PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY: proposals that delink the cost of research from the price of the product need to be pursued

At the forthcoming World Health Assembly, Member States will be asked to review the report of the WHO Secretariat on the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA), and the Director-General will report back on Member States' comments on the report of the Expert Working Group on research and development coordination and financing (EWG).

The GSPA provides a path to tackle the fundamental problems associated with the current system for drug, diagnostic and vaccine development which creates both innovation and access barriers. Driven by commercial rewards, it is a system which leaves many pressing health needs unanswered – needs noted by Médecins Sans Frontières (MSF) in its medical programmes include a point-of-care tuberculosis diagnostic test, and better diagnostics, test of cure and medicines for neglected diseases such as Chagas. The system also creates monopolies and thus high prices for health products, accentuating barriers that prevent the poor from accessing life-saving medicines.

Although the report by the Secretariat lists a number of dedicated activities towards the implementation of the GSPA, the majority of these seem to represent existing activities of various actors. It appears that there is little stimulus for new action, despite the urgency of the needs. The implementation of the GSPA requires greater dedicated efforts and higher prioritisation by the WHO leadership to achieve progress.

Individual initiatives that can be established quickly such as a prize fund for a TB point-of-care test are important but work must also begin on longer-term systematic changes that will provide sustainable financing for health needs-driven R&D in a way that ensures equitable access.

Concerns with the Expert Working Group report

The EWG was mandated to further explore mechanisms to stimulate and coordinate R&D as well as identify new sources of funding. Yet the report of the Expert Working Group is flawed in several methodological aspects.

In particular, the evaluation criteria used to assess different financing proposals did not include a proposal's capacity to delink the cost of R&D from the price of health products which allows innovation and access. It is of great concern that delinkage was not used as a key criteria to evaluate proposals and is not mentioned in the EWG report although it is contained in Resolutions WHA60.30, WHA62.15 and Element 4 and Element 5.3(a) of the Global Strategy and Plan of Action.

The methodology used to evaluate the proposals is neither transparent nor replicable. Little or no detail is provided on how proposals performed against the evaluation tool. Proposals that the EWG assessed as not meeting the agreed

criteria,[1] such as a biomedical R&D treaty, removal of data exclusivity and large end-stage prizes are listed with no detail on how they performed against the evaluation tool. The performance of other proposals is discussed but in such general terms that it is not clear whether or how the evaluation tool was applied.

In addition, the methodology is weighted in favour of incremental change rather than the fundamental change required. For each proposal the report gives significant attention and space to 'acceptability' which seems to indicate that this criteria strongly influenced rating. 'Acceptability' was based on perceptions only of donors and product developers[2] and did not solicit views of product users in developing countries. The consequence has been to bias the report's conclusions in favour of product developers, who naturally favour the status quo. As such, many of the proposals evaluated favourably by the report mainly support the current, inadequate R&D framework.

This is a missed opportunity, given that the Global Strategy aims to promote new thinking. Instead the report focuses on a 'more of the same' strategy, on raising extra financial resources or relying primarily on incremental improvements to the current system. This represents a backward step from the GSPA.

In addition to these methodological flaws, MSF has also raised concerns about the process at different stages, including in an intervention made at the 126th Executive Board Meeting in January 2010.[3]

Towards a sustainable framework for innovation and access

Looking ahead to future work in this area, MSF wants to emphasise the following aspects:

Firstly, with the recent financial crisis, the capacity of innovative financing mechanisms (such as financial transaction taxes, currency taxes) to raise funds is increasingly attracting attention in policy circles. The contributions to health R&D could be critical: a levy on currency transactions, even if set at a very low tax rate of 0.005%, could, if applied to all major currencies raise in the region of US$33 billion annually.[4] [5] It is important that such innovative mechanisms are considered as additional to existing overseas development aid commitments by donors and national commitments to health research and development funding.

Secondly, the delinkage of the cost of R&D from the price of health products needs to be the key principle used to evaluate and develop mechanisms to stimulate R&D and ensure access.

Current approaches to stimulate R&D into diseases that disproportionately affect developing countries, such as through direct grant funding of researchers or financing product development partnerships (PDPs), are important but cannot provide a complete solution to the R&D needs.

Delinking the cost of R&D from the price of the product is important because the price of the final product is critical for affordability and access, and because R&D should be driven by health priorities, not profitable markets. Innovation by itself is of

[1] 'Research and Development Coordination and Financing: Report of the Expert Working Group', 2010, WHO. Annex 2. http://www.who.int/phi/documents/ewg_report/en/index.html
[2] 'Research and Development Coordination and Financing: Report of the Expert Working Group', 2010, WHO, p85. http://www.who.int/phi/documents/ewg_report/en/index.html
[3] Intervention by Médecins Sans Frontières during the 126th WHO Executive Board, Agenda Item 4.3, Public health, innovation and intellectual property: global strategy and plan of action, January 2010. http://www.msfaccess.org/main/access-patents/intervention-at-who-msf-concerned-about-report-on-r-d-financing/
[4] 'The Currency Transaction Tax: Rate and Revenue Estimates', Schmidt, R., 2007 http://www.unu.edu/unupress/sample-chapters/currency_transaction_tax_web.pdf
[5] 'Profound Impact for a Small Change', Dr. Tido von Schoen-Angerer, Huffington Post, February 2010. http://www.msfaccess.org/main/access-patents/profound-health-impact-for-small-change/

little value if the tools developed are unavailable or unaffordable to the people who need them. By paying for R&D through financing rather than through product prices, delinking removes the need to incentivise R&D through high prices, which exclude people without purchasing power from the fruits of medical innovation. Delinking also stimulates R&D where there is no profitable market.

Considerations of the affordability and availability of any new medical tool must be dealt with from the outset of R&D. A range of different funding mechanisms that allow delinkage are needed, either to 'push' R&D via upfront funding (e.g through Product Development Partnerships (PDPs)) or to 'pull' R&D via incentives that focus investment efforts on products needed in developing countries (such as prize funds).

Selected push and pull mechanisms must be designed in a way that ensures both that they deliver products that are able to answer medical needs, and that they encourage developers to consider the final cost of products during the design process, in order to ensure affordability.

Médecins Sans Frontières' experience shows that competition is the most effective way to achieve sustainable affordable prices.[6] Intellectual property should therefore be managed in a way that ensures that a new medical tool can be copied by other producers, fostering competition and access. A recent example is the patent-free development of the malaria fixed-dose combination ASAQ by the PDP Drugs for Neglected Diseases *Initiative* (DND*i*) in collaboration with sanofi-aventis.[7] A prize fund to incentivise the development of a new tuberculosis diagnostic test could be designed in a way that requires open licensing, so that the test can be copied or further improved by other manufacturers.[8] In cases such as vaccine development where competition may not be technically feasible in the immediate term even when favourable licensing terms exist, a pathway to facilitate access is needed, including technology transfer.[9]

Finally, there is a need for global coordination and international norms to guide R&D. The challenge currently faced by WHO and Member States lies in identifying areas such as R&D priority setting, where global coordination and international norm settings are both useful and feasible. Discussions need to be held by interested governments and relevant organisations in order to develop such norms.

In light of the upcoming World Health Assembly, Médecins Sans Frontières therefore urges:

- WHO to publically advocate for the funding needs of health research and development to be considered with due weight in all fora where innovative financing mechanisms are discussed, and Member States to support such proposals. In particular, Member States should support a financial transaction tax with a portion going towards health needs including R&D.

- WHO to review current and proposed mechanisms to stimulate R&D, to assess whether these deliver against the principle of delinking the cost of research from the price of a product.

[6] 'Untangling the Web of Antiretroviral Prices, Médecins Sans Frontières'. Available at: www.utw.msfaccess.org
[7] 'ASAQ: Hope for Malaria'. http://www.actwithasaq.org/en/asaq1.htm and http://www.dndi.org/index.php/asaq.html?ids=3
[8] 'Prize Fund for Development of Low-Cost Rapid Diagnostic Test for Tuberculosis', proposal by Bangladesh, Barbados, Bolivia, and Suriname, April 2009 http://www.who.int/phi/Bangladesh_Barbados_Bolivia_Suriname_R_DTreaty.pdf
[9] 'Improving Access and Stimulating Vaccine Development for Use in Resource-Poor Settings', Médecins Sans Frontières & Oxfam consultation, 26 January 2010, Geneva, Switzerland

- WHO to provide guidance to Member States and stakeholders on ways to develop and support effective R&D frameworks that implement the principle of delinkage.

- Member States to establish innovative mechanisms that are based on delinkage principles, in accordance with Element 5.3 of the Global Strategy and Plan of Action.