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INFORME

THE ROLE OF INTERNATIONAL LAW IN FACING ANTIMICROBIAL RESISTANCE: A GLOBAL HEALTH CONCERN

Arianna Gamba
Health Policy Adviser

ABSTRACT

Antimicrobial resistance (AMR) is a global threat comparable to global warming and it should not be underestimated: diminishing antimicrobial drugs' efficacy would increase the risk of death and prolong the duration of diseases with the risk to infect more people. Global trade and the movement of citizens and products can contribute to AMR phenomenon. Hence, international regulations have to play a bigger role and foster the fight against AMR.

RESUMEN

La resistencia a los antimicrobianos es una amenaza global comparable al calentamiento global y no debe ser subestimada: la disminución de la eficacia de los medicamentos antimicrobianos aumenta el riesgo de muerte y prolonga la duración de las enfermedades, con el consiguiente riesgo de infectar a más personas. El comercio mundial y el movimiento de los ciudadanos y de los productos pueden contribuir a este fenómeno. Por lo tanto, las normas internacionales tienen que jugar un papel más importante y fomentar la lucha contra la AMR.

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I. INTRODUCTION

Antimicrobial resistance (AMR) is rapidly spreading throughout the globe and it has been estimated it could claim up to 40 million victims if not arrested on time (Taylor, et al. 2014). It consists in a selection pressure problem that is a normal evolutionary process in which biological organisms (such as bacteria, fungi and virus) learn to survive against the "attack" of antimicrobial agents and evolve (Tenover, 2006). The term antimicrobial includes all types of antibiotics, antifungal medicines against mycoses, anti-parasitic drugs that can heal diseases like Malaria or antiretroviral drugs against HIV. Diminishing antimicrobial drugs' efficacy would increase the risk of death and prolong the duration of illnesses. Besides, with longer convalescences there are higher chances of infecting other people (WHO, 2015). Potential losses in medicine progress (such as performing surgical procedures) would be combined with direct increased health costs to treat patients that cannot be healed with first-line antimicrobial, such as longer hospital stay and more expensive treatments. On the other hand, indirect costs might be even greater if expressed in terms of loss of productivity, loss of food safety, lack of confidence in healthcare facilities and inability to control future disease outbreaks. (Smith, Coast, 2012)

Although antimicrobial resistance has been denounced already in the forties, new drugs are still not broadly available because AMR has been underestimated and the production of new drugs has not been encouraged enough (Cars, Nordberg, 2005).

Excessive use of antimicrobials has been reported in the medical field due to over-prescription, inducement, treatment inappropriateness (such as prescribing antibiotics for the treatment of viral infections) and patients' behaviour (Tomson, Vlad 2014). The lack of sanitation and hygienic measures has been indicated as one of the leading causes of resistant infections' widespread in developing countries (Walsh, Toleman, 2012). Besides, extensive use of antibiotics in food and agriculture or livestock (such as growth promoters) has been pointed as another cause of increased resistance (Laxminarayan, et al. 2013). The impact of antibiotics used in agriculture on human health is also emphasised by the concept of "one health" acknowledged by the international community. Animals and humans health are interdependent because humans belong to animal species, they share and exchange certain type of bacteria and even use the same drugs for some diseases (Marais, et al. 2012).

In light of all these different but interdependent aspects, a single national intervention cannot solve the problem. AMR has been observed everywhere worldwide and it is difficult to monitor as it is rapidly spreading in an irregular manner. Least developed countries are the one who are suffering more from this problem, where access to medicines is not always guaranteed (as the ability to pay for second-line treatments is lower), there are no strict regulations for antimicrobial use and diseases can spread more easily due to inadequate hygienic conditions. Also, global trade and movement of citizens can contribute to AMR phenomenon. Hence, joint international efforts are needed to promote and guarantee high and harmonized international standards of safety, but this becomes problematic when regional and national regulations are contrasting. For instance, the European Union (EU) and United States (US) are in the process of creating a Free Trade Area (FTA), but regarding the use of antibiotics in food and agriculture there are big discrepancies between their legislation. (Martinić, Maljak, 2014)

International health law plays a crucial role in regulating antimicrobial use: by considering AMR a global public health threats, this articles intends to clarify what are the international standards and policies that should be implemented to tackle antimicrobial resistance. The more resistant pathogens spread on a global scale, the more the role of international law is expected to increase to contain this global threat.

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II. INTERNATIONAL HEALTH LAW

The current panorama of international health law seems to have limited power when it comes to implement regulations that can tackle antimicrobial resistance. Even if the WHO has the authority to produce binding regulations, it decided to publish a Draft Global Action Plan to face AMR that is made of useful, but not mandatory, recommendations (WHO, 2015).

The WHO has traditionally adopted this approach, producing since its creation in 1946 only two mandatory instruments: the International Health Regulation (IHR) and the Tobacco framework convention. Fidler (1998a) criticises this choice because the WHO was created as a supranational organisation that could actually legislate in any area that affects health. In accordance with art.21 of the WHO Constitution, these areas include many trade-related aspects like quarantine rules to contain the spread of infectious diseases, sanitary and phytosanitary, and various issues regarding the international trade of medical products like advertising, labelling, safety and quality standards. In addition, the WHO could also set international standards for public health practices and diagnostic procedures. After the Second World War, infectious diseases were a major global threat and there was the need for an international legal system and standards that could be valid everywhere. On the contrary, nowadays there is a lack of global health jurisprudence because the WHO has almost neglected its opportunity to produce binding regulations for several reasons (Fidler, 1998a).

On the one hand, for many countries it would be arduous to cope with compulsory surveillance and diagnosis tool systems. On the other hand, Fidler (1998a) points out that the WHO personnel is mainly composed of medical doctors that approach health issues from a medical and technical perspective without producing legal instruments. With the scientific progress and the discovery of antimicrobials and vaccines, the eradication of several diseases and the use of new health technologies became more relevant than international health law, and physicians mainly began to directly heal the disease instead of containing and preventing it with regulations. Also, adopting a voluntary approach seems easier for the WHO also because this organisation does not have the necessary legal body to interpret international treaties and manage disputes. (Fidler 1998a)

II.1 Surveillance and monitoring

The first step in AMR management requires the creation of an efficient and mandatory surveillance system that can monitor the emergence of new resistant pathogens, the level of incidence of the existing ones and the level of antimicrobial consumption in humans and animals (Gerards, 2011). The WHO first attempt of Global Surveillance Report provides an overview of the degree of incidence on existing resistance pathogens. Nevertheless, the lack of an international classification system and the level of surveys' response from certain countries, show that surveillance efforts need to be improved (WHO, 2014).

The International Health Regulation revised in 2005 establishes a system of global surveillance that aims at fostering international scientific cooperation among all countries. According to the regulation, countries have the duty to inform the international community about the emerging of any diseases and epidemic that might threaten public health (Baker, Fidler, 2006). AMR is not explicitly cited, but by considering AMR a public health threat, countries should be compelled to report AMR trends (Wernli, et al. 2011).

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Once surveillance would be established as a legal duty, fulfilling this task will require economic resources that developing countries may lack (scientific tools, IT equipment, etc...). Therefore, by providing with financial support and technological assistance through international organizations and agencies, those countries could obtain an efficient global surveillance system (Vernet, et al. 2014). Efficient AMR mapping also in under-resourced countries would benefit every country, because resistant pathogens can move freely across borders.

In the case of high income countries, in 2011 the European Union has already implemented a comprehensive regional plan, based on 12 objectives. In addition, the EU cooperated together with the WHO, FAO and OIE to develop the draft of the recent global plan. Thus, the EU might be taken as a good example for the other regions as it is working on several fronts and a number of Member States have already achieved successful results. (European Commission, 2015)

More specifically, by the Council Recommendation 2002/77/EC on the prudent use of antimicrobial agents in human medicine, Member States are called to take action on the development of national surveillance systems on antibiotic use and resistance, implementation of prevention methods and infection control, improvement of education and training of health professionals and informative approaches to raise awareness of prudent use of antibiotics among the general public (Gerards, 2011). As a result, Iceland, Norway and all Member States participated in several different networks like the European Surveillance Antimicrobial Consumption Network (ESAC-Net) (European Commission, 2015).

Compared to the European plan, the new strategy launched by Obama in 2014 is based on 5 objectives that also include the improvement of the national surveillance system, which is considered essential to collect more evidence and better assess the impact of antimicrobial use in agriculture on human health. However, this plan does not provide enough information about planning and implementation of surveillance yet. (Jooma, 2015)

In the US the majority of public health policies are the responsibility of States, but according to Fidler (1998b), a shift of power would be desirable, in order to let the federal government to better control eventual disease outbreaks. Thus, it could be beneficial to apply the same principle of the IHR (or similar to the European networks) also within the US at the federal level, so that every State would have the duty to keep federal health institutions aware of what is happening at the local level. (Fidler, 1998b)

II.2 Innovation

From the pharmaceutical industry's perspective, producing antibiotics is not the most profitable activity for several reasons. One of them is that antimicrobial revenues are lower compared to other drugs, because they are supposed to be taken by individuals for short term periods and few times in a year. While for instance, medications for chronic diseases are a safer investment because regularly used. (Spellberg et al. 2004)

International law could also help in organising international public funding not only for better surveillance of AMR phenomena, but also to sponsor further research and development (Hoffman et al. 2015). This can be done through the help of international organizations, but also with the creation of PPP as it has already been done to improve access to medicines in developing countries, and for rare and neglected diseases (Nathan, Cars, 2014). PPP could be a good initiative, but it is crucial to balance the power among the parties, otherwise joint efforts would be meaningless.

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In terms of international cooperation, the Trans-Atlantic Task Force on Antimicrobial Resistance (TATFAR) drafted a proposal to identify areas of future cooperation on policy alignment between the US and EU undertakings and State agencies to deal with the development of new medical products (European Commission, 2015).

Moreover, the FDA has launched interesting initiatives like the target product profile (TPP) and the Generating Antibiotics Incentives Now (GAIN) act. The former guides undertakers and inventors in setting their R&D priorities, as it opens the dialogue among the FDA and sponsors that have to follow this "drug development programme" (Cooper, Shlaes, 2011). The latter offers 5 more years of market exclusivity for developing an antibiotic able to treat "qualified infectious diseases". This extra time may be preferred by companies because the grant of a patent is more uncertain (Gaffney, 2014).

II.3 Stewardship

International law could also help countries to preserve the efficacy of antimicrobials by prohibiting the sale without medical prescription. Additional issues could arise from medical associations when governments would try to promote antibiotics stewardship, as it might hamper their clinical autonomy; further, guidelines might be difficult to apply because of the influence of their peers (Laxminarayan, et al. 2013). For these reasons, medical and veterinary associations could be encouraged to draft antibiotics utilization guidelines themselves (Fidler, 1998b).

III. INTERNATIONAL TRADE LAW

International trade has both negative and positive impact on people's well-being and health. Economic growth turns in higher purchase power: people would benefit from a greater choice and availability of goods, which could result in better health status and higher schooling rate (Strauss, Thomas, 1998). Apart from promoting general economic growth and greater interdependence among states, all trade and investments-related treaties under the umbrella of the WTO may have a particular impact on health that cause concern. Trade in goods regulates the import/export of food and the use of labelling, trade in services influences the health insurance and healthcare market, Intellectual Property law can affect access to medicines through patents and copyright, the free movement of workers may cause a deficit of health professionals in poor areas or facilitating the spread of diseases, and finally the protection of foreign investments can undermine national sovereignty and the implementation of health policies. (Labonté, 4/29/2015)

More precisely, rules in the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) allow States to implement their standards and regulations with the aim of guaranteeing the health and safety of its citizens. But the Agreement aims at avoiding that governments use safety standards as a form of protectionism and as a barrier to prevent other countries to export their products (WTO, 2015). The WTO and FAO created the Codex Alimentarius Commission that has the role of setting international safety standards for trading food such as the Maximum Residual Levels (MRLs) of antibiotics. The interpretation of evidence-based safety standards is highly controversial as shown by the EU-US beef hormone dispute. The US accused the EU of infringing the SPS agreement when prohibiting the sales of beef meat with growth hormones by implementing the European precautionary principle. Since the European regulation is stricter than the international code, the US claimed that scientific evidence to enforce such restriction should have been based on risk assessment studies for the health of the citizens instead of being justified through the angst that something wrong might

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happen in the future (Fidler, 1998b). The SPS agreement has probably the biggest impact on AMR for the reasons discussed in the section IV.

Under the TRIPs, patents can last between 20 and 25 years. However, some developing countries have been able to make use of the TRIPs flexibilities and to refuse to grant full patent protection to certain products with the aim of guaranteeing access to medicine and protecting public health. But, compulsory licensing and parallel import, combined with lack of control on prescription behaviours and antimicrobials peddling, have been pointed as one of the causes of TB, malaria and HIV resistance in developing countries, because they were not able to properly regulate and administer the use of these drugs (Shridhar, 2011). On the other hand, it has been argued that one important cause of multidrug resistant Tuberculosis is patient compliance to treatment: TB treatment lasts at least 6 months and non-adherence is quite common because of social factors (i.e. alcoholism, stigma and comorbidity) and the cost of the drugs (Jain, Dixit 2008). Hence, longer patent protection for a drug that can heal XD TB will not be very effective if infected people cannot afford it. Access to medicines should never be restricted. As stated in the WHO report, poverty and insufficient access to medicines are causes of AMR, especially in developing countries. (WHO, 2014)

All these international trade agreements are therefore particularly relevant to the problem of AMR because they regulate many of the causes of AMR, especially those related to the market access and approval of pharmaceuticals, food and agriculture. Besides, the current trend of creating and extending Free Trade Areas (FTAs) like the Trans-Pacific Partnership (TPP), the Transatlantic Trade Investment Partnership (TTIP) (to cite a few examples) and promoting greater market liberalization, is putting a lot of pressure on national health systems. There are two sides of the moon: on the one hand, these agreements can be seen as an opportunity to create a common legal framework that would improve safety standards and common health practices through mandatory guidelines. In contrast, on the dark side, they are seen by many researchers and a big share of the civil society as a great deal for Transnational Corporations and a threat to ordinary citizens and health systems (Siles-Brügge, 6/15/2015).

The main health concerns of the civil society regarding FTAs that are relevant to the discussion about AMR are the harmonization of standards and the Investor-State-Dispute-Settlement (ISDS) provisions. In the case of the TTIP for example, European consumers are afraid of opening the market to US food products because of the use of growth promoters and GMOs. The European precautionary principle is meant to preserve the efficacy of antibiotics and the fear is that this law could disappear if there will be a regulatory harmonization among the EU and US (Bergkamp, Kogan, 2013). Moreover, the creation of a "private tribunal" against the discrimination of foreign investors may cause the so-called "regulatory freeze where policymakers will dilute their policy under the threat or fear of ISDS: they will delete the implementation of a regulation in order to see how an ISDS dispute will end up" (Labonté 4/29/2015).

To sum up, the features and nature of Free Trade Areas seem unable to provide the necessary instruments for policy makers to tackle antimicrobial resistance, as these agreements aim at increasing economic profits and not necessarily at improving public health provisions.

IV. INTERNATIONAL ANIMAL HEALTH LAW

Every single state has its rules for food safety and animal health (Johnson 2011). However, there are common frameworks at the international level that are references for regulating international markets. Overall, antimicrobials are used for three different

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purposes: 1. to treat sick animals, 2. to prevent the spread of disease and 3. Antibiotic Growth Promoters allow animals to grow more and quicker compared to other animals. Preventive and growth-promoter antibiotics are usually administrated to all animals (without distinguishing between the healthy and sick ones) through medicated feed (N. Pushkarev, interview, 30/07/15). Intensive farming is a cost saving practice that allows producers to earn more, but due to the condition in which animals are kept, this system relies on antibiotics. Hence, there is a trade-off between using antibiotics to keep production large and cheap and containing AMR by curving the utilization of these drugs, implementing alternative methods and producing less.

Outdated risk assessment studies may allow larger rooms for negotiations in international trade at the expenses of the safety of the consumers: for instance, Ractopamine is a growth promoter drug already banned in 160 countries (among which the European Union) but utilised in the US as considered safe by the FDA (Suppan, 2014). The Ractopamine MRL allowed by the Codex Alimentarius has been set on the base of only circa 12 studies carried out two decades ago and the US is making some pressure to remove the ban on this drug in the EU through the negotiations of the TTIP (Suppan, 2014). By considering the size of the US and EU food markets, the standards that are going to be set by the TTIP will inevitably influence the global standards. Sadly, "consumers who expect to discover in the draft SPS chapter where the negotiations stand on specific consumer concerns, such as the non-therapeutic use of veterinary drugs like antibiotics allowed in US meat and poultry production, or the import and labelling of food containing genetically modified organisms, will be disappointed" (Suppan 2014, p.1). This statement foresees the missed opportunity of using an international agreement to improve standards and collaborate against AMR.

Moreover, it seems that what is under negotiation for MRLs in the TTIP is contradicting the current European efforts to improve animal health and food safety and quality. According to Johnson (2011) Europe and New Zealand have the strictest regulations on the use of antibiotics in animal husbandry and in my opinion, standards improvement should start on the base of these types of strict rules in order to protect the health of consumers and promote antimicrobial stewardship. According to Bergkamp and Kogan (2013) the "better safe than sorry" approach applied by the European precautionary principle asks producers to prove the safety of their products and this should guarantee higher protection to consumers. On the contrary, I think that using only the "scientific-evidence" approach could be less reliable because scientific studies may be biased, outdated or not capable of estimating all the possible adverse effects caused by certain residual level of antimicrobials that may occur in the long term.

Since 2006 EU legislation on additives for use in animal nutrition prohibits the use of antibiotics as growth promoters in animal food and since 2010 European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project has been launched (European Commission, 2015).

Moreover, in 2013 the creation of a European animal health law has been proposed with the aim of harmonising standards and procedures within the European market and improving the way animals are treated (European Commission, 2015). Despite it does not ban the preventive use of antimicrobials, it seems to stress the attention on labelling information requirements, compulsory prescriptions and the validity of prescription for the use of antimicrobials in animal feed and the quantities allowed. The use of medicated feed is going to be traced from the manufacturing process to its actual use. Moreover regulations on the trade of medicated feed are created to avoid distortions in the Members' competition (N. Pushkarev, interview, 30/07/15).

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On the other hand, the US legislation on antimicrobial use should rely on the Preservation of Antibiotics for Medical Treatment Act (PAMTA). It distinguishes among those antibiotics that can be used only for humans, as they are particularly relevant and need to be preserved and those that can also be used in agriculture (Johnson 2011). This bill that has been proposed several times since 1999, but never approved by the Congress, has been reintroduced this year.

V. CONCLUSION

Without being redundant, it seems easy to draw a line and state a direct proportionality that the more antibiotics are prescribed, the more resistance grows. Hence, In order to tackle AMR priority should be given to surveillance and the prudent use of antibiotics. Fostering antimicrobial stewardship is essential as it has been estimated that current antibiotics are a scarce resource and their therapeutic affect may run out by 2070 (Shridhar, 2011).

Action requires global governance and international regulations that must prohibit the sale of antibiotics over the counter. The WHO has the legal powers to produce binding regulations that can tackle this problem, but also other international organisation like the WTO or OIE should cooperate and being involved to combat AMR. The Directive 2001/83/EC of the European Parliament and the Council on the Community code relating to medicinal products for human use stated that it is not possible to sale prescription medicines without prescription in pharmacies (European Commission, 6/11/01). This type of regulation could be duplicated by those countries that do not have one in place. Regulations should be combined with sanctions rather than relying on voluntary adherence. In line with the "scientific-technical" approach of the WHO, the current WHO global action plan consists in recommendations with no binding power. Given the paralysis of the scientific sector and the multidisciplinary nature of AMR, the WHO should consider the idea of making use of its binding powers and start to assign a part of its budget to the development of an apt legal apparatus (Fidler 1998a). The choice of providing non-binding recommendations may be also based on the fact that countries are not prepared to comply with such regulations yet. However, distinctions based on countries' income or technological availability could have been made as first step, letting the others following by a certain period of time (it is important to set targets).

Drug and medical technological discovery need to find a sustainable business model that can help foster production. This can be financed internationally and international law can set a percentage of national GDP that should be given to R&D. Among the alternatives, public private partnerships with an adequate balance of power seems to be a valid short term option, as harmonising patents and regulation approval standards worldwide would be more difficult to implement in the short term. Similarly, the US Target Product Profile and the GAIN act could be valid alternatives, as they incentivise pharmaceutical companies to prioritize R&D in the field of antibiotics.

Given the "one health" approach, the role of food and agriculture in AMR should not be underestimated. Reducing antibiotics consumption in food and agriculture through an international ban on growth promoters and preventive use is a key step in antibiotics stewardship. This international ban should be combined to the national conversion of intensive farming into more sustainable farm practices that would guarantee a healthier lifestyle for animals and higher food quality. To sustain this process the OIE could lobby for the creation of an international animal law that includes these provisions. The European Union is working on this, but one continent alone is not sufficient. Moreover, allowed MRL of antimicrobials set by the Codex Alimentarius should be based on updated studies in order to guarantee consumers' safety.

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