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## Reflections on the Report of the UN Secretary General's High Level Panel on Access to Medicines

Reflexões sobre o Relatório do Secretário-Geral das Nações Unidas do Painel de Alto Nível em Acesso a Medicamentos

*Frederick M. Abbott*<sup>1</sup>

I am honored to be asked by Dr. Jorge Bermudez to provide some additional commentary in reaction to his essay regarding the way forward following publication of the Report of the UN Secretary General's High Level Panel on Access to Medicines (HLP). As a member of the Expert Advisory Group (EAG) to the HLP I had the opportunity to participate in the meetings and dialogues in London, Johannesburg and New York, and had a number of opportunities to present my views.

The Report is in many ways a milestone achievement. The HLP has called on governments, international organizations, the private sector, the science community and research institutions, and civil society to adopt new approaches to the way in which innovation and access are addressed. If the HLP's call for action makes its way into General Assembly debate, and recommendations are more generally taken up, this could be the beginning of a transformation in the global approach to innovation and access. The recommendations are addressed, in any case, to a wide spectrum of stakeholders that may act independently of the General Assembly and its member states. Whether the Report has an enduring impact naturally will depend on what comes after, and that is what Dr. Bermudez addresses in his essay. However, even as a "standalone process", the meetings and dialogues, in conjunction with the many submissions, undoubtedly advanced the progress of ideas.

### Strong advocacy remains essential

As Dr. Bermudez has pointed out, the HLP Report fits within a series of developments at the international level directed toward promoting innovation in the pharmaceutical sector while emphasizing the importance of assuring access to the resulting treatments, preventives (such as vaccines) and diagnostics. There have been some very important successes, most notably the wide expansion of access to HIV-AIDS treatments brought about by sustained pressure from patient advocacy groups, supported by developing country governments (including that of Brazil), with

substantial financing ultimately coming from the developed world. It is important to remember that progress on access to HIV-AIDS treatment is the result of a real political and economic struggle. Strong advocacy remains at the heart of achieving progress on access issues.

### The HLP recommendations

The HLP Report makes a number of important recommendations. Among these are insistence that governments refrain from exerting pressures against other governments in the course of trade negotiations, or in the course of the implementation of laws, to limit measures to promote and protect public health; that governments implement intellectual property laws, including patent laws, in a manner that guards against the grant of exclusive rights where not warranted by substantial inventive contribution; that governments make use of TRIPS Agreement flexibilities to promote access, including by taking advantage of "quick, fair, predictable and implementable" compulsory licensing; that new models of innovation delinking R&D costs from the price of medicines be pursued; that the results of publicly funded research be made widely available and accessible for use; that governments, multilateral organizations and private sector companies must be more transparent and accountable for the way in which innovation and access is addressed, including through the provision of specific information regarding R&D costs and pricing, as well as clinical trial data and accessible patent status information.

The phenomenon of exerting pressure in trade negotiations to limit adoption and use of TRIPS flexibilities, and subsequent pressure in specific cases, started before the ink on the TRIPS Agreement dried (i.e., more than 20 years ago). This is neither a secret nor a new development. But, identification of the practice by the UN Secretary General-appointed group, and a strong call for its end, should bolster the position of governments on the receiving end of pressure, and may give some pause to the *demandeurs*. It is an incremental step, but an important one.

Many of the submissions to the HLP were directed toward new models for innovation, including new mechanisms for financing. The HLP recognized that problems with respect to

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the relationship between innovation and pricing are now of serious concern among high as well as lower income countries, and that solutions must be found. The Panel was somewhat cautious, however, regarding proposals for new models of innovation. The Report reflects concern that new models might “break” the existing patent/market exclusivity-based model without an adequate replacement, leaving the global community without funding for research. Discussion in the Report primarily focuses on antimicrobial resistance (AMR) and neglected diseases. I might have been more ambitious about new models because the existing system already is broken. I do not think the scientific community will abandon research on new treatments for disease because capital markets in New York and Hong Kong are dissatisfied with rates of return. Ways to fund research will be found since the demand for treatments, vaccines and diagnostics is not going away.

Each of the HLP recommendations reflects a history of policy and legal identification and advocacy work. Notable is the demand for transparency with respect to drug R&D costs, which have been deliberately shrouded by the originator industry, forcing policy-makers to guess at the legitimacy of industry pricing practices. It is self-evident that the R&D costs of major originator companies are well-known and identifiable within those companies. While it may be that predicting the success of any given R&D project is difficult depending on the nature of the project (e.g., harder with respect to basic research, easier with respect to incremental modification), the idea that major companies do not keep careful books and records that enable them to determine their actual R&D costs defies common sense.

#### **An unfortunate reminder**

I serve as Co-Chair of the Global Health Law Committee (GHLC) of the International Law Association. The GHLC made two submissions to the HLP on behalf of its members. One of these included proposal for establishing an essential medicines patent pool (EMPP) that would initially request voluntary licensing, and incorporate “effectively automatic” non-voluntary licensing should voluntary licenses not be forthcoming. Submission to the UN High Level Panel on Access to Medicines by the Global Health Law Committee of the International Law Association, Prepared by Ellen ‘t Hoen LL.M., Prof. dr Brigit Toebes, Katrina Perekhodoff MSc, LL.M., and Prof. Frederick M. Abbott, Feb. 22, 2016. The compulsory licensing

provision was proposed to be implemented immediately, pending establishment of the EMPP system, with the systems thereafter integrated.

For reasons that are not entirely clear, there was a view expressed by some members of the HLP that the proposal of “effectively automatic” compulsory licensing would somehow be inconsistent with the TRIPS Agreement, and in particular Article 31. Of course, Article 31(a) provides that “authorization of such use shall be considered on its individual merits”. As noted in our submission to the HLP, the Doha Declaration long ago confirmed that “Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.” There is nothing in the TRIPS Agreement suggesting that a determination by public health authorities that a medicine is “essential” for the population, whether at the national or at the WHO level, cannot be used to determine the merits of granting an individual compulsory license. To the contrary, it is difficult to postulate a more compelling basis for such a determination. In processing the request for a compulsory license, the fact that a medicine has been determined to be essential can and should provide the grounds for an affirmative determination regarding the individual merits of that license.

There are other provisions of Article 31 that would be addressed in constructing an “effectively automatic” compulsory licensing mechanism for essential medicines. In our brief submission to the HLP, we observed that the refusal of a patent holder to grant a voluntary license on the terms established by the EMPP system would satisfy the requirement that the grantee had attempted to obtain a license on reasonable commercial terms and conditions. By way of illustration, Canada’s Access to Medicines Regime adopted to implement the WTO August 30, 2003 waiver for export under compulsory license uses a comparable mechanism. We noted, of course, that government use and emergency licenses do not in any case require an effort to secure a voluntary license.

The GHLC is not alone in having proposed a system for facilitating compulsory licenses for patented essential medicines. As a starting point for resolving tensions between international trade and IP rules, public health and human rights interests, this frankly appears a relatively straightforward and modest starting point.

Ultimately, a “sizable minority” of the HLP would not agree to a proposal for effectively automatic compulsory licensing of essential medicines, according to the Report, “because of concerns over the potential incompatibility of such measures

with the TRIPS Agreement and the unintended consequences that may result from such an approach. The High-Level Panel therefore did not reach consensus on this particular issue”.

The issue of potential “unintended consequences” of several essential medicines-related proposals had been discussed at some length at the London Dialogue, including concern about potential strategic gaming (including lobbying) of essential medicines lists and the potential impact on investments in innovation. These concerns tie into broader issues regarding models of innovation and access. I do not believe that these concerns justify impeding access to medicines that have been determined to be “essential”, though this does not mean these issues should not be addressed.

More concerning for present purposes is that a group of Panel members used unfounded concern regarding interpretation of the TRIPS agreement as the basis for rejecting a proposal to facilitate access to essential medicines. It is regrettable that the Report went off in this direction. Yet, even here there is an important lesson to be drawn from the process. Namely, despite high-minded pronouncements that the TRIPS Agreement can and should be interpreted to promote access to medicines for all, the High Level Panel chartered by the UN Secretary General to address incoherencies between public health, human rights, trade and intellectual

property rules became hung up on a debate about a few words of the TRIPS Agreement -- a distraction from meaningful change. This proves the point of the UN Secretary General’s charter to the HLP: conflict between IP, trade rules, human rights and public health objectives remains to be resolved in a convincing manner.

### **The way forward**

As noted earlier, diverse stakeholders are addressed by the recommendations of the HLP, and these stakeholders should pursue the recommendations in the Report. Beyond that, Governments must be persuaded to take up the Report and its recommendations in the UN General Assembly. It may be useful to promote adoption of a UN General Assembly Declaration embodying basic principles on access to medicines so as to embed the progressive ideas in the Report, and elsewhere in the submissions, into the body of international law. While such a Declaration might not have the immediate impact of creating a new funding mechanism, or in changing the terms of an already negotiated trade agreement, it might help persuade legislatures and judges to prioritize the right to health over narrow commercial interests, and it might provide the basis for longer-term systemic change.

## Commentary on Jorge Bermudez's article

Comentário sobre o artigo de Jorge Bermudez

*Mohga Kamal-Yanni*<sup>2</sup>

Thank you for inviting me to comment on the article by Dr. Jorge Bermudez, which provides a succinct overview of the debate on access to medicines as it progressed within the UN organizations and within the global trade system represented by the World Trade Organization (WTO). The overview focuses on the High Level Panel (HLP) and its report. My comment will centre on the HLP and the follow up needed for the world to benefit from its recommendations.

Dr Bermudez rightly emphasized the importance of access to medicines as a human rights' issue and as a necessary pillar to achieve the SDGs. The HLP on health technologies was established by the UN Secretary General to "recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies". This aim carries a number of elements of critical importance to access to medicines. For a start, it does acknowledge the potential conflict of human rights and intellectual property (IP) rules- even though the US denies any such a conflict.

The right to health is enshrined in UN declarations and conventions since 1948<sup>1</sup>. The Office of the UN High Commissioner on Human Rights clearly states that access to medicines is an entitlement of the right to health<sup>2</sup>. On the other hand the right of the inventor is also recognized in the HLP mandate as well as in the human rights declaration. However, the right of the inventor does not equate IP rules. Inventors can be rewarded in many ways including financial and non financial compensations.

The aim of the HLP is carefully worded as "policy coherence" rather than achieving "balance". In my view, it is wrong to "balance" the human right to health with the IP so-called "rights". The human right to health, unlike IP "rights", is acknowledged as a natural right. The HLP clearly states, "human rights are fundamental, universal entitlements that people inherently acquire by virtue of their birth". "IP rights" are one policy tool among many for encouraging innovation and technological research and development (R&D)"<sup>3</sup>.

The HLP is an important step on the path to access to health technologies for a number of rea-

sons including its scope. Previous policy debates focused on R&D for neglected diseases and prices of medicines in developing countries. The HLP' remit extends to all diseases and all health technologies in all countries. The price of medicines is recognized as a global problem. In reality, there is hardly a day that goes by without a media story about the high prices of medicines, especially in the US, the country that heavily supports the monopoly of pharmaceutical companies, which leads to high prices. In Europe, where funding for health services is mainly through tax, health systems ration medicines or exclude expensive medicines from national reimbursement<sup>4</sup>.

Dr Bermudez's article also reminds us that access to medicines is one of the health targets of the Sustainable Development Goals (SDGs)<sup>5</sup>. In fact, the HLP' published consultations, and especially its recommendations represent a serious step towards achieving the SDG health target through its strong recommendations to incentivize innovation and affordable prices<sup>6</sup>.

On the innovation side, the HLP report emphasized proposals that have been already proposed through the work of WHO and of civil society<sup>7,8</sup>. These include a strong focus on delinking the cost (and hence the funding of R&D) from the price of the resulting products. This is a critical recommendation because the pharmaceutical industry justifies the ever increasing prices of medicines by the high cost they incur in R&D. However, it is almost impossible to find out the real cost of R&D for medicines because of pharmaceutical companies' secrecy. Therefore, the HLP report also strongly recommends transparency on all aspects of R&D including on other costs that are normally included in the R&D package such as marketing.

Deciding the global R&D agenda cannot be left to market incentives. The current system, based on IP monopoly, facilitates the highest possible profit to finance R&D, through the highest price that a market can bear. The HLP report recommends increasing public financing for R&D- a recommendation that both civil society and the WHO have been promoting for decades. However, increasing public financing alone will not produce affordable medicines without changing the monopoly of the pharmaceutical industry

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because the new funds will end up in the old system producing the same high prices. Therefore, affordable prices must be a contractual obligation for all public financing programs.

The HLP report proposed that the UN Secretary General starts a process for UN member states to start negotiating an R&D agreement on coordination, financing and development of health technologies. The agreement needs to result in a binding convention that delinks the cost of R&D from the price of the end product in order to promote access to health technologies for all. The latest UN declaration on antimicrobial resistance (AMR) signed by world leaders in September 2016, recommends delinking the cost of R&D of antimicrobial medicines from price and volume of the resulting products. We need to see how this is translated into affordable antimicrobial medicines, diagnostics and vaccines.

On the access side, Dr Bermudez's article elucidates that the HLP made important recommendations, especially in emphasizing the importance of the Doha Declaration which places public health before commercial interests. The HLP report also recognizes the huge political and economic pressures that countries face when governments try to use the Declaration to implement measures such as compulsory licensing to decrease the price of highly priced medicines. The HLP report recommends that countries lodge at the WTO any pressure they face from other governments when they try to use the flexibilities enshrined in the Trade Related Aspects on Intellectual Property Rights (TRIPS) agreement. Unfortunately the HLP report was not bold enough to ban such pressure or to strongly request the WTO to treat such pressure as a violation of the TRIPS agreement that requires punitive sanctions.

The flourishing of Free Trade Agreements (FTAs) greatly limits governments' ability to use the Doha declaration or any of the TRIPS flexibilities. The HLP report gives clear examples of the limitations that are imposed on countries through the FTAs. The proposed Trans Pacific Partnership (TPP) is a prime example of FTAs, which ratchet up IP protection and enforcement. The HLP report acknowledges these TRIPS+

measures and their negative impact on public health and calls for governments to conduct an impact assessment before signing FTAs in order to evaluate potential impact of the measures included in the agreement on public health. However, the Report falls short of condemning TRIPS + and of recommending a ban on including IP in all bilateral and multilateral FTAs and treaties

Despite its shortcomings, the HLP report proposes important recommendations to enhance access to health technologies. Yet the US government and pharmaceutical companies have been attacking the HLP even before the report was published. There is a great concern that the work of the HLP could end up gathering dust on UN shelves. Concerted advocacy by relevant stakeholders needs to be escalated in order to ensure the implementation of the report's recommendations.

The HIV story has taught us that political actions and real change require public campaigns and vigorous advocacy. Civil society organizations play an important role in advocacy for pro health global and national policies. Despite lack of financial and human resources, there has been a revival of the access to treatment movement that campaigned for access to HIV medicines. As the HLP report recommends, civil society organizations need to be funded in order to fulfill their advocacy role for access to medicines. However, this advocacy cannot be left only to civil society. Members of the HLP and also the secretariat have to play their part in demanding political action.

Yet the main actions must start from the UN itself. The UN Secretary General, who established the HLP in the first instance, needs to show his public support for the HLP report and to set up mechanisms to engage UN member states to commence implementation of its recommendations - for example starting to negotiate an R&D agreement. He should urge relevant UN bodies and other multilateral organizations such as the WTO to start implementing the recommendations relevant to their mandates.

Implementing the recommendations of the HLP report is the first litmus test of the world leaders' serious commitments to the SDGs and their pledge to leaving no one behind.

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## Ensuring access; halting pressures!

Assegurando acesso; basta de pressões!

*Claudia Vaca*<sup>3</sup>

*Carolina Gómez*<sup>3</sup>

It is with great pleasure that we, people in the developing world working on global public health issues, receive the UN Secretary General's High Level Panel Report on Access to Medicines (henceforth The Report). The importance of The Report relies perhaps not so much in its contents and recommendations, which of course are of the outmost relevance, but on the fact that it stems from the highest possible level at the UN System, as Dr. Bermudez pointed out on his article.

Maybe it is not a coincidence that the concern for the lack of access to medicines gained such momentum when it became an issue for developed countries too. This is how Dr. Bermudez mentions it: "Additionally the issue of access to medicines and health technologies is no longer considered as a problem or threat restricted to low and middle-income countries, but is a problem that affects all human kind and also not restricted to a group of diseases. We are no longer dealing with AIDS, TB and malaria or with the so-called Neglected Tropical Diseases, but with all diseases that affect human kind all over the world, including chronic non-communicable diseases."

The debate sparked by the price of Hepatitis C medicines, the ever-increasing price of already existing cancer medicines, the portrayal of some types of cancers almost like orphan diseases (i.e. market fragmentation) have started to put at risk the financial sustainability of all healthcare systems of the world, regardless of their level of development. It is now evident, more than ever, that the paradigm for incentivizing health innovation is failing the rich and the poor of the world, even though the High Level Panel could not reach a consensus on this aspect.

We in the developing world, wonder what needs to happen in order to reach such most needed consensus. The WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property and the CEWG managed to make it more or less politically correct to sustain that failure exists for developing countries, regarding their diseases (mainly tropical, communicable, infectious, neglected diseases). Between CEWG and The Report shocking things happened in the developed countries that would

make all think that it is now accepted that the scope of the failure is wider: Sovaldi and its never-seen-before-sky-rocket-price came into the market and Spain, for instance, said that it could not pay for it for all patients that need it, sparking a wave of social unrest and street demonstrations; hundreds of US Oncologists wrote an open letter warning about unpayable prices of cancer drugs; the English Cancer Drugs Fund (CDF) ran out of money. These are just some milestones that were not enough to make the panel reach consensus. Chikungunha, Zika and Ebola also happened in the meantime, and we cannot avoid wondering whether consensus would have been reached, had those epidemics affected more people living in the global north.

It is sad, but there is hope. Change does not happen abruptly. Countries now need to push the UN Secretary General, WHO, all other relevant UN agencies and the WTO to do something with The Report. A resolution accepting and adopting it must be passed and the UN must work to implement its recommendations and also to help countries implement them. We need to keep pushing, as we have done for about 20 years since the "Revised Drug Strategy"; we have already come far, but not far enough. For a real change to happen, consensus needs to be reached on the failures of the current R&D system based on legal monopolies (patents, data exclusivity) as the main incentives for health innovation. Developed countries, that foster the companies that have innovated, need to understand this.

As Dr. Bermudez correctly expresses it:

*In all forums, we have to state clearly that we cannot continue with a narrow scope of diseases or addressing only low and middle-income countries, but address all diseases and move the terminology from neglected diseases to neglected populations [...] If access to medicines is to be considered an essential human right, further than voluntary and compulsory licensing, the current IP system must be profoundly discussed and changed.*

We could not agree more: something fundamental in the way we innovate needs to change. TRIPS flexibilities, especially compulsory licenses, are not the ideal solution the developing world bargained for when it agreed to TRIPS and to granting product patents for medicines. Flexibilities have failed to deliver. Their promise

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as the way embedded in the intellectual property system (e.g. totally legitimate), to address public health needs, is generally void. The rationale is simple: compulsory licenses are an ad-hoc, case-by-case solution to a structural, systemic problem. This should not be understood as a call for abandoning all attempts at compulsory licensing. On the contrary, they are all we have now, so we should embrace them, enable them, and make them easier to use, as The Report does.

But, to illustrate our point, let us examine more closely the case of Colombia, mentioned both on the Report and on Dr. Bermudez' article. In Colombia, the patent for imatinib was initially denied by the patent office in June of 2003. Novartis then took the patent office to court and won in February 2012, in part because the patent office did not litigate the case. During those almost 10 years, several generics entered the market, but they had to exit once Novartis started enforcing its patent. Even though Novartis won the case in court in 2012, they just started enforcing their imatinib patent in 2014, right after the government had regulated, for the second time in the previous 3 years, the price of Glivec, reducing it in about 11%. Novartis claims that it took them that long to double check that their competitors were indeed infringing their patent (they bought samples and analyzed them in order to prove that the generic compound was the same as the patented one). Nonetheless, NGOs have affirmed that Novartis decision to enforce the patent is a reaction to governmental price setting.

By 2014, 13 companies, including Novartis, held marketing authorizations for imatinib in Colombia. A difference of 198% was registered between the average price per milligram for all imatinib generics (which ran between COP\$50 per mg. and COP\$98 per mg.) and Glivec (sold at the time at COP\$324 per mg.). Hence, the exit of all those competitors from the Colombian market and the sudden existence of a scenario of monopoly after so many years of competition, would have a considerable financial impact on the public health budget. It is worth mentioning at this point that in Colombia, imatinib was declared as an essential medicine in 2011 (years before WHO did) and it is fully covered by the public health insurance.

In fact, at the beginning of the process, Novartis made the argument that there were no real access issues around imatinib because it was fully covered. This argument had worked years before, in the Kaletra case (the only other attempt for a Compulsory License in Colombia) and at that

time, the Ministry of Health decided there were no merits for declaring Kaletra a medicine "of public interest" (a previous step required in Colombia for a compulsory license) because, even though it was proven that the price was high compared to other countries, it was not being paid directly by patients. At the time, the Ministry of Health seemed to be saying "price does not matter, as long as the State can guarantee access". But things have changed dramatically in Colombia where price controls for medicines had been introduced. Nowadays no ministry of health in the world could take such a stand. Novartis, who has been represented by the same lawyer that represented Abbott when the Kaletra case took place in Colombia, quickly realized that that argument would not work, and replaced it with other arguments.

But lets not loose track of the story line. Given the eminent disappearance of competition and the extra financial burden for the healthcare system, on November 2014, civil society organizations decided to trigger the process for the issuance of a compulsory license based on "public interest reasons", which is just one of the many justifications allowed by the Colombian law for a compulsory license. In our country, the process for this kind of compulsory licenses has two phases: one at the ministry of health, who declares that the health technology is "of public interest"; the second one at the patent office who issues the compulsory license and calculates the royalties. Nobody knows, because it has never happened (nor even tried out), whether the patent office can deny a compulsory license even though MOH declared the medicine to be "of public interest".

Besides the juridical details and complexities of the case, the whole government, not just the Ministry of Health was subject to enormous amount of pressure by Novartis, Pharma, Switzerland, the USA and others, as mentioned in The Report. Some of the letters pressuring Colombia were leaked and some of them are published in the MOH's website (<https://www.minsalud.gov.co/salud/MT/Paginas/medicamentos-propiedad-intelectual.aspx>). The Minister of Health also received enormous amount of support from civil society around the world: a letter signed by hundreds of academics and activists was sent to the President of Colombia. The US congress also got involved and a letter of support by a number of Congressmen, including Senator and at the time presidential candidate Bernard Sanders was received. In sum, in Colombia, as in India,

the Glivec case transcended our territory and became a battlefield where titans clashed.

The pressure resulted in the delaying of the decision and on division within the government. Almost a year and a half after the initial request was filed by civil society organizations, the Minister of Health, on July 2016, declared that imatinib was a medicine “of public interest”. Nonetheless, there will be no compulsory license, just additional price controls. This decision is the result of tough negotiations between the minister of trade and the patent office on the one hand, and the ministry of health on the other. The pressure and threats paid off. The trade sector of the government opposed the whole process especially because in the meantime Novartis triggered the Investor- State Dispute Settlement Mechanism contained in the Bilateral Investment Treaty between Switzerland and Colombia. The Deputy Director of the Patent Office issued a formal opinion, which was published by the Ministry of Health, arguing that in this case, given that there were no merits for a “declaration of public interest”, a compulsory license would amount to an expropriation. The Colombian Constitution declares that there shall be no expropriation without due compensation. Hence, he concluded, besides the royalty generics would have to pay Novartis, the State would have to compensate the company too.

At least the Minister of Health was able to “save” the declaration of public interest, because the goal of Novartis was that not even that would take place. This was due, majorly, to the support by respected people and organizations of the world, including WHO, whose deputy director wrote a letter encouraging the Minister of Health and the UN high level panel, that decided to mention the case on The Reprt. The compromise reached between the sectors of the government was that the declaration would be issued, not for the purpose of a compulsory license, but for price controls that should be more stringent than the ones currently in place. The price for Glivec, it was agreed, should simulate competition. The Minister has announced that there would be additional price cuts for Glivec of about 40% to 45%. This has not happened yet. In Colombia, a commission is in charge of the control of prices of medicines. The minister of trade, the minister of health and an appointee by the president compose it. So the Minister had to take the battle to this new scenario. A few weeks ago, the commission issued, for public consultation, a draft methodology for the regulation of prices

of medicines declared “of public interest” by the Ministry of Health. It is based on international reference pricing and the lowest price registered in countries where branded and generics are sold, will be the cap price in Colombia. The difference between this method and the already existing one is that this new one references prices of generics which the old one does not, and it sets the price at the lowest percentile, sets it at the 25th lowest percentile.

If this method is adopted, then it will be applied to Glivec. The good news is that it is a general method, not an ad-hoc one just for Glivec. The other good news is that given that in spite of competition, Glivec still held 80% of the Colombian imatinib market, the savings for the health care system might be greater than those obtained if the competitors remain in the market, because if a compulsory license was granted, they would have to raise the prices to cover the royalties due to Novartis.

Yet, this is still a speculation, because the new price for Glivec has not been set and no doubt Novartis will keep up the pressure. Civil Society organizations that triggered the whole process wonder whether this detour from a compulsory license towards mandatory governmental price controls was legal, because the norms that regulate the declaration of public interest explicitly say such declaration is done for the purpose of a compulsory license. Nonetheless, it seems a waste of resources to fight that legal battle given the evident lack of political will by the patent office, the ridiculous amount of time that litigation takes in Colombia but specially, given the fact that the patent will expire on June 2018. By the time some sort of result is envisaged, the patent, if not expired yet, will be so close to doing so, that it is expected that generic producer would rather wait for it to expire than pay royalties to Novartis.

Thousands of pages could be written telling all the details of this case. The point of writing these ones down was to illustrate the hardships a country must surmount to issue a compulsory license. All this energy, resources, time and political capital invested in just one medicine, is it worth it? From a public policy perspective, is it not possible to invest the same amount of resources aiming at having a wider impact? Given the current R&D system, we are bound to these battles that are worth fighting but that seem pointless, when there are thousands of medicines all around that should be accessible to all. For example, parallel to this enormous fight, the sells of nilotinib, a me-too of imatinib with a considerable higher

price, whose patent is also held by Novartis, have been rising consistently in Colombia while those of Glivec have lowered. Simply put: because the patent for Glivec has started to expire around the globe, Novartis has concentrated on promoting nilotinib, which is still under patent and will sustain profits. This is proof of the distortions of our innovation model, and, we repeat along with Dr. Bermúdez, that unless something fundamental changes, countries are just not simply equipped to keep up just using compulsory licenses.

## The authors reply

Os autores respondem

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Initially, I would like to acknowledge very much the efforts and the solid background of the comments made by the eminent discussants on the original text “Contemporary challenges on Access to Medicines: beyond the UNSG High-Level Panel”.

Professor Frederick Abbott, the first discussant, very clearly spells the relevance of the HLP Report as a milestone achievement, calling on all stakeholders to move forward, beyond the UN General Assembly. A series of developments addressing innovation and access within the pharmaceutical sector have seen important successes, at the same time highlighting the relevance of developments supported by developing country governments.

Trade negotiations, pressures coming from developed countries to limit the adoption of TRIPS Flexibilities point to an immediate call for its end. Submissions received by the HLP are also mentioned seeking for new models for innovation, considering the current system as already broken. The need to carefully weigh policy, legal and advocacy work to ensure feasibility is at the core of his comments.

The proposal for establishment of an essential medicines patent pool, incorporating voluntary licensing but at the same time ensuring incorporation of “effectively automatic” non-voluntary licensing is remarkably demystified with solid legal arguments and regretting that the HLP Report did not move further on exploring this absolutely feasible proposal, as well as arguing the need to discuss whereas a UN General Assembly Declaration would be a useful powerful tool in prioritizing human rights over individual commercial rights and pursuing a systemic longer-term change.

The second discussant, Dr. Mohga Kamal-Yanni, from OXFAM UK initially agrees on the importance of addressing access to medicines as a human rights’ issue and a link to the achievement of the SDGs, acknowledging the conflict between human rights and IP as an individual right. Very sharply, Mohga states as wrong to try to balance human rights with IP as a right, as human rights must always prevail as natural rights. Talking about innovation, she highlights the HLP

report on the work of WHO and civil society and stresses the need to delink cost and price within the pharmaceutical sector. Very correctively, we are reminded that market incentives are not adequate to decide the global R&D agenda and she supports a binding convention which the UN Secretary General is called to trigger a process for discussion, further than the recent UN declaration recommending delinkage related to Antimicrobial Resistance (AMR).

Important recommendations are praised on the HLP report, acknowledging the negative impact that TRIPS Plus provisions have on free trade agreements. Some shortcomings of the report are highlighted, including a stronger message requiring the banning of pressures on IP provisions on bilateral or multilateral trade agreements.

Finally, the lessons learned with HIV are a message that we need strong advocacy and public campaigns to ensure access as a human right, so a multiple stakeholder initiative must follow a strong push from the UN to really leave no one behind on achieving the SDGs.

The third discussants, Drs. Claudia Vaca and Carolina Gomez initially welcome the HLP Report and its importance for the developing world, besides coming from the highest possible level at the UN System. At the same time, they reaffirm that the issues of access to medicines are no longer a restricted problem but affects all countries, regardless of their level of development and this has been a great change from previous discussion restricted to the WHO forums. Examples and milestones are correctly described by the discussants, especially the most recent examples that have instigated this worldwide debate.

The discussants call for immediate changes on implementing the HLP recommendations and on discussing relevant issues related to innovation, TRIPS Agreement, the failures on deliveries with TRIPS Flexibilities as not the ideal solution to address public health needs.

A great contribution to the debate by Drs. Vaca and Gomez is the indepth discussion on the recent case of Colombia, mentioned in the HLP and also in my article. The discussants share with us details of the process involving Novartis, imatinib (Glivec) and generic versions and the difficulties faced by the Colombian Government on attempting to publish a declaration of public in-

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terest by the Ministry of Health as an initial step on the possibility of issuing a compulsory license. This would be the first time of a case like this in Colombia, with great external pressures to halt this Government action.

Of special interest is being the discussion that the discussants bring to this debate, including the polemics intra-government and the “public interest” as a step not necessarily toward compulsory licensing but also aiming additional price controls. I must highlight that a sign of alert is very clear from their comments and we need urgent further debate on the impact and implications of the triggering of the Investor-State Dispute

Settlement Mechanism contained in bilateral investment agreements, which transfers the dispute from WTO to a distinct forum, allowing even companies to sue governments when they consider that private trade interests are being hampered with the issuing of governmental actions.

Anyway, the future is there to come, but the implementation of concrete consensual recommendations, while at the same time, the debate of ideas and proposals comes high in the international forums, must pave the way to the building of a more equitable and solidarity future and a better world for generations to come, leaving no one behind.