Declaration on Antibiotic Resistance

Antibiotic Resistance Coalition

Antibiotic resistance[1] threatens to undermine the effectiveness of modern medicine. More and more strains of bacteria are resistant to an ever-rising number of antibiotics, with no new antibiotics on the horizon to treat some of the most serious infections. The change is global and accelerating. Millions of people are infected with antibiotic-resistant bacteria each year; hundreds of thousands lose their lives. The toll will increase.

Antibiotic use causes resistance to emerge, and their misuse and overuse accelerates its spread. Without a radical change in antibiotic usage, antibiotic resistance will become one of the greatest threats to humankind, to security and to the global economy.

The lack of effective antibiotics against resistant infections has the potential to affect us all – doctors and patients, farmers and consumers, humans and animals – without regard for international borders.

Efforts to slow the march towards this dire future have largely failed.

The Antibiotic Resistance Coalition (ARC), comprising civil society organisations from all sectors on six continents has therefore been formed to demand policy shifts and action.

We affirm that:

- Clinically useful antibiotics are a finite resource and a global, essential public good. Consumer protection and public health must not be subordinated by governments or international institutions to the pursuit of profit.
- An ecological understanding of bacteria and their importance for human, animal and ecosystem well-being must underpin all policy and practice concerning the use of antibiotics.
- Public leadership is needed to enact new, needs-driven research and development models, with open research and transparent data, which support rational use and equitable access to antibiotics.
- National-level action is paramount, international cooperation is essential, and the collective responsibility of all stakeholders is crucial in order to bring about a solution to the escalating healthcare crisis caused by antibiotic resistance.
- Effective action on antibiotic resistance requires that the social and economic determinants of infectious diseases be addressed. In many parts of the world, these are manifested through poverty, exploitation, international power relations and local inequities, as well as through poor access to nutrition, safe drinking water and sanitation.

The Antibiotic Resistance Coalition commits itself, according to the principles and actions in this declaration, to urgently work to avert the looming post-antibiotic catastrophe.

We call on international organisations, governments and concerned citizens to support us in this endeavour.

We invite civil society and other organisations to join us in signing this declaration, with the following analysis and action points.

Original signatories: Alliance to Save Our Antibiotics • Centre for Science and Environment • Center for Science in the Public Interest • Consumers International • Duke University's Program on Global Health and Technology Access • Food Animal Concerns Trust • IFARMA Foundation • Initiative for Health & Equity in Society • Institute for Agriculture and Trade Policy • Health Action International • Health Care Without Harm • Healthy Food Action • Keep Antibiotics Working • Peoples Health Movement • Public Citizen • ReAct – Action on Antibiotic Resistance • South Centre • Sustainable Food Trust • Third World Network • Universities Allied for Essential Medicines • What Next Forum • *22 May 2014* • *For signing onto the declaration contact signon@arcdeclaration.org* •

Problem Statement

1. Lack of effective antibiotics is a global concern with the potential to affect all humans and domesticated animals. It threatens to undermine the effectiveness of modern health care. An ever-widening range of bacteria, causing a spectrum of diseases in humans and animals, is becoming resistant to most available antibiotics. Unchecked, escalating antibiotic resistance will lead to the global spread of untreatable infections and massive deterioration in health and loss of life. It will also make most surgery impossible and end organ transplantation and cancer chemotherapy.

2. Antibiotic resistance makes it difficult and sometimes impossible to treat even the most common bacterial infections. It prolongs recovery, greatly increases treatment costs and is leading to greater mortality and morbidity. It results in serious side effects, since antibiotics of last resort are often more toxic than drugs of choice.

3. While antibiotic resistance is a natural phenomenon, it has greatly accelerated with decades of unrestrained marketing by the pharmaceutical industry, which promotes overuse and misuse of antibiotics in human medicine, industrial food animal production and the food-processing sectors. For some infections resistance has already reached critical levels.

4. Inadequate regulation and control of the sale and use of antibiotics in animals and humans, including financial incentives for prescribers and dispensers, has been a major factor leading to this crisis.

5. International organisations, such as the World Health Organization (WHO), the Food and Agriculture Organization (FAO) and the World Organisation for Animal Health (OIE), have so far failed to exercise effective leadership in the stewardship and responsible use of antibiotics. National bodies that set food standards and regulate pharmaceuticals have largely failed to control human and animal antibiotic use. Data systems for monitoring antibiotic resistance and use remain very fragmented. New trade and investment regimes threaten to place commercial interests above public health and consumer protection, thereby undercutting effective control of antibiotic use and resistance.

6. The policy frameworks for research and development are further fuelling resistance without advancing innovation. They are failing to build on available scientific research in developing new antibiotics and diagnostics, and there is a severe antibiotic discovery gap. They are also failing to ensure access for all people who need treatment and are ineffective in limiting excessive and irrational use of antibiotics.

7. Inappropriate antibiotic use is also driven by public misunderstandings about the difference between bacterial and viral infections, and an ill-informed fear of bacteria in general. It is essential to promote understanding of the critical importance of bacteria for all life forms, in order to use antibiotics only when necessary to deal with the small fraction of bacteria that, at times, threaten to harm us. Prudence and restraint from excessive consumption must inform a new paradigm for how to live well and what 'good health' means.

Thematic Action: Access, Not Excess

Curbing excessive use while ensuring access for people in need

8. Antibiotic treatments and diagnostics should be considered global public goods – common resources requiring common stewardship.

9. Effective regulation and control of antibiotics must be exercised to ensure that existing and new antibiotics are made available and are affordable to those in need in all countries, while not being overused or misused. This calls for further strengthening of public health systems everywhere.

10. All countries should adopt a national policy on rational use of antibiotics, as well as taking necessary action to prevent excessive antibiotic use. Regulatory controls must address prescription and marketing practices.

11. Securing access for everyone in need is as vital as curbing overconsumption. Price should not be used as an instrument to ration use for humans. Limiting access leads to preventable suffering and death.

12. Activities to curb excessive use must include better training of health professionals through non-commercial, evidence-based programmes and sustained and targeted public education. Standard treatment guidelines should inform antibiotic administration. Antibiotic stewardship, involving optimal antibiotic drug regimens and appropriate duration of therapy and route of administration, as well as future effectiveness, should be incentivised, and unnecessary use should be disincentivised.

13. Hospitals, which are known to have a high degree of resistance, as well as other healthcare delivery centres should be encouraged to collect regular data on both hospital-acquired and community-acquired infections, to make the data publicly available and to follow infection control protocols to minimise such infections.

14. The public sector in every country needs to build a robust national system for monitoring antibiotic use and resistance trends in humans and animals, as well as contributing to the development of an effective global monitoring system. Essential inputs to a global surveillance system include data on prices, availability, affordability, sales and use of antibiotics, by drug and by indication, as well as drug resistance patterns and changes in antibiotic efficacy. These data for both human and non-human uses must be gathered and publicly disclosed in sufficient detail to enable effective action by stakeholders such as civil society, medical professionals and governments.

15. Diagnostic uncertainty must be minimised through development and availability of rapid diagnostic tools and techniques. This is instrumental for timely determination of the nature of infection and to prevent irrational use of antibiotics. Such tools should meet WHO ASSURED[2] criteria, including being affordable and adapted to meet the needs of low- and middle-income countries.

16. Promotion and advertising of antibiotics, including marketing for inappropriate uses or incentivising medical and veterinary personnel to overuse or inappropriately prescribe antibiotics, is harmful to health and should be prohibited. Regulatory authorities should be funded out of general taxation, and fees from pharmaceutical companies and the livestock industry should be paid directly to governments rather than to these authorities. This is in order to avoid any conflicts of interest.

17. Enhanced attention should be given to preventing the occurrence and spread of infections, and to addressing infections in ecologically informed ways. An over-reliance on new antibiotics as the main solution should be avoided. Public health communication should focus on restraint and balance.

18. We should avoid seeing ourselves as being at war with bacteria and learn to live more harmoniously with them, except on the rare occasions when infectious strains threaten our health. Treatment of infections must be balanced with the importance of maintaining healthy populations of bacteria for humans and animals.

19. Civil society and governments should engage in raising broad-based public awareness and efforts to support behaviour change in society, grounded in creativity, popular education, art, social movements and reformed school curricula.

Thematic Action: Non-human Use

Tackling excessive non-human use in food and agriculture

20. The preservation of effective antibiotics for human health should take priority over their use for commercial gain in food production. A disproportionately high amount of antibiotics is used in animals, particularly in the industrial production of food animals. Antibiotics should only be used for treating animals when indicated by a genuine therapeutic need and based on antibiotic therapeutic guidelines.

21. Antibiotic use for mass disease prevention must not substitute for good animal husbandry and welfare. Farm practices such as overcrowding, unhygienic conditions, inappropriate diets, and early weaning requiring routine antibiotic administration, must be prohibited. Similarly, antibiotic use for growth promotion must be banned.

22. All countries should participate in a global surveillance system that promotes and supports infrastructure and periodic survey data to assess animal antibiotic use and resistance patterns in farm animals and foods.

23. To help secure effective antibiotics for the future, the role of veterinarians should be delineated, to guide infection prevention and discourage non-therapeutic use of antibiotics.

24. Antibiotics considered critically important for humans must not be used for animals, except in specific circumstances in order to save life or prevent serious suffering.

25. Regulations should be instituted and enforced to ensure antibiotics are marked with appropriate warnings and clear distinctions between human and animal use, so as to help control and monitor antibiotic consumption.

26. Food produced without routine use of antibiotics and without antibiotic residues should be labelled through reliable, certified schemes to facilitate consumer choice. Food produced with routine use of antibiotics must be clearly labelled, until effective prohibition of such antibiotic use can be introduced.

27. Food produced without antibiotics in animal feed, or routinely used in any other way for its production, should be a prerequisite in all public procurement of food. Hospitals should take a leadership role in procuring food produced without routine use of antibiotics, as doing so is consistent with their core health mission.

28. Civil society and consumer movements should target the supply chain by exposing and boycotting corporations that produce or provide food with routine use of antibiotics.

29. Governments should initiate regulatory measures to control the environmental pollution that allows the spread of antibiotic-resistant genes across soil, water and air. Environmental movements have an important role in supporting and mobilising actions towards limiting such pollution.

Thematic Action: Innovation

Developing an effective innovation system for new antibiotics, diagnostics and other tools that supports health, access and rational use

30. Short of radical changes in our innovation system, we stand at the precipice of a post-antibiotic era. We call for public leadership promoting new, needs-driven research and development models based on the principle of de-linkage: divorcing price from research and development costs, as well as from sales volumes. Public funding is essential, and benefits of these investments should accrue to the public. Incentives should target new antibiotics with novel mechanisms of action or with significant public health value. We must couple these incentives with measures conserving antibiotics use.

31. Public leadership for innovation must also look beyond antibiotics. New avenues of treatment may provide entirely new opportunities and merit investment as well. Complementary technologies can reduce the selective pressure of antibiotic use on the microbiome. Diagnostics are an important tool to help reduce inappropriate use, aid surveillance and recruit patients to clinical trials. Vaccines can prevent the need to use antibiotics.

32. Innovation requires access to the building blocks of knowledge. We call for public leadership to establish pooled efforts and support open research. These might include enriching compound libraries with potential new drug candidates, providing specimen banks to aid developers of new diagnostics, building clinical trial networks to ease recruitment of patients, sharing pre-clinical and clinical data, and publishing findings in open access journals.

33. Screening of existing compound libraries has resulted in few promising drugs. We call for public leadership to establish a network of bio-repositories that can harness bio-diversity for natural products that might become tomorrow's antibiotics. This will require committing public funding, enlisting the informed participation of low- and middle-income countries, where much of this biodiversity exists, in the process of innovation, and ensuring returns through fair and equitable benefit-sharing arrangements with those countries.

34. Complete trial data and other information concerning the safety, efficacy and resistance profiles of antibiotics and diagnostics should be made publicly available, to advance scientific progress and rational use, with privacy protections in place.

35. We reject additional intellectual property measures. These are likely to compromise patient access and reward high sales volumes without altering the current failing incentives structure. The needs of one patient group should not be sacrificed to another, for example, via proposals for an Intellectual Property (IP) voucher that would transfer the cost of antibiotic development to other patient groups.

36. The paramount concern of regulatory review of new antibiotics must be the improved health outcomes and safety of patients facing multi-drug resistant infections. In recent years, drug regulatory agencies have amended regulations for antibiotics to approve them based on clinical trials with small sample sizes and surrogate endpoints. However, lowering standards of clinical trials only to incentivise drug companies to bring drugs to market without significant public health benefit is not acceptable.

37. A broad, holistic approach, based on an ecological understanding of bacteria, should be encouraged so as to spur innovative ways of discovering new antibiotics as well as finding solutions and approaches to infections other than through the use of antibiotics. From redesign of hospitals, to targeting inter-bacterial communication, to fecal transplants, a 'reimagination' of resistance and bacteria can open whole new avenues for solutions.

International Action and Cooperation

38. A global framework for action must be developed by governments through the United Nations system, in close collaboration with all stakeholders. Such a framework must include targets and ways of tracking their achievement that can be applied according to national circumstances.

39. National governments should formulate specific, measurable, achievable, realistic and time-bound targets for controlling antibiotic resistance.

40. International cooperation should support low- and middle-income countries financially and technically, including through capacity-building, to enable them to implement the set targets effectively.

41. International action should ensure that the terms of any global, regional and bilateral trade, investment or intellectual property rules do not undermine laws and policies that aim to implement effective controls over antibiotics.

42. International organisations, including both the United Nations system and other institutions, should scale up their actions and coordination to match the urgency of the crisis posed by antibiotic resistance.

» WHO should enhance its efforts to take a genuine leadership role by significantly expanding its in-house capacity, making a strong case for Member States to provide the necessary funds, providing enhanced training and policy guidance to developing countries for strengthened national regulatory structures, establishing closer collaboration with organisations and movements with non-profit, public health interests at the core, and effectively challenging institutions and interests working against the containment of antibiotic resistance.

» The Codex Alimentarius, the joint WHO and FAO international food standards, should develop new sets of standards for antibiotic use in food animals which take into account not only residues in food, but also antibiotic resistance.

» FAO and OIE should prioritise efforts to ensure radical reductions of antibiotic use in food production and processing, and not shy away from the far-reaching implications this may have on the industrial agriculture model of food production.

» International organisations should work together with national governments to develop a robust system of surveillance of antibiotics usage and resistance.

The Antibiotic Resistance Coalition affirms that the principles and actions in this declaration are necessary to prevent a global catastrophe. Actions must be taken now.

[1] Antimicrobial resistance (AMR) is a more general term that refers to resistance to a compound that kills or stops the growth of microorganisms, including bacteria, fungus, parasites and viruses. Antibiotic resistance (ABR) refers specifically to resistance to anti-bacterial agents.

[2] ASSURED stands for Affordable, Sensitive, Specific, User-friendly, Rapid and robust, Equipment-free and Deliverable to end-users.