Better life through medicine—let’s leave no one behind

The Lancet Commission on Essential Medicines Policies' rightfully addresses the need to guarantee access to essential medicines for all. However, we cannot achieve any real progress without acknowledging that the current patent-based business model and the way we apply international patent rules need to change. The system is broken.

Let’s look at the business model first. Sofosbuvir-based medicines are an important breakthrough in the treatment of patients with chronic hepatitis C. The problem is that one-time treatment costs between €48 000 and €96 000 in high-income countries (2015 prices).² There are an estimated 20 000 patients with this disease in the Netherlands,³ and there are millions of people with hepatitis C virus infection throughout the world. When we take a look at the development and clinical trial costs of these products, the current prices appear even more outrageous. Manufacturer Gilead Sciences Inc invested an estimated US$12 billion in the rights and development costs of sofosbuvir.⁴ Gilead Sciences Inc has already accumulated over $35 billion in global revenue from sofosbuvir-based hepatitis C medicines since their launch in December, 2013, and it anticipates about $20 billion annually in the years to come.¹ This revenue will largely be based on the protection and exclusivity of its patents.¹

Patent and intellectual property exclusivities are the only cornerstone of the current model. Companies can ask the price they like. This will no longer do. We need to develop alternative business models. And if public money is used for the development of new medicines, agreement upfront is needed about what this public investment will mean for the final price. We believe that companies must provide full transparency regarding the costs of research and development (R&D).

The Dutch Government has recently given a grant to a Dutch initiative called Fair Medicine. This initiative could serve as a potential game changer for the development of new medicines. Fair Medicine brings together all stakeholders around the development of a new pharmaceutical product at an early stage. These Fair Medicine coalitions are transparent about the focus of their R&D agenda and investment costs, and they also cap the profit at a level the government determines is acceptable. With the addition of agreement on who pays what beforehand, then the model of the future takes shape.

In developing countries the patent-based model fails in making much needed essential medicines available. Companies do not invest in medicines for so-called neglected diseases, for which there is no reliable market. Product development partnerships have already shown their value in tackling this problem. The Drugs for Neglected Diseases initiative (DNDi), for example, delivered six new treatments and established a solid drug development pipeline with a limited €182·5 million budget.⁴ Their success stems from putting the needs of patients at the centre of the innovation process. Through upfront public and philanthropic contributions, R&D costs are delinked from final consumer prices, to the benefit of affordable and equitable access to patients. The public sector has shown its willingness to put money on the table. The time has come for the pharmaceutical industry to also come forward with more substantial financial contributions.

The way global patent rules are applied is another cause for concern. These rules provide for safeguards to make sure that all people have access to the medicines they need. However, in practice, governments are often submitted to pressure not to use these safeguards.⁵ This situation contradicts the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO) and its explicit provisions for a flexible implementation of patent rules in the interest of public health. For example, in April, 2016, the Colombian Government followed up on recommendations by a technical expert committee to declare imatinib (marketed by Novartis) of public interest for the treatment of chronic myeloid leukaemia to enable the issuing of a compulsory licence.⁷ Subsequently, this decision was criticised by states and corporations clearly attempting to dissuade the Colombian Government from issuing a compulsory licence.⁵–⁷ The drug has generated over $47 billion in global sales for Novartis.⁸–¹¹ The Novartis price for the drug in Colombia per patient is about $15 000,¹² almost twice the Colombian gross national income per person.¹³ After negotiations on a reduced price failed, the government, on June 14, 2016, issued resolution 2475 declaring the existence of public interest to imatinib¹⁷ In September, 2016, the Colombian
Comment

Ministry of Health announced its plans to proceed with the price reduction.\(^5\)

This example illustrates that steps need to be taken to bolster the safeguards the TRIPS agreement provides.

The Netherlands is campaigning for these safeguards to be maintained in negotiations on free trade agreements with developing countries.\(^6\) We will intensify our efforts to prevent so-called TRIPS+ provisions in free trade agreements that are being negotiated by the European Union and other high-income countries. Such provisions allow for even longer or more restrictive patent protection—that is certainly not what the world needs now. In this respect we agree with the recommendations of the UN High-Level Panel on Access to Medicines\(^5\) that now. In this respect we agree with the recommendations

for all, at all ages. “Leave no one behind”, the UN’s slogan, will prove to be empty words.

\*Lilianne Ploumen, Edith Schippers

Ministry of Foreign Affairs, Bezuidenhoutzweg 67, 2594 AC The Hague, Netherlands (LP); and Ministry of Health, Welfare and Sport, Par-nassusplein 5, 2511 VX The Hague, Netherlands (ES)

com@minbuza.nl

LP is Minister for Foreign Trade and Development Cooperation and ES is Minister of Health, Welfare and Sport for the Government of the Netherlands. We declare no other competing interests.


