Towards access 2030

The Lancet Commission on Essential Medicines Policies identifies five areas as crucial to ensure access to medicines for 2030: “paying for a basket of essential medicines, making essential medicines affordable, assuring the quality and safety of medicines, promoting quality use of medicines, and developing missing essential medicines”. These are issues that WHO has promoted for some time. The question, however, is whether the Commission’s recommendations—mostly aimed at governments—are sufficient to ensure progress towards universal health coverage and the Sustainable Development Goals.

The Commission estimates that between US$77·4 and $151·9 billion per year (or $13 to $25 per capita) is needed to provide a basic package of 201 essential medicines for all low-income and middle-income countries.1 Affordability and pricing of quality medicines is perhaps the major challenge on the path to access and this concern is what we focus on here.

Everyone relies on the pharmaceutical industry to manufacture and deliver essential medicines. Yet we have at present a problem with two facets. The pharmaceutical industry is demanding higher prices for most new products that are being developed, so that medicines such as the direct-acting antivirals for hepatitis C are unaffordable even in high-income and middle-income countries.2 Affordable and pricing of quality medicines is perhaps the major challenge on the path to access and this concern is what we focus on here.

What the Lancet Commission proposes for addressing this problem is a combination of policies that are clearly important. These include information systems for routine monitoring of affordability, price, and availability; implementation of a comprehensive set of existing pricing policies, including Trade-related Aspects of Intellectual Property Rights (TRIPS) flexibilities, to achieve affordable prices; use of health technology assessment to define benefits packages and determine value; and increased transparency.

Our concern, however, is whether these recommendations, which have featured in many WHO publications over the past years,3 take us far enough. Will monitoring national prices in relation to international reference prices and using external reference pricing, in combination with other pricing policies for setting prices, be sufficient? Or will the push for low prices for generic products in particular be a real pathway to affordability? It is unlikely in our view, and some countries are already struggling with access to essential medicines as a result of inadequate pricing policies based only on lowering prices and external price referencing. At the WHO European Regional Committee in September, 2016, countries discussed the impact of pricing regulations on access to medicines, especially in small countries with limited markets.

We believe that it is time to develop new approaches for setting prices of pharmaceuticals. To do that much more information is needed about what drives price-setting strategies for new medicines, as well as what the market needs to do to retain disappearing essential medicines at prices that ensure quality products and a viable commercial model. Discussion to date, including in the report of the UN High-Level Panel on Access to Medicines,4 has focused on the effect of research and development costs on prices and, therefore, the need to delink these two issues. But there is insufficient published information about the effect of investment strategies and hedge funds on price setting of new medicines, even though financial markets and shareholder expectations are driving drug prices up, especially for products with limited markets.5 None of the current policies used for price setting
consider shareholder expectations and what could be an acceptable return on investment. The influence of financial markets on the price of essential medicines must become part of the discussion.

There is also little published information about the true production costs of some off-patent essential medicines, and there are also increasing reports of quality problems with some generic drugs. Are global procurement processes starting to push prices to below what is actually reasonable? Anecdotes from generic manufacturers suggest that prices paid might not even cover costs, particularly for products with limited markets. We need to understand these issues if we are to advance the essential medicines agenda.

In trying to address the problem of unsustainable prices, countries are now starting to collaborate on global solutions. For example, the Netherlands and Belgium supported a process in 2016 to define scenarios for new systems for ensuring development of needed new medicines. Four scenarios were identified: needs-oriented public-private partnerships; a state-sponsored, not-for-profit drug development track; a multinational fund for paying for patents of promising products so that they can be further developed; and a scenario in which the public sector takes over drug development and the private sector’s role becomes that of a contractor to manufacture products that the international community wants. However, the challenge with all of these options is that there is no clarity on how the global community could start implementing them. Disease-specific, public-private partnerships, such as the Drugs for Neglected Diseases initiative (DNDi) and Medicines for Malaria Venture (MMV), have changed the landscape of availability and access to new medicines for neglected tropical diseases and malaria, respectively. But how best to harness international collaboration for all new and old essential medicines is uncertain.

As countries move towards universal health coverage, new global mechanisms are needed that ensure fair prices for medicines. Fair in that patients can get access to the medicines they need, health systems are sustainable, and industry can produce quality products with a reasonable return on investment. The policies recommended by the Lancet Commission are a good starting point, but without new creative collective thinking, we do not think they will be sufficient to get us to access for all in 2030.

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7 Cohen D, Raftery J. Paying twice: questions over high cost of cystic fibrosis drug developed with charitable funding. BMJ 2014; 348:g1445.