

CARLOS M. CORREA: NOTE ON THE CIPIH REPORT

1. The CIPIH Report can make an important contribution to the current debates on the ways of addressing the development of medicines that predominantly affect the poor. It contains some important considerations and recommendations. However, given the composition and the mandate of the CIPIH, it was perhaps inevitable that different views would arise in dealing with such complex and sensitive issues.

2. I have expressed the view that the CIPIH should have concentrated in the drafting of an essentially action-oriented report examining the institutional and other changes needed to promote innovation for the diseases prevailing in developing countries. Other members, however, insisted on a much broader approach, including regulatory and delivery issues, which has necessarily led to a less focused analysis and set of recommendations.

3. The broad range of issues dealt with and differences in the Members' opinions did not permit the CIPIH to carry out an in depth- analysis and reach more substantive conclusions on some of the key issues addressed in the Report, such as:

- the differential impact of patent regimes in developed and developing countries;
- the costs that the granting of patents generate in developing countries, which are not offset by the benefits that could be theoretically derived therefrom;
- the ways in which developing countries can fully implement and utilize the flexibilities built into the TRIPS Agreement¹;
- the serious distortions that affect the patent system, which is increasingly polluted with the granting of patents over minor or trivial developments, as well as with patents that conceal the knowledge necessary to effectively implement the protected inventions;
- the important changes that have taken place in the structure of the pharmaceutical industry and the new roles played by biotechnology firms and contract research organizations in pharmaceutical R&D;
- the crisis in R&D productivity, as evidenced by the decline in the rate of development of new chemical molecules and the emphasis on 'me-too' drugs;
- the lack of transparency about the actual costs of R&D for new drugs;
- the strategic use of patents to prevent or delay generic competition through 'evergreening' of patents on minor or trivial variants of existing products.

4. The Report, however, makes one important point crystal clear: the patent system does not play any significant role in bringing about the medicines needed by the poor. The reason for this, as spelled out in the Report, is that patents only work when profitable markets exist. Given this basic finding, it is crucial that governments take the necessary steps to implement other suitable mechanisms for developing and making available such medicines.

5. In this regard, the report recommends further work and elaboration on the idea of a R&D treaty proposed by several non governmental organizations and scholars. It also recommends that WHO initiates the development of a global plan of action that should encompass a central role for WHO, as the leading health agency in the world, in designing mechanisms for priority setting and

¹ See, however, on this issue, the study prepared for the CIPIH by S. Musungu and C. Oh, 'The use of flexibilities in TRIPS by developing countries: can they promote access to medicines?' (available at <http://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf>).

sustainable financing of essential health R&D. Unfortunately, the Commission was unable to make more concrete and operative proposals on this critical matter.

6. The Report rightly acknowledges the crucial role that competition plays in improving access to medicines. Further analysis is required on the various barriers (anti-competitive practices, abuses of patent rights, etc.) that are often erected by brand name companies to keep competitors out and maintain high prices. The report also mentions compulsory licenses and government use as measures that can be applied to increase the affordability of medicines. But it fails short of recommending their wider utilization in the new scenario that emerged after the TRIPS Agreement became fully mandatory in developing countries, where a single company may virtually control the worldwide the supply of a medicine.

7. While the Report recommends that WHO should play a proactive role in the continuous review of the effects of the TRIPS Agreement implementation. WHO should also assess the negative implications of the TRIPS-plus standards adopted in the context of free trade agreements. Where applied, such standards (including data exclusivity, extension of the patent term, patent-drug registration linkage) can erode the room for maneuver left by the TRIPS Agreement and unnecessarily reduce access to pharmaceutical products.

8. Some members of the CIPIH insisted on including references to donations of medicines made by the pharmaceutical industry, in spite that this issue was not central to its mandate. A consideration of this subject, in the appropriate context, would require to better examine the volume and type of donations, the conditions under which they are made, and their effects on sustainable access to drugs. For instance, there is evidence suggesting that in some cases the donation schemes were too complex to implement for local health authorities, and that they have led to no availability at all as they kept generic products out of the market.

9. Although it is important to promote a critical participation of developing countries in the International Conference on Harmonization (ICH), this process is run by developed countries' industry and responds to the particular circumstances prevailing in those countries. The International Conference of Drug Regulatory Authorities (ICDRA), seems to provide a more adequate framework to promote the improvement of drug regulatory policies in developing countries.

10. The report recommends the implementation of an obligation to disclose the origin of genetic resources and associated information at the national level. International rules should also be adopted for this purpose, since the application of that measure solely at the national level would not provide a sufficient basis to take actions in cases of bio-piracy on the basis of patents granted in a foreign jurisdiction.

11. Finally, I think that the CIPIH could have undertaken a more substantial analysis and make more concrete recommendations if all its members had participated and contributed to its work with greater independence from industry's interests. The Chair of the CIPIH deserves full respect for her efforts to find adequate responses to the health needs of the poor. The Secretariat must be commended for its competent work and invaluable assistance.