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Pan American Conference on Drug  
Regulatory Harmonization  
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## **SUMMARY OF CONCLUSIONS**

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1. The participants reiterated the need to give priority to health considerations in trade and economic integration processes, which implies that drugs should have a differentiated treatment in such processes. They expressed unanimous concern over such measures as the decentralization of drug registration and tacit approval where the administration fails to take action, which in some subregions and individual countries have been incorporated into the modernization processes, making it possible for products to appear on the market that are unacceptable from the health standpoint.
2. The following aspects were identified as priority components of harmonization processes:
  - The Standards for Good Manufacturing Practices and the advantages of using those recommended by WHO as a reference were recognized. The need to provide training for inspectors and to conduct joint inspections as way to facilitate future mutual recognition among them also became evident. It was also emphasized that the Certification Scheme recommended by WHO for the international trade in pharmaceuticals is not being employed properly despite its advantages over other systems such as that of the certificate of free sale.
  - It was recognized that uniform criteria were needed for: a) accreditation of laboratories for the analysis of drug samples, b) requirements for bioavailability and bioequivalence, c) product stability studies, d) conversion from the requirement for sale by medical prescription to sale without prescription (OTC), and e) the observance of Good Clinical Practices. For all of these the guidelines already developed by WHO and the ICH should be taken into account.
3. The need to define and disseminate the criteria used by some regulatory authorities to construct their lists of “reference countries” for the registration of drugs was recognized, mainly because of the manifest concern of some participants over a possible reduction in the autonomy or decision-making capacity of recipient countries in the issuance of marketing authorizations.
4. It was unanimously recognized that, to operate properly and efficiently, the regulatory agencies needed to be strengthened by: a) making them administratively and financially autonomous while keeping them attached to the ministry of health, b) establishing adequate schedules of registration fees and providing for the direct and exclusive use of the resources so obtained, c) endowing them with qualified human resources and up-to-date technology, and d) establishing procedures for updating and training in all areas of drug surveillance.
5. Adequate communication and coordination between ministries of health and the specialized commerce and trade agencies became evident as essential for: a) obtaining information about the ownership of the products to be registered, b) ensuring that the use of trademarks, registered or not, does not lead to misuse or confusion about their

- therapeutic use, and c) that the trade names do not make improper use of International Nonproprietary Names (INN).
6. It was recognized that, in compliance with current international legislation, it is important to respect the confidentiality of unpublished information used in registration procedures.
  7. With regard to the harmonization processes under way, the participants acknowledged the necessity of: a) continuing them through the specific agencies and mechanisms currently operating in the Region, such as MERCOSUR, NAFTA, LAIA, and the Andean Community, while recognizing the serious limitations existing in other subregions, such as Central America, where there is no legal framework to authorize and operationalize the commitments made by technical groups at the subregional level, b) taking the particular needs of each subregional bloc and the different degrees of development of their constituent countries into account in order to implement the subregional agreements in the countries, which means that the agreements must be implemented gradually, and c) setting up a system for circulating detailed information on the standards, requirements, and procedures in place in every country and geographical bloc, to develop a common terminology.
  8. As for global harmonization mechanisms, it was recommended that two representatives from the Region of the Americas as well as the six regions of WHO be included in the meetings of the ICH to ensure that countries with different degrees of development are represented.
  9. It was unanimously recommended that a hemispheric Forum be established, with PAHO as its Secretariat, to articulate the different subregional blocs on the subject of drug regulation. There was emphasis on the importance of: a) having a Steering Committee in which the subregional groups active in the drug regulatory harmonization process are represented to coordinate the activities in preparation for the Forum and lend continuity to its recommendations; b) including in the Forum all actors involved in addressing the problems connected with drugs: the regulatory authorities, industry (domestic and multinational), representatives of the integration entities, consumers, and professional associations, c) guaranteeing financing for the forum as well as the work of the Steering Committee, for which the support of industry (domestic and multinational) and the governments was recommended.
  10. Finally, PAHO was asked to support the countries and integration blocs in the following areas:
    - Information on pharmaceutical legislation.
    - Collection and dissemination of documents, experiences, and procedures on drug regulatory harmonization in each country and subregional bloc.
    - Research to document compliance with existing harmonization agreements.
    - Definition of the analytical methodology for addressing common problems and charting of lines of work.

- Exchange of information among the harmonization efforts of the different integration processes.
- Institutionalization of a hemispheric forum that articulates the countries and different subregional blocs.