https://dx.doi.org/10.1590/1981-7746-sol00226

Transparency in the Pharmaceutical Industry: A New Dimension in the International Debate Regarding the Access to Medicines?

The last World Health Assembly, the decision-making body of the World Health Organization (WHO), which was held in May 2019 in Geneva, approved a new resolution on the transparency regarding the costs of medicines, vaccines and other health products (World Health Organization, 2019)[1]. The text recognizes the need to enhance transparency in the pharmaceutical industry and the role of the States in monitoring and promoting institutional cooperation, relating the lack of information on prices and costs directly with the issue of the high prices charged for products that are essential to health.

Generally, greater transparency regarding the prices and costs enables governments, consumers and the remaining actors to have a clear idea of which prices are (and should be) charged for medicines. Thus, not only the social control over the functioning of the pharmaceutical industry is enhanced, but, likewise, the ability to negotiate public purchases at different prices for countries with lower available budgets[2]. Transparency regarding the issue of patents, the issue involving the regulatory approval of medicines and the results of clinical trials makes the development of generic medicines easier, and increases competition within the markets – thus reducing prices. It can also enable an analysis and a precise investigation about the potential anticompetitive nature of certain practices, and so on. In a context in which the expenditure with medicines increases worldwide, even in industrialized countries, it is the most recent development in the long (and current) international debates regarding the access to medicines and the human right to health[3], and it points to the possibility of intensifying this field of discussion in the near future.

Having followed the negotiation of the resolution, one may state that it was a long and hard process that could have resulted in nothing. Its symbolic value is undeniable because it was the 'launching' of this topic. The approval was obtained after great pressure from the civil society, who acted together with their respective governments – in some cases, even changing the original position of the countries –, and with the previously improbable leadership of Italy within a group mostly composed by developing countries[4]. Likewise, the issue was viewed with great reluctance by the representatives and associations connected to the pharmaceutical industry, which consider it outside of the scope of action of the WHO. Delegates of the member States got together for countless hours in 'informal' – yet highly restrictive – meetings throughout the week to debate and finally reach a consensus. Consequently,

when compared with the original text, which proposed transparency measures in every step of the chain of production, including the preliminary stages of research and development (R&D) and the price to the final consumer, the approved resolution is very limited. Particularly, it does not involve binding instruments that impose obligations and establish sanctions against the States through international courts or similar mechanisms. It also does not create a new mandate of action for the WHO – even though it establishes a set of activities to be performed by the institution.

Thus, one must recognize that the text largely meets the wishes of the industrialized countries. Even though some of these nations may accept the international commitments in the field of health and recognize the gravity of the general issue regarding the access, many of them at the same time champion at any cost the current global innovation system, that is, a model based on intellectual property rights as the great catalyst for the creation of new medicines through private companies (even though this often occurs directly or indirectly with large amounts of public funding). This would justify – at least theoretically – the high prices, in spite of the important criticism regarding the functioning of the current model. There are no databases with clear and consistent information regarding the actual expenditure with R&D in order to obtain a new medicine, which hinders a true analysis of the tension present there[5]. However, even though it is mentioned in the resolution, the issue of the R&D costs was excluded from the measures to be taken by the States and by the WHO Secretariat.

Therefore, the complex interrelationship between technological innovation, reward devices and effective access to new and already existing products is the main backdrop of the debate regarding transparency. The result within the context of the resolution is a paradoxical situation: on the one hand, it is derived from the recognition that the current global R&D model is insufficient and inadequate, at least in the sense that there is not enough innovation for the great global health issues and there is no adequate access to the products. On the other hand, it only provides one incremental change, through greater transparency, without proposing structural alternatives and without increasing the existing information about the hegemonic R&D model[6]. In this broader picture, the debate regarding transparency still echoes the logic of the geopolitical dispute between the countries that house the headquarters of large pharmaceutical companies and the developing countries, which are the most affected by the high prices of health products[7].

Transparency is not an issue that is exclusive to the pharmaceutical industry. It may even be considered a precondition for the proper functioning of the markets, as foretold by the current economic theories that deal with the asymmetry of information within the markets as an element that makes their proper functioning impossible (Akerlof, 1970, p. 488-500). Likewise, it

is a central issue in the current debates regarding the international system of governance and the health of deliberative democracies. Generally, we tend to accept that more transparency is salutary, which is mostly true. The possible problem, however, is the possibility of limiting the more general debate regarding the access to medicines to an issue solely related to the competitiveness of the markets and the negotiation strategies of the States.

Thus, if transparency is essential, it is not the only element to keep in mind. 'Old' problems are as current as before, such as the impact of strategies to extend the terms of patents and the lack of local production in many countries. Moreover, many different actual experiences and proposals have been flourishing. For instance, the idea of dissociating the R&D costs from the final price of medicines (delinkage), which could result in lower prices in a more conclusive manner, which has also been debated in international negotiations. The (financial, institutional etc.) ability of the countries to implement such measures is another pressing concern.

It is important that, in the following debates, transparency is not converted into a smoke screen to avoid dealing with essential issues, such as the high prices of medicines and the relative lack of investments in neglected diseases, for example. Even if transparency increases in the pharmaceutical industry, and if governments take steps in order for that to happen, the issue of the access to medicines and other health products must still be linked to broader considerations, particularly the perspective of the human right to health. Thus, it is also necessary that this agenda enables a broader reflection of the persistence of the conflict of interests in the context of health, especially in the improper lobby of certain private actors in the determination of public policies and international negotiations.

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Notes

[1] Resolution of the Seventy-second World Health Assembly, 'Improving the Transparency of Markets for Medicines, Vaccines, and Other Health Products.' The resolutions of the World Health Assembly, which are not legally binding, are historically made by consensus, which requires a great deal of diplomatic negotiation in order to reach a result. Likewise, the support of a country does not tell enough about its actual commitment to the issue. The United Kingdom, Germany and Hungary have chosen to 'dissociate' themselves from the resolution, which, in this context, means a disagreement regarding its content.

[2] Particularly, many essential medicines are sold through voluntary licenses to countries with lower relative development at lower prices, and, theoretically, those prices are better suited for those national budgets. However, most countries do not have access to the process charged by the same companies to similar countries regarding development and population, which makes it harder to envision what would be 'adequate' in terms of prices.

[3] Since this issue mobilizes very distinct geopolitical interests and instances of public health urgency worldwide, it is not possible to dissociate an analysis regarding the transparency of a broader scenario regarding the movement of access to medicines, a dispute that has lasted for decades. Particularly, as a consequence of the ascertainment that the prices of health products (medicines, vaccines, devices, among others) are often excessively high and inaccessible to the patients, especially in countries of the Global South. The more current scenario, however, is that certain medicines are sold at such high prices that even industrialized countries cannot afford to finance them. Sofosbuvir, a medicine for hepatitis C, new cancer medicines, and medicines with a biological origin are regarded as cases that have made this topic also a problem in the countries of the Global North.

[4] The resolution was proposed by South Africa, Andorra, Brazil, Egypt, Slovenia, Spain, Eswatini (formerly Swaziland), Greece, India, Italy, Luxemburg, Malaysia, Malta, Portugal, Kenia, Russia, Serbia, Sri Lanka and Uganda.

[5] Generally, the pharmaceutical industry points that the costs involving R&D in order to obtain a final product are very high, so any measures aiming at lowering prices – or, to put it better, to make them accessible and ensure that those are not anticompetitive practices – would not be a proper mechanism. Estimates from the pharmaceutical industry point to gargantuan values, but those include marketing costs and the costs of failed medications as part of the expenses. Other attempts lead to much lower values, which would make it feasible to indicate that an alternative global model – less geared towards private profits – would be possible.

[6] It must be mentioned that there are several alternative initiatives to the existing model, especially when we consider that neglected and rare diseases get little or no investment in a model based on the wish for profits. Particularly, organizations such as the Drugs for Neglected Diseases initiative (DNDi) provide a structure for investment 'outside' the markets, as well as conditions for the licensing of the medicines that were created not based on the logic of exclusive rights and patent monopoly.

[7] However, recent geopolitical reconfigurations worldwide have created new things. Brazil, for example, was one of the countries that proposed the resolution, giving continuity to an enduring international policy of leadership in the access to medicines, despite the explicit change in the domestic policy ever since the new President came into office. Moreover, the resolution was approved with the categorical support of the United States. Paradoxically or not, the United States is the country that keeps adopting unilateral measures of pressure and imposing strict rules against other countries regarding intellectual property in free-trade agreements; these rules restrict legitimate national policies of these countries that aim to extend the access to medicines. Additionally, at the national level, the current US Administration rejects any health public paradigm, while at the same time attempts to lower prices in the country. This relative detachment – or strategic use – of the international sphere regarding the national context brings about precisely the reflection about the effectiveness of a debate on transparency at the level

of national policies, and, moreover, which might be its consequence (or lack thereof) regarding the access to medicines, even with the ideology shift in certain countries.

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