

C) An information and alert system, which includes all the members of the pharmaceutical process, and coordinated with the health agencies of the other countries.

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D) A work of the justice and the police focused, efficient, and effective, with high capabilities, modern technical means, and a flexible and coordinated organization, strongly connected with the national and international agencies and organizations working in this matter.

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The proliferation of operations and convictions, could affect the disuasive capability of police and justice, besides the huge amount of resources that they demand

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In short, a combination of incentives penalties and benefits that keeps the balance among stimulus, dissuasion and repression

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The keys of the anti-counterfeit system are:

Education
Prevention
Coordination
Cooperation
Dissuasion

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III – The counterfeit of medicines and the organized crime

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The counterfeiting of medicines is a form, in most of the cases,of the organized crime

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The peculiar characteristics of such kind of criminal activities, makes necessary to relay on a legal, technical and operative means proper for an efficient response

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In the legal field comprises the need of a specific civil and criminal legislation and a specialized justice

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At the operative level, public health sections and police, need also to count with special task forces

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Considering the complexity of counterfeiting activities, the action of judges, prosecutors and police, would depend on the technical capabilities of health authorities

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Looking at the great differences of resources with the criminal organizations existing in the small developing countries, the cooperation and coordination among the different entities becomes a fundamental factor of success

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Independent and high qualified technical agencies, contribute to the respect to law, and provide guaranties to the different players of the system

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Also, those type of technical services contribute to maintain the fair competition among private players in the strongly regulated market of medicines

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The counterfeit of medicines is an international problem, then the struggle is not a task of a sole country or organization, it needs the coordination and cooperation among countries and international organizations

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IV – URUGUAY: Recent initiatives in the anti-counterfeiting medicines combat

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Creation of two new criminal courts specialized in organized crime with its adequate staff.
Two criminal prosecutors were assigned to this matter.

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An special team engaged in anti-counterfeiting on the Health Department is addressed to handle this matter at national, regional and international level

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Regulations about Manufacture and Commercialization of medical products have been updated, and the capabilities of Analysis and Control have been improved

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Participation in regional and multilateral fora about the matter , specially in the OMS, OPS and MERCOSUR

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Information an coordination meetings have been organized with the participation of all the involved parts, specially Police customs authorities and Justice

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V - MERCOSUR

The strong activity on harmonization in health matters includes a chapter on anti-counterfeiting of medicines

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Resolution 13/08 of the Common Market Group of June 20,2008 “Guidelines concerning the counterfeiting and fraud of medicines and medical products in the MERCOSUR”

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The health authorities of the parties must develop and improve their actions in the combat to counterfeit, based on the references and guidelines issued by the WHO and PAHO

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Health authorities must develop their activities in coordination with the other government agencies working in the topic, specially with police, judicial and custom authorities

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Health authorities must encourage the training of agents and the promotion of informative campaigns for the society, so as to restrain the circulation of medicines manufactured or marketed out of the legal framework

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Those authorities will look for defining strategies for the adoption of mechanisms of tracking and authenticity of medicines in the whole line of manufacturing and commercialization.

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V – Falsification of medicines and Intellectual Property

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Although falsification could occur in coincidence with infringements to IPRs, it is necessary to make a careful distinction between both in order to avoid distortions and counter–productive effects.

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The recent definitions of the concept of falsification at multilateral level, take care of its independence with regard the IPRs infringements

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Recommendations issued by the IMPACT Group of WHO at the meeting in Hammamet on December, 2008 (“Principles to be promoted by the stakeholders”)

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The primary focus of the combat to counterfeit medical products is the protection of public health, because the main victims of counterfeiters are patients

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Ensure that combating counterfeit medical products does not result in hinderig the availability of legitimate generic medicines

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Patent violations or disputes must no be confused with counterfeiting of medical products

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Medical products (both generic or branded) that are not authorized for to be marketed in a given country but authorized elsewhere are not considered counterfeit

A definition of counterfeit medical product was agreed, which, in the line with recommendations, exclude in particularly the violations or disputes about patents

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The confusion of the concepts between counterfeit and infringement of IPRs, may lead to harm the essential activities guided to protect public health

That could happen if the scarce available resources are misguided, the actions focused on counterfeiting are distorted, or the access to medicines for citizens from developing countries are in some way affected

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The interferences between activities directed to prevent the commerce of counterfeited medicines and the actions to defend the IPRs, may admit an approach focused in the cooperation among the different players

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That approach may be based in the recognition of the differences and peculiariities existing in each ground, the different hierarchy of the involved rights, and the search for common fields of action

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In the framework of a cooperation oriented vision, the coincidence of both types of infraction may result an opportunity to join different actors in a common strategy against the counterfeit of medicines

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As counterfeit affect many different interests, then the involved actors could cooperate to carry out a more effective fight against it

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Alliances among the representative organizations of the different sectors of the pharmaceutical industry, including both producers of generics and those of patented medicines, do have precedents in other matters.

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Presentation of
José Antonio Villamil,
Director of Patents Division
DNPI - URUGUAY
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