

HOW A GLOBAL R&D CONVENTION COULD FILL THE GAPS LEFT BY TODAY'S MEDICAL INNOVATION SYSTEM

Today's R&D model doesn't work for the needs of developing countries

The current R&D (research and development) system is driven by market forces, not health needs. It relies on patents on drugs and medical tools to recoup the money invested in their research by charging high prices when those products reach the market. This creates two key problems:

- (1) **The diseases of the poor remain largely ignored and unaddressed**, as the needs of people in wealthy countries trump the needs of people in poor countries. Wealthy country needs drive innovation, and when those products are rolled out to developing countries, little or no thought is given to adapting them e.g. developing child-friendly versions of HIV drugs, or vaccines that don't need to be administered with needles or cold chains to keep them cool.
- (2) When diseases affect both rich and poor countries alike and there is enough of a market pull, the resulting **medical tools are often priced out of reach of the poor**.

Solving the problem

There have been some efforts to address the ever-widening gaps in innovation and R&D, including through public-private partnerships. However, **current efforts have been ad hoc and inadequate**.

There is an urgent need to build a sustainable system to drive and fund innovation for people in developing countries. This could speed up the development of vaccines, diagnostics and drugs designed for the medical needs of people in developing countries and subsequently save millions of lives every year.

A World Health Organization expert group was tasked with investigating solutions to this long acknowledged problem. The Consultative Expert Working Group on R&D: Financing and Coordination (CEWG) - submitted its final report in April 2012 concluding that if this fatal imbalance in R&D is to be overcome then governments need to create a binding agreement to ensure that priorities are set, funding is secured and innovation that leads to access is delivered. For this to happen the CEWG recommends that all governments work together to establish **a binding Convention on R&D to meet the health needs of developing countries**.

What could a Convention on health R&D achieve?

The detailed terms and conditions of a binding Convention would be negotiated by WHO Member States. A Convention could deliver a sustainable system of medical innovation with adequate and predictable financing in order to deliver products designed for developing country health needs. The Convention would establish principles to ensure that resulting innovation and new medical products are accessible and affordable.

The CEWG's report suggests that the Convention could:

- **Establish an evidence-based, inclusive process to set priorities for medical R&D**
- WHO and its partners have already defined the R&D agendas for some diseases. A more comprehensive effort across all medical needs should now be undertaken through the R&D Convention.

- **Link global R&D priorities with adequate and sustainable financing**

The CEWG report recommends countries spend 0.01% of GDP on government-funded R&D for developing country needs, with at least 20% of this amount going towards a pooled mechanism.

- **Ensure money is used to stimulate R&D in the most effective way**

With donor funds increasingly scarce, funding should support innovation models that allow limited funds to go further. This could be done by relying on alternative models of research and development – such as through prize funds – and harnessing the potential offered by the lower costs of emerging country manufacturers.

- **Establish principles to ensure access to the fruits of R&D**

In today's system of patent-protected monopolies, products are often unaffordable for developing countries. Initiatives based on the principle of *de-linking* - separating the cost of R&D from the price of the resulting product - are needed. A convention could help deliver accessible and affordable products by considering the need to ensure access to final products at the very start of the innovation process. It should set norms that ensure developers who access funds raised by the convention, ensure their innovation is accessible and affordable. For example through price commitments or licensing policies that bring prices down.

Why is a Convention on R&D needed?

MSF field teams see the consequences of this every day, and struggle to deliver quality care when appropriate medical tools do not exist. When medical tools do exist, they are all too often unsuitable for use, as they are first and foremost developed with wealthy markets in mind, and only subsequently rolled out in developing countries. There are many gaps.

Two examples:

- **Tuberculosis:** No new TB drugs have come to market since the 1960s. The current drug pipeline will not be able to produce the number of new drugs needed to eliminate TB. Diagnostics are also overlooked, the most common method is microscopy but this detects less than half of cases. A new diagnostic test for TB – the Xpert MTB/RIF – will be difficult to roll out in resource-limited settings because it requires a stable electricity supply and low temperatures. It is also still a sputum-based test making it difficult to diagnose people co-infected with HIV and children. And for the rising number of children who are infected with drug-resistant TB, no paediatric formulations of drugs exist.

“Most of the time, where we work, you have to just make a decision based on your clinical observation – ‘should I or should I not treat this child for TB?’ And making that decision when you’re talking about the life of a child is really challenging. If we could have a point-of-care test for TB that could say yes or no to TB in just fifteen minutes and could be used in the most remote kind places where we work, it could transform our work and so many children’s lives.”

Dr. Bern-Thomas Nyang’wa, MSF Advisor for tuberculosis

- **Vaccines:** Many vaccines are unsuitable for developing country needs – they are in needle form which require trained health workers, they are not heat stable so require cold chain, they are sometimes not adapted to the country's specific disease epidemiology and they require multiple doses meaning children must be vaccinated five times in their first year. An R&D Convention could adapt vaccines to be more suitable for developing countries and thus help reach the 19.3 million children who are unreached by basic immunisation every year.

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“Keeping the cold chain to conserve the vaccines at the right temperature, when it’s 45 degrees Celsius outside is a major challenge. In some rural areas, just maintaining the fridges in working order is hard to guarantee, and we need to produce enough ice packs so that the vaccines are still cold by the time we get to the children. You can imagine how many icepacks are needed, so even getting the vaccines out to the villages is a huge logistical effort in itself.”

Dr. Michel Quéré, MSF Medical Advisor for programmes in Niger, Chad and DRC