



**Expert statement to Intergovernmental Working Group
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The ongoing activities in research and development mentioned by different Member States yesterday are welcome. But they must not distract us from the enormous gaps that still exist in research and development for diseases that disproportionately affect people in developing countries.

These gaps exist at different levels.

Entire areas of need remain unaddressed. Weak levels of investment into diagnostic tools for different diseases are a striking example. There are desperate and immediate needs for better and simpler diagnostics which are not matched by financing decisions: diagnosing tuberculosis, for example, with the most widely available tool, microscopy, only detects 40-60% of patients - yet only 4% of the already limited TB R&D spending goes into diagnostics. There are no robust point-of-care methods to diagnose HIV in infants, nor do we have suitable tests to diagnose sexually transmitted infections – and hardly any funding is made available.

Because no public body has undertaken the exercise of mapping the needs and set priorities for health R&D depending on potential outcomes for world health, these gaps go unnoticed.

Five years ago, the R&D pipelines for neglected diseases were empty. Today, there are at least pipelines again. However, these pipelines are still very weak and will not give us the breakthroughs that we need. Médecins Sans Frontières has recently released an analysis of the pipelines for TB diagnostics and drugs [1]. The analyses conclude that the pipelines are weak because of an insufficient number of compounds, insufficient investment into the drug discovery stage, and the lack of clinical trial capacity and funding for clinical trials.

Five years ago, we documented that only 1% of the drugs reaching the market between 1975 and 1999 were developed for neglected diseases. We updated the research last year and found that the figure had not changed.[2]

The current investment by public bodies into product development is highly insufficient.

Taking again the example of tuberculosis, the funding needs have been

estimated at \$2 billion per year, of which only one fifth is covered at the moment. [3]

The global pharmaceutical market today is worth over US\$ 500 billion. Most of this money is made in wealthy countries. It is therefore no surprise that the market opportunities in these wealthy countries dictate the R&D agenda - with devastating effects for people in developing countries.

R&D financing is largely dependent on monopoly pricing of patented drugs. As long as this remains the core of the global R&D system we will continue to see huge neglect in R&D, and we will continue to see access problems because of high prices.

Through the WTO TRIPS Agreement, this innovation system is now globalised. The CIPIH report very adequately describes how the promises of increased innovation that came with the TRIPS Agreement have not been fulfilled and how monopoly pricing leads to access problems.

With the right policies and agreements between countries in place, it should be possible to turn some of the US\$ 500 billion towards addressing the health needs of developing countries. A key first step in our view is the identification of the gaps and needs – the drawing up of an essential medical R&D agenda.

We need policies to steer financing towards meeting these needs. We need financing mechanisms that ensure that R&D financing is not dependent on high drug prices. Priority setting and financing mechanisms is a key government responsibility and cannot be left to private charitable foundations only.

In summary, this working group has to do two things:

1. make a plan of action to implement the CIPIH recommendations
2. At the same time, it must draw up a framework for needs driven R&D.

R&D and drug pricing issues are rarely discussed in the same forum while both issues are interlinked. Therefore this intergovernmental working group is a historic opportunity to ensure that they are considered together, giving health concerns the primacy that they deserve.

References:

1. Tuberculosis R&D pipeline reports, October 2006, available from <http://www.accessmed-msf.org/documents/TBPipeline.pdf> and <http://www.accessmed-msf.org/documents/Diagnostics%20Pipeline%20Report.pdf>
2. Chirac P, Torreele E, Global Framework on essential health R&D, The Lancet 2006: 367:1560-61
3. Tuberculosis Research and Development: a critical analysis, Treatment Action Group, available from <http://www.aidsfornyc.org>