

Declaration of the G7 Health Ministers

8 - 9 October 2015 in Berlin



G7 GERMANY

2015 | Gesundheitsministertreffen

*Think Ahead. Act Together.
An morgen denken. Gemeinsam handeln.*

1. In continuation of the G7 Summit in Elmau on 7 and 8 June 2015, we, the G7 Health Ministers, discussed the health topics Antimicrobial Resistance (AMR) and Ebola during our G7-Meeting in Berlin on 8 and 9 October 2015.
2. The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being. We are therefore strongly committed to continuing our engagement in this field with a specific focus on strengthening health systems through bilateral programmes and multilateral structures.
3. The G7 Health Ministers agreed on the following actions for the implementation of the G7 Leaders' Declaration as outlined in the "Berlin Declaration on AMR" and "G7 Health Ministers' Commitment - Lessons learned from Ebola".
4. We thank Germany for hosting and successfully organising this G7 Health Ministers meeting and welcome the proposal of Japan to host the next Health Ministers Meeting in Kobe in September 2016.

Berlin Declaration on Antimicrobial Resistance – Global Union for Antibiotics Research and Development (GUARD)

Agreed by G7 Health Ministers in Berlin 2015

1. Based on the G7 Leaders' Declaration, we, the G7 Health Ministers, pool our national efforts in order to share best practices and promote the prudent use of antimicrobials among all relevant stakeholders. These best practice examples from our G7 countries are summarised in the brochure "Combating Antimicrobial Resistance - Examples of Best-Practices of the G7 Countries" aiming to support other countries in developing national antimicrobial resistance (AMR) action plans. In our discussion at the G7 meeting we agreed on to the following conclusions and the need to pursue the following actions:
2. We acknowledge that the emergence of AMR is an increasing global health threat and that the spread of AMR affects all nations. Unless effective action is taken now, this will lead straight into a time when the efficacy of antimicrobials is severely curtailed. Many initiatives by public and private actors have contributed to improving the awareness of the challenges of AMR. We recognize these efforts and call for greater coordination between these initiatives and an integrated approach of WHO, FAO, and OIE to ensure consistency in responses to this global challenge.
3. We recognize that infection with AMR pathogens leads to prolonged treatment times, higher mortality, heavy burdens on health systems, and high economic impacts.
4. We take very seriously the recent work of the Organisation for Economic Co-operation and Development (OECD) and others on the costs on AMR, indicating that AMR poses not only a significant threat to the economic sustainability of healthcare systems but also negatively affects the broader economic performance of countries. Globally, 700,000 deaths may be caused each year by resistant pathogens. An antibiotic-resistant infection – compared to an antibiotic-susceptible infection - can be responsible for approximately 10,000 US dollars (USD) to 40,000 USD in extra healthcare costs. Compared to a world with no AMR, current rates of AMR may cause a gross domestic product contraction in OECD countries equal to 0.03% in 2020, 0.07% in 2030, and 0.16% in 2050. This would result in cumulative losses of approximately 2.9 trillion USD.
5. We emphasize that combating AMR requires a three-fold approach: first, by improving infection prevention and control; second, by conserving the effectiveness of existing and future antimicrobials; and third, by engaging in research to optimise such approaches and to develop new antimicrobials, vaccines, treatment alternatives and rapid diagnostic tools.

6. We are aware that AMR is a multisectoral problem, encompassing human and animal health, agriculture and the environment. Combating AMR requires a global approach and joint international efforts. We fully support the World Health Organisation's (WHO) Global Action Plan on AMR, adopted in May 2015 by the World Health Assembly, and the World Organisation for Animal Health's (OIE) Resolution No. 26 Combating Antimicrobial Resistance and Promoting the Prudent Use of Antimicrobial Agents in Animals adopted in May 2015, and are committed to the already-adopted OIE standards on AMR and prudent use of antimicrobials. We will work in close cooperation with WHO, the Food and Agriculture Organisation (FAO), and OIE on this issue.
7. We are committed to develop or review and implement our national AMR Action Plans taking into account the requirements of the WHO Global Action Plan. The One Health approach is a crucial element of our Action Plans, and we will work at the national and international levels to ensure an integrated involvement of all relevant sectors including human and animal health, agriculture, environment and research.
8. We will support other countries with the development and implementation of their National Action Plans, building global capacity to combat AMR and coordinating activity through the WHO, FAO, and OIE and mechanisms such as the Global Health Security Agenda (GHSA) AMR Action Package, as appropriate.
9. Infection prevention is a crucial element when tackling AMR as it reduces the need for antimicrobials. We will support initiatives that strengthen infection prevention within our countries. We will make information on national approaches to infection prevention and its favourable effect on combating AMR publicly accessible and support other countries in developing and implementing national measures.
10. We are concerned that insufficient awareness among the general public of the impact of AMR hinders the prudent use of antimicrobials. We will strengthen our efforts to establish new initiatives and build on existing ones, such as the WHO World Antibiotic Awareness Week, to inform the public about AMR.
11. In order to reduce the inappropriate use of antimicrobials, health care providers must have access to timely identification of pathogens and knowledge of appropriate treatment options. We will strengthen antibiotic stewardship programs for professionals in the medical and veterinary fields within our countries.

12. We strive to preserve the use of antibiotics¹ only for the purpose of medical treatment after appropriate diagnosis. Antibiotics both in human health care systems and in veterinary medicine should be available through prescription only or the veterinary equivalent only. We call on other countries to enforce the availability of antibiotics by prescription only in order to strengthen the prudent use of antimicrobials.
13. Ensuring the production of high quality antimicrobials in human and veterinary medicine is necessary for the prudent use of antimicrobials. We will continue to make substantive efforts to enhance quality, in particular in veterinary medicine, including harmonizing quality standards where appropriate.
14. We consider that a lack of comparable data on the quantity and kind of use of antibiotics and the prevalence of AMR in the population results in an incomplete understanding of the antibiotic resistance situation. The availability of comparable international and national data is a pre-condition for targeted action within countries. We will strengthen our support to establish and extend existing national and regional surveillance systems on AMR and antimicrobial consumption and to support the WHO Global Surveillance of Antimicrobial Resistance, among other international surveillance mechanisms such as OIE and FAO.
15. The development pipeline of new antimicrobials has slowed down significantly in recent decades. The research and development of new antimicrobials, vaccines, alternative treatment options and diagnostics has to be strengthened and encouraged. We consider that current initiatives address this issue, but efforts need to continue and be greatly enhanced.
16. We support the continuous identification, assessment, and agreement of pathogens of greatest concern and most urgently needed antimicrobials globally, to inform research prioritization to address the most pressing public and animal health needs, and enhanced partnerships to hasten the development and adoption of new and urgently needed antibiotics, alternative therapies, and rapid point of care diagnostic tools.
17. We will work, in collaboration with WHO, building on existing networks, to promote a global network of researchers; experts from academia, industry, healthcare, veterinary care, regulatory agencies, food safety and agriculture; philanthropic organizations; and international organizations to provide opportunities to exchange information on ongoing research activities, access to expertise for funded projects, and retention of accumulated knowledge. We welcome the initiative by Germany to organise the first expert meeting in 2016/2017.

¹ Noting differences in the G7 country definitions of the term antibiotics and referring here to those antibiotics with an impact on human health.

18. Given the global nature of drug research, development and commercialisation and the global challenge antimicrobial resistance poses, we call for greater interaction and synergies between research initiatives. We see the need for global access to – and availability, affordability and rational use of – safe, effective and quality-assured antimicrobials. We will therefore explore the feasibility and need of setting up a global antibiotic product development partnership for new and urgently needed antibiotics, vaccine development, alternative therapies and rapid point of care diagnostics and seek collaboration with others such as WHO and Drugs for Neglected Disease Initiative (DNDi).
19. We encourage international cooperation on antimicrobial stewardship and regulatory dialogue on the approval and regulation for antibiotics. Convergence and harmonisation on technical requirements including for clinical trials and for the approvals for new antibiotics can help to bring new antibiotics faster to the market. In this perspective, we support the ongoing efforts in the wider context of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), and its veterinary equivalent VICH and emphasise to take the special needs for antibiotics into account. We will take into account the recommendations and action areas of antibiotics of the Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) as it enters the next five year implementation period.
20. We are committed to explore innovative economic incentives to enhance the research and development of new antibiotics, other therapeutic options, and diagnostics. We will investigate various instruments, such as a global antibiotic research fund and a market entry reward mechanism for truly new antibiotics targeting the most important pathogens and most needed for global public health. We recognise and commend the work of various reviews on AMR, such as the OECD, and other independent Reviews on AMR, tackling the lack of new antibiotics internationally and the initial proposals on how governments around the world could act collectively to stimulate innovation from a range of organisations, private or public, big or small.
21. We will continue close collaboration with our science ministers to advance these goals related to research and development, and invite other countries, international and philanthropic organizations to join this initiative.
22. We call for a High Level Meeting on AMR in 2016 at the United Nations General Assembly to promote increased political awareness, engagement and leadership on antimicrobial resistance among Heads of States, Ministers and global leaders.

G7 Health Ministers' Commitment

Lessons Learned from Ebola

Agreed by G7 Health Ministers in Berlin 2015

1. Aligned with the decisions at the G7 Summit in Elmau, and recalling the “Beyond Ebola” statement issued at Lübeck on 15 April 2015 by G7 Foreign Ministers, we, the G7 Health Ministers are strongly committed to continuing our engagement in the field of preventing, detecting and responding to global health threats and Ebola virus disease in particular, recognizing the importance of strengthening health systems to enable the provision of basic healthcare, including vaccination and treatment, as well as water, sanitation and hygiene. The aim is to progressively achieve universal health coverage with a view to realize healthy lives for all at all ages through bilateral programmes and multilateral structures.
2. We take note of the current situation in West Africa where the Ebola epidemic is close to being successfully contained. However, we remain concerned that the outbreak has not yet been brought to an end, and that a resurgence of the virus is still possible.
3. We reaffirm our ongoing support to the countries most affected by the Ebola virus disease epidemic in order to stop transmission completely, including our support for ongoing clinical trials and the availability of an effective vaccine, therapeutics, diagnostics, personal protective equipment, healthcare infection prevention control and expertise. We also reiterate the importance of supporting recovery, including building and reconstructing resilient and sustainable health systems to better prepare for and respond to potential future health threats.
4. We applaud the ongoing efforts of national and international responders managing the epidemic and supporting recovery efforts on-the-ground.
5. We stress that the legally binding WHO’s International Health Regulations (IHR 2005) are the primary international instrument designed to help protect countries from the international spread of disease, including public health risks and public health emergencies. To this end, we support the IHR in expressly requiring countries to collaborate with each other in developing and maintaining the core capacities for IHR implementation. Full IHR compliance is ultimately each country’s responsibility.
6. The Ebola crisis has shown that enhancing capacities and building resilient and sustainable health systems, combined with strong and functioning domestic and international governance are fundamental to ensure effective prevention, early detection and warning, as well as response for public health emergencies and to provide healthcare for all leading to the highest attainable standard of health. Specific healthcare needs of the most vulnerable people, including migrants and refugees, have to be adequately considered.

7. We are convinced that national governments, the international community, including the WHO, global health initiatives, and other United Nations (UN) agencies can achieve considerably better results if partner countries provide strong leadership, and if international efforts and support are aligned to the needs and plans of partner governments.
8. We support all efforts undertaken to strengthen the global response capacities to such outbreaks and epidemics in the future, namely within the UN system under the committed leadership of the WHO, in a One Health approach, and through other international initiatives aimed at improving the implementation of the IHR, such as the Global Health Security Agenda.
9. Full implementation of the IHR in the three most-affected countries would have mitigated the scale and impact of the Ebola outbreak. In this regard, the WHO plays a decisive role in coordinating the efforts for IHR implementation, and the World Health Assembly has taken a decision to support West African, Central African, and other at-risk countries to achieve the IHR core capacities by 2019.
10. We support the ongoing work of the IHR Review Committee and look forward to the Committee's findings on effectiveness and functioning of the International Health Regulations, as well as its recommendations for improvement, for instance, related to training, for innovative ways forward for standardized, transparent, and reliable instruments for effective monitoring and reporting under IHR. In this regard, we support a clear role for the WHO to assist countries in IHR implementation.
11. In order to prevent future outbreaks from becoming large-scale public health emergencies, the G7 Leaders have agreed to offer to assist at least 60 countries, including the countries of West Africa, over the next five years to implement the IHR, including through the Global Health Security Agenda (GHSA) and its common targets and other multilateral initiatives. By the end of 2015 we will, in collaboration with WHO, announce the countries that the G7 are collectively supporting or have consulted with or agreed plans to support to fulfill the Leaders' commitment. This work is responding to country needs and entails building on existing in-country expertise and partnerships, programmes and projects. It is an integral part of an overall health systems strengthening agenda, which includes the development of basic health care systems as well as water, sanitation and hygiene programs. The initiative will be conducted in close cooperation and coordination with the WHO. We will continue also to work closely with other relevant institutions including the World Bank, the Global Fund to fight AIDS, Tuberculosis and Malaria, and Gavi, the Vaccine Alliance.
12. The serious domestic and international consequences of the Ebola virus disease outbreak have highlighted the need for a more effective global system of disease surveillance, allowing early event detection, in part through the development of rapid diagnostic tests and the

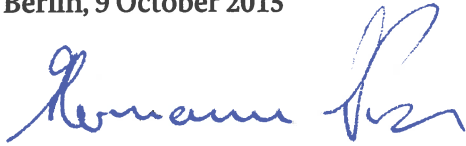
development of better risk modelling, prevention, and surveillance to trigger timely national and global responses. In the future, countries should be encouraged to immediately notify health risks to the WHO in accordance with the IHR, in addition to removing bureaucratic barriers to escalating early notifications at the local, country and global levels. We commend ongoing efforts of the African Union and its regional organizations to build up a surveillance system that will, in cooperation with WHO, be instrumental in the struggle against future disease.

13. In the research and development (R&D) response to the Ebola crisis, we identified a number of gaps and inefficiencies where actions are needed to prevent and manage future outbreaks. We stress that progress should be made as a matter of preparedness on lead candidate products (vaccines, treatments, diagnostics, and personal protective equipment) pre-established protocols, and capacity to ensure the ability to quickly move to advanced phase clinical trials, product development, and scaled-up product manufacturing, which may only be performed when the outbreak occurs. We highlight the need for a more comprehensive applied and translational research in partnership with at-risk countries. We underline the importance of direct collaboration between countries and health research funders, and we call for continued financing, collaboration and coordination on their collective response to emerging epidemics of global concern, including through initiatives such as the proposed WHO blueprint for research and development preparedness and rapid research response during future public health emergencies and the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R).
14. We are convinced that it is essential to ensure that country-owned research is enhanced, including non-medical research such as social, behavioural, medical anthropology, and communication research. We consider that a broad range of capacity-building is needed in developing countries afflicted by or at risk of serious infectious disease outbreaks. It also requires training of research workers and of health staff extending down to the local level. It is important to ensure that epidemiological and, wherever possible, relevant trial information data is shared openly and transparently and shared early in the event of a public health emergency. It is also important to ensure good coordination and prioritisation of timely access to biological materials and clinical samples for research in accordance with national and international legal frameworks.
15. We recognise global gaps in medical facility infection control and related occupational health and safety frameworks designed to protect and train healthcare workers. Healthcare workers are critical national assets at the front line of initial epidemic detection and containment. Enhanced, national occupational health and safety administrations play a key role in the development of resilient, sustainable, and ready health systems.

16. The Ebola crisis has demonstrated a critical lack of safe and effective systems for deployment of medical experts to public health emergencies of this nature, in particular around insurance, medical evacuation and safe return to work post-deployment. It has also highlighted a lack of standard procedures and protocols across deployable teams which limits their inter-operability. Therefore, we will support national and international efforts, including the WHO's global health emergency workforce, to provide a sustainable multi-disciplinary pool of experts. WHO should play a central role in coordination and facilitating the deployment of these experts. We welcome the process of developing one such initiative within the European Union (EU) (European Medical Corps), which will provide certain capacities to the global health emergency workforce.
17. We recognize the valuable recommendations of the WHO Ebola Interim Assessment Panel and the reform measures adopted by the 68th World Health Assembly in May 2015 – including the establishment of a contingency fund and the decision to establish a global health emergency workforce, making use of existing and strengthened partner mechanisms. We share the assessment that the WHO needs to be strengthened, and we support the reform process to make WHO fit for purpose to effectively fulfil its core functions in health emergencies.
18. We commit ourselves to strengthening WHO in order to better perform its leadership coordination roles on global health issues, and particularly in the face of epidemic threats, global health security, and the necessary support to countries in their efforts to be better prepared for global health crises. We share the view that the WHO must re-establish itself as the authoritative body, providing leadership, and coordinating the international preparedness for and response to health emergencies. This includes informing governments and the public around the world about the extent and severity of an outbreak as rapidly and as comprehensively as possible.
19. It is important that financial resources and mechanisms be strengthened, both within the WHO and elsewhere, to ensure timely, effective and coordinated response to disease outbreaks. Therefore, along with WHO's Contingency Fund, we support the initiative by the World Bank to develop a Pandemic Emergency Facility.
20. We, the G7 Health Ministers, have, together with the Secretary-General's High Level Panel on the Global Response to Health Crises, discussed ways forward to strengthen national and international responses to public health emergencies. We look forward to receiving the High Level Panel's report in December 2015.

Signed by G7 Health Ministers

Berlin, 9 October 2015



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