

Outcome Documentⁱ

”Commitments to Responsible Use of Antimicrobials in Humans”

13-14 November, 2014

Oslo, Norway

We, the participantsⁱⁱ of the Oslo meetingⁱⁱⁱ on responsible use of antimicrobials in humans, gathered in Oslo, Norway on the 13-14 of November, 2014 to discuss the urgent need to improve human use of antimicrobials, and to identify clear strategies and actions to increase their appropriate responsible use while assuring their access. We recognize that prompt coordinated and collective action is essential because of the rapidly growing global spread of antimicrobial resistance.

We acknowledge antimicrobial resistance to be a severe threat to global health that could undermine decades of progress in combating infectious diseases and preventing surgical and other health care related infections, and that misuse and overuse of antimicrobials are key drivers. At the same time, we recognize that where use is warranted, the lack of antimicrobial treatment, or inadequate treatment, either through lack of access or inappropriate use, remains an important contributor to death and illness. We applaud the efforts by WHO to place antimicrobial resistance on the global agenda to assure continued effectiveness of and access to effective antimicrobials for future generations. In reference to the consultation in The Hague, Netherlands on 25-26 June 2014, we agree that antimicrobial resistance needs a “One Health” approach^{iv} engaging all stakeholders from the human and animal health, agriculture, aquatic and environmental sectors, both governmental and civil society. We see the ongoing collaboration between the WHO, OIE and FAO as a cornerstone in this work.

We recognize the need to strengthen health systems, noting the importance of interventions to assure infection prevention and control. This should be done through behavioral change, appropriate and timely treatment, immunization coverage and development of new vaccines, access to safe water, hygiene, sanitation, and waste management. Models for supporting research and development into new and novel antimicrobials need to be aligned with global needs. These models should actively explore alternative mechanisms for incentivizing research and development, including delinking research and development costs from product prices, and decoupling reimbursement to manufacturers from the volume of consumption. These models need to include mechanisms to reserve the use and maintain the effectiveness of these new antimicrobials.

This consultation has focused on concrete strategies to shift words into action. We acknowledge the challenges of developing a global action plan which aims to guide efforts to combat antimicrobial resistance in all countries, taking into account the many differences in health systems, culture, ecology, epidemiology and economic status. However, we consider international collective effort, including political commitment at the national level, to be essential for the success of the proposed Global Action Plan in combating antimicrobial resistance. The final Global Action Plan should send a clear and strong message that addressing antimicrobial resistance and responsible use of antimicrobials is a priority for *all* countries and stakeholders, and the plan should give

guidance on how to implement mitigating actions. Political will coupled with concrete steps are the keys to meaningful impact.

Meeting recommendations:

We believe that all stakeholders, including policymakers and regulators, providers and health professionals, patients and the public, producers and distributors, and payers, from the public and private sectors and civil society alike, have a shared responsibility to tackle antimicrobial resistance. Together they should develop mechanisms to work cooperatively and constructively to understand the health systems, societal, and economic drivers of inappropriate antimicrobial use, share good practices, limit harmful practices and achieve the goal of responsible use of antimicrobials in humans. These mechanisms are needed to drive locally appropriate and sustained action.

We also agreed that assuring access to appropriate and effective antimicrobial medicines is an integral part of the universal health coverage agenda, as well as maintaining effectiveness of antimicrobials.

This consultation recommends that the following issues that received support during the meeting should be strongly considered during the final formulation of the Global Action Plan on Antimicrobial Resistance:

1. All nations should develop and implement national action plans, including awareness campaigns based on a good understanding of social and cultural realities, for combating antimicrobial resistance and promoting responsible use of antimicrobials, based on a multi-sectoral One-Health approach.
2. Infection prevention and control is essential for minimizing the development of antimicrobial resistance and needs to be prioritized across health care systems.
3. All nations should commit to improving and ensuring universal access to essential vaccines, rapid diagnostic tools, and effective antimicrobials, and to the further development of these important tools.
4. All nations should implement antibiotic stewardship programs across their health care systems. In support of this, the international community should establish a framework (including standards and metrics) to support stewardship efforts, and countries with established expertise should assist other countries to set up their own stewardship programs. For those countries with limited resources and internal capacities, international assistance with financial, material and technical support should be an important consideration.
5. Evidence-based treatment and stewardship guidelines, adjusted for local resistance patterns, epidemiology and differences in health systems, need to be developed, implemented, monitored and evaluated to guide health professionals and other providers in appropriate and sustainable use of antimicrobials.

6. Regulation and assurance of the efficacy, safety and quality of antimicrobials, addressing the full supply and distribution chain, needs to be implemented in all countries.
7. International collaborations should be initiated to address the problems of substandard/spurious/falsely-labelled/falsified/counterfeit medical products as part of the efforts to ensure responsible distribution and dispensing of antimicrobials of good quality, particularly in areas with limited access to health care.
8. Local, national, and international monitoring systems on distribution and consumption of antimicrobials and current resistance patterns (including regional and sub-regional approaches to address cross-border dynamics including areas of conflict, high mobility, and refugees) should be developed and implemented. This information needs to be made publicly available to support an understanding of extent, trends and impact of antimicrobial resistance in all countries using common, validated surveillance methodology.
9. Education and continuing professional education of all health workers who dispense or promote the use of antimicrobials, should include strong elements on the threat of antimicrobial resistance, the drivers and dynamics of antimicrobial resistance, and antibiotic stewardship and other measures to avoid, minimize and mitigate the spread of antimicrobial resistance.
10. Healthcare providers and health professionals should take greater responsibility for promoting responsible use within their communities, including engaging in awareness raising and educational activities among their peers and the public to encourage behavioral change to optimize the effective use of antimicrobials.
11. Access to antimicrobials should be by prescription only or by a similar form of authorization appropriate to the local health care system (e.g., dispensing based on regionally appropriate guidelines).
12. National authorities should implement reimbursement schemes that encourage responsible and appropriate use of antimicrobials.
13. Financial incentives and marketing that stimulate inappropriate antimicrobial prescribing and dispensing practices (including use of broad-spectrum agents, inappropriate prescriptions, dosages or pack sizes, or wrong route of administration or duration of treatment) should be eliminated through legislation or other nationally appropriate measures.
14. Direct-to-consumer-marketing of antimicrobials should be prohibited or tightly regulated in all countries. Although some participants expressed the view that all such marketing should be fully prohibited, consensus was not reached on this point.

15. Antimicrobial manufacturers, importers, wholesalers, and distributors should adopt a code of conduct, limiting the marketing of antimicrobials, while promoting their appropriate use as part of antibiotic stewardship.
16. Medically-important classes of antimicrobials should be restricted to clearly defined criteria for the use of selective medical practitioners only, aimed at preserving the effectiveness of these medications while assuring accessibility and affordability to low income populations. Although some participants expressed the view that new classes of antimicrobials should be restricted to humans only, consensus was not reached on this point.
17. Countries should regulate and enforce control measures on manufacturing waste from production of antimicrobials, and other routes by which antimicrobially active substances, their constituents and byproducts are released into wastewater, soil and air, and should monitor possible impact on the environment and the biosphere.
18. The success of the Global Action Plan is dependent upon international and intersectoral collaboration, to support the development of implementation mechanisms. International bodies should explore ways to strengthen intersectoral collaborations and discuss possibilities for international agreements to combat antimicrobial resistance, including full use and application of the core capacities of the International Health Regulations (2005).

ⁱ This Outcome Document is not formally negotiated text but refers to discussions at the meeting that reflect prevailing views expressed.

ⁱⁱ Countries and organizations participating in the Oslo meeting on responsible use of antimicrobials in humans, 13-14 November can be found on the webpage of the Norwegian Institute of Public Health.

ⁱⁱⁱ The meeting on responsible use of antimicrobials in humans is hosted by Brazil, France, Indonesia, Norway, Senegal, South Africa and Thailand, organized together with the WHO.

^{iv} The One Health concept addresses issues of infectious diseases and their control at the interface between human health, animal health, food and agriculture, and the ecosystem, recognizing that infectious organisms often cross species in ways both known and unknown.