



# **The Value Added of the United Nations General Assembly High-Level Political Declaration on Antimicrobial Resistance**

**By Viviana Muñoz Tellez**

In September 2016, the United Nations General Assembly (UNGA) in New York held a dedicated meeting to muster strong political commitment for an effective global response to the problem of antimicrobial resistance (AMR). As a result, a High-Level Political Declaration on Antimicrobial resistance was adopted.<sup>1</sup>

The High-Level Political Declaration (hereafter “the Declaration”) reaffirms that the blueprint for tackling AMR is the World Health Organization (WHO) Global Strategy and Action Plan on Antimicrobial Resistance, its five objectives, and the principles for effective national action plans: a one-health approach, prevention first, and access.<sup>2</sup>

Below is a synthesis of the main elements of the Declaration that add value to the comprehensive WHO Global Strategy and Action Plan on AMR (GAP).

## **Linking AMR to the 2030 Agenda for Sustainable Development**

The Declaration provides the basis for a sustained commitment of all United Nations (UN) Members at the highest political level, by linking action against AMR to the achievement of the 2030 Agenda for Sustainable Development.

The WHO GAP,<sup>3</sup> adopted in May 2015, does not mention the 2030 Agenda for Sustainable Development.<sup>4</sup> In contrast, the Declaration includes an explicit reaffirmation of the 2030 Agenda which recognizes the need to address growing anti-microbial resistance. The Declaration notes that the 2030 Agenda offers a framework to ensure healthy lives, and recall commit-

ments to fight communicable diseases and epidemics (e.g., malaria, HIV/AIDS, tuberculosis, hepatitis) including by addressing growing antimicrobial resistance. The Declaration also reiterates that AMR challenges the sustainability and effectiveness of the public health response to these and other diseases as well as gains in health and development and the attainment of the 2030 Agenda.

## **Financial and Technical Resource Mobilization for developing countries**

The WHA resolution adopting the GAP recognized the need for a significant increase in the mobilization of resources to support effective action, including through the provision of technical and financial assistance, particularly to low and middle income countries, and urged member States to mobilize human and financial resources.<sup>5</sup> The resolution also requested the WHO Director-General to work with the United Nations Secretary-General and bodies in the UN system to identify the best mechanisms to realize the investment needed to implement the GAP, particularly with regards to the needs of developing countries.<sup>6</sup>

The WHO GAP echoes this call under objective 5, and includes the call to the World Bank and other development banks to develop and implement a template or models to estimate the investment needed to implement national action plans (NAPs) and to collate and summarize these needs.

The Declaration adds to these calls and extends to elements that were not emphasized in the WHO GAP. It recognizes the need to enhance

capacity building, technology transfer and technical assistance, and cooperation for controlling and preventing AMR, as well as international cooperation and funding to support the development and implementation of NAPs, including surveillance and monitoring, to strengthening of health systems and research and regulatory capacity, and infrastructure.

The Declaration explicitly calls for these actions to be done without jeopardizing – in particular in the case of low and middle-income countries – health or posing barriers for access to care.<sup>7</sup>

The Declaration also includes a commitment to mobilize adequate, predictable and sustained funding and human and financial resources and investment through national, bilateral and multilateral channels to support the development and implementation of NAPs, research and development on existing and new antimicrobial medicines, diagnostics and vaccines, and other technologies, and strengthening of related infrastructure.<sup>8</sup>

The Declaration also calls upon WHO in collaboration with the Food and Agriculture Organization of the United Nations (FAO), the World Organization for Animal Health (OIE), regional and multilateral banks, including the World Bank, UN agencies, intergovernmental organizations, civil society, and multi-sectoral stakeholders to support the development and implementation of the NAPs and AMR activities at the national, regional and global levels.<sup>9</sup>

### **Access and affordability to health services and to new and existing medicines, vaccines and diagnostics**

The Declaration builds on the GAP and the WHA resolution, making more prominent the issues of access and affordability.

The WHA resolution adopting the GAP noted that developing countries are still facing a multitude of challenges in improving affordability and universal access to quality, safe and effective antimicrobial medicines and diagnostics tools.<sup>10</sup> Accordingly, the WHO GAP established as a principle that all national and global

action plans to address AMR to be effective in implementation should ensure access to health facilities, health care professionals, veterinarians, preventive technologies, diagnostic tools, and access to knowledge, education and information.<sup>11</sup>

The Declaration goes further to clearly highlight that affordability and access to existing and new antimicrobial medicines, vaccines and diagnostics should be a global priority and should take into account the needs of all countries.<sup>12</sup> Moreover, the Declaration clearly links the access challenge for developing countries to the right to health. The human rights approach is a new introduction in the Declaration that was not present in the WHO resolution or the GAP. The Declaration notes with concern that the fulfilment of the right to the enjoyment of the highest attainable standard of physical and mental health, as well as access for millions of people to health services and to quality, safe, efficacious and affordable antimicrobial medicines, food, clean water and a healthy environment, remain a distant goal, especially in developing countries.<sup>13</sup>

Importantly, the Declaration also notes that the current lack of access to health services and to antimicrobial medicines in developing countries contributes to more deaths than antimicrobial resistance.<sup>14</sup>

The Declaration establishes that keys to tackling AMR are promoting access to existing and new quality, safe, efficacious and affordable antimicrobial medicines, diagnostics, vaccines and other important technologies, interventions and therapies, as well as promoting affordable and accessible healthcare.<sup>15</sup> Accordingly, it recognizes that effective antimicrobial medicines and their prudent use are a global public benefit and that for addressing AMR it is essential to allow people to have access to affordable antimicrobial medicines and other technologies when they are needed.<sup>16</sup>

The Declaration also highlights that the global development and stewardship framework that WHO, FAO and OIE are mandated to finalize should include as a core objective, to promote affordable access to existing and new antimicrobial medicines and diagnostic tools.<sup>17</sup>

## **Increase investment in R&D for new antibiotics and other medicines, diagnostics and vaccines through de-linkage mechanisms**

The GAP notes that: “the cost of investment in R&D may need to be de-linked from price and the volume of sales to facilitate equitable and affordable access to new medicines, diagnostic tools, vaccines and other results from R&D in all countries.”<sup>18</sup> This appropriately brings together two key challenges of AMR: the innovation and the access challenge.

The innovation challenge, identified in the WHO resolution<sup>19</sup> and in the GAP, is that: “No major new class of antibiotics has been discovered since 1987 and too few antibacterial agents are in development to meet the challenge of multidrug resistance.”<sup>20</sup> The GAP notes that: “Lack of such investment reflects, in part, fears that resistance will develop rapidly and that returns on investment will be limited because of restrictions in use.” R&D of new antibiotics is seen as a less attractive business investment than that of medicines for chronic diseases. Currently most major pharmaceutical companies have stopped research in this area, a situation that has been described as a “serious market failure” and “a particular cause for concern”.

Although public financing for medical R&D can be substantial, the private pharmaceutical industry is the main actor in new medical product innovation. The pharmaceutical industry is driven by profit maximization, and thus decisions on investment in R&D are based on expectations of profits derived from product sales. For profit maximization, setting product price and volumes is highly strategic. Intellectual property rights (e.g., patents) is a tool used by the pharmaceutical industry to keep competitors from entering key markets for some time and placing downward pressure on prices. The potential demand (e.g. health need) is considered alongside the profit expectations. If a market does not appear profitable, private investment in R&D is likely to be low or non-existent. This is market failure.

To address this challenge, the GAP notes

that: “new concepts are needed for providing incentives for innovation and promoting cooperation among policy-makers, academia and the pharmaceutical industry to ensure that new technologies are available to prevent, diagnose and treat resistant infections.”<sup>21</sup> “New processes are needed ...to facilitate renewed investment in R&D of new antibiotics,<sup>22</sup> and “more widespread recognition of antimicrobial medicines as a public good is needed to ...encourage investment in research and development (R&D).”<sup>23</sup>

The main “concept” that the GAP advances for R&D is that of “de-linkage.” The GAP states that: “The cost of investment in R&D may need to be de-linked from price and volume of sales to facilitate equitable and affordable access to new medicines, diagnostic tools, vaccines and other results from R&D in all countries.”<sup>24</sup> The GAP however does not specify what de-linkage mechanisms should be supported.

The GAP call for de-linkage mechanisms is clearly dual: to increase investment in R&D for new antimicrobial products (e.g. medicines, diagnostic tools, vaccines and other interventions), and to ensure it leads to equitable and affordable access to new antimicrobial products.

The objective 5 of the GAP aims “to increase investment in new medicines, diagnostic tools, vaccines and other interventions”. One of the agreed actions for WHO member States under objective 5 is “piloting of innovative ideas for financing R&D and for the adoption of new market models to encourage investment and ensure access to new antimicrobial products”.

Also under objective 5 of the GAP, actions to be taken by the WHO Secretariat include to: “Coordinate the work of many unlinked initiatives aiming to renew investment in R&D of antibiotics (including follow up initiatives from the Consultative Expert Working Group on Research and Development); to identify priorities for new treatments, diagnostics and vaccines on the basis of emergence and prevalence of serious or life-threatening infections caused by resistant pathogens; to act as the vehicle(s) for securing and managing investment in new medicines, diagnostics, vaccines and other interventions; to facilitate affordable and equitable access to existing and

new medicines and other products while ensuring their proper and optimal use; and to establish open collaborative models of R&D in a manner that will support access to the knowledge and products from such research, and provide incentives for investment".<sup>25</sup>

The Declaration adds value and goes further than the GAP by making an unequivocal call for investment in de-linkage models that are based on accepted guiding principles, specially to facilitate equitable and affordable access to new medical products. Ensuring affordability and equitable access is defined in the Declaration as a global priority.

The Declaration underlines that: "All research and development efforts should be needs-driven, evidence-based and guided by the principles of affordability, effectiveness and efficiency and equity, and should be considered as a shared responsibility. In this regard, we acknowledge the importance of delinking the cost of investment in research and development on antimicrobial resistance from the price and volume of sales so as to facilitate equitable and affordable access to new medicines, diagnostic tools, vaccines and other results to be gained through research and development, and welcome innovation and research and development models that deliver effective solutions to the challenges presented by antimicrobial resistance, including those promoting investment in research and development."<sup>26</sup>

Furthermore, the Declaration goes further than the GAP in objective 5 by specifying that the R&D to be supported should be based on priorities and local needs set by governments, and ensuring public return on investment.<sup>27</sup>

### **A global development and stewardship framework on AMR**

The Declaration calls on WHO together with FAO and OIE to finalize a global development and stewardship framework.

The WHA in its resolution 68.7 had previously called on the WHO together with FAO and OIE to provide options for the establishment of the framework and report back to

WHO member States. The Declaration goes further to call on these agencies to finalize the framework, restating that the aim is to support the development, control, distribution and appropriate use of new antimicrobial medicines, diagnostic tools, vaccine and other interventions, while preserving existing antimicrobial medicines, and to promote affordable access to existing and new antimicrobial medicines and diagnostic tools, taking into account the needs of all countries and in line with the GAP.<sup>28</sup>

### **Inter-Agency Coordination Group to provide guidance for sustained effective global action on AMR**

The Declaration requested the Secretary-General to establish, in consultation with WHO, FAO and OIE, an ad hoc inter-agency coordination group (IACG), co-chaired by the Executive Office of the Secretary-General and the World Health Organization, drawing, where necessary, on expertise from relevant stakeholders. The IACG was tasked to: "Provide practical guidance for approaches needed to ensure sustained effective global action to address antimicrobial resistance."<sup>29</sup>

The Secretary-General is requested to submit for consideration by member States by the seventy-third session of the General Assembly: "A report on the implementation of the Declaration and on further developments and recommendations emanating from the ad hoc inter-agency coordination group, including on options to improve coordination, taking into account the global action plan on antimicrobial resistance."<sup>30</sup>

The IACG has a clear mandate and should have the competence to report on the implementation, by all relevant actors in all areas addressed by the GAP and the Declaration and based on the agreements embodied in them, and to go further with recommendations that emanate from its work, specially towards improving global coordination.

### **Conclusion**

There is strong political agreement among United Nations Members to take action on AMR. It is captured in the High-Level Political Declaration on AMR adopted in September 2016.

The Declaration reaffirms and adds value to the WHO Global Strategy and Action Plan on AMR (GAP) in five main areas: link AMR to the 2030 Agenda for sustainable development; Mobilize financial and technical resources for developing countries; increase investment in R&D through de-linkage mechanisms; finalize a global development and stewardship framework; and establishment of an inter-agency coordination group to provide recommendations to the UNGA on how to ensure sustained effective global action on AMR building upon the GAP and the Declaration.

The challenge remains implementation – following through these hard-fought, balanced agreements and translating them into a multitude of effective and appropriate actions at local, national and global levels, involving multiple stakeholders, based on a one-health approach, that together ultimately achieve the aim of containing the rate of emergence and spread of AMR and the threat it poses to the achievement of the sustainable development goals.

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### Endnotes

<sup>1</sup> UN General Assembly Resolution A/RES/71/3, Political Declaration of the High-Level Meeting of the General Assembly on Antimicrobial Resistance, adopted on 6 October 2016, available from [http://www.un.org/en/ga/search/view\\_doc.asp?symbol=A/RES/71/3](http://www.un.org/en/ga/search/view_doc.asp?symbol=A/RES/71/3).

<sup>2</sup> World Health Assembly Resolution WHA 68.7: “Global Action Plan on antimicrobial resistance”, available from <http://apps.who.int/medicinedocs/documents/s21889en/s21889en.pdf>; Global action plan on antimicrobial resistance. Geneva: World Health Organization; 2015. Available from [http://apps.who.int/iris/bitstream/10665/193736/1/9789241509763\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/193736/1/9789241509763_eng.pdf).

<sup>3</sup> Global Action Plan on Antimicrobial Resistance, World Health Organization, 2015. Available from [http://apps.who.int/iris/bitstream/10665/193736/1/9789241509763\\_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/193736/1/9789241509763_eng.pdf?ua=1).

<sup>4</sup> Resolution adopted by the General Assembly on 25 September 2015, 70/1 “Transforming our world: the 2030 Agenda for Sustainable Development”, paragraph 26. Available from [http://www.un.org/ga/search/view\\_doc.asp?symbol=A/RES/70/1&Lang=E](http://www.un.org/ga/search/view_doc.asp?symbol=A/RES/70/1&Lang=E).

<sup>5</sup> Ibid at 2, preamble.

<sup>6</sup> Ibid at 2, Paragraph 2.2 and Paragraph 4.8.

<sup>7</sup> Ibid at 1, Paragraph 10 (f).

<sup>8</sup> Ibid at 1, Paragraph 12 (b).

<sup>9</sup> Ibid at 1, Paragraph 14.

<sup>10</sup> Ibid at 2, preamble.

<sup>11</sup> Ibid at 3, Paragraph 21 (3).

<sup>12</sup> Ibid at 1, Paragraph 10 (d).

<sup>13</sup> Ibid at 1, Paragraph 7.

<sup>14</sup> Ibid at 1, Paragraph 8.

<sup>15</sup> Ibid at 1, paragraph 9.

<sup>16</sup> Ibid at 1, Paragraph 10 (a).

<sup>17</sup> Ibid at 1, Paragraph 13.

<sup>18</sup> Ibid at 1, Paragraph 46.

<sup>19</sup> Ibid at 2, preamble, recalling the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property and resolution WHA 66.22 on follow-up of the report of the Consultative Expert Working Group on Research and Development: Finance and Coordination.

<sup>20</sup> Ibid at 1, Paragraph 19.

<sup>21</sup> Ibid at 1, Paragraph 19.

<sup>22</sup> Ibid at 1, Paragraph 46.

<sup>23</sup> Ibid at 1, Paragraph 41.

<sup>24</sup> Ibid at 1, Paragraph 46.

<sup>25</sup> Research and Development to meet health needs in developing countries: strengthening global financing and coordination. Report of the consultative expert working group on research and development: financing and coordination. Geneva: World Health Organization, 2012.

<sup>26</sup> Paragraph 10 (c) of the Political declaration of the high-level meeting of the General Assembly on antimicrobial resistance.

<sup>27</sup> Ibid at 1, Paragraph 12 (b).

<sup>28</sup> Ibid at 1, Paragraph 13.

<sup>29</sup> Ibid at 1, Paragraph 15.

<sup>30</sup> Ibid at 1, Paragraph 15.

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