FUTURE GLOBAL GOVERNANCE FOR ANTIMICROBIAL RESISTANCE

Antibiotic Resistance Coalition Response to the Interagency Coordination Group on Antimicrobial Resistance Public Consultation

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Signatories:

Alliance to Save Our Antibiotics
American Medical Student Association
Centre for Science and Environment
Ecumenical Pharmaceutical Network
Food Animal Concerns Trust
Health Action International
Health Care Without Harm
IFARMA
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ReAct – Action on Antibiotic Resistance
ReAct Africa
ReAct Asia Pacific
ReAct Europe
ReAct Latin America
ReAct North America
Society for International Development
Sustainable Food Trust
Third World Network
What Next Forum

The IACG commendably has taken up the important issue of global governance for AMR. Interested members of the Antibiotic Resistance Coalition (ARC) convened to develop this joint response to the paper. We understand that this discussion paper represents the work of a subgroup of the IACG members and that this is just a starting point for discussion.

The IACG discussion paper lays out some useful principles, but prioritizing and building upon these might have been informed by applying them to concrete, next steps. How does an engagement of "stakeholders from across the AMR system" result in a "global and true One Health approach" when the incentives faced by some stakeholders may run counter to such measures? How will the governance approach "secure binding global commitment for action, with accountability clearly assigned at every level" when the last and not least principle of "securing and more effectively organising sufficient funding and resourcing to implement and deliver AMR transition initiatives" rings empty? Hopefully, this will emerge from a bottom-up analysis of what is needed to catalyze change rather than solely a top-down exercise.

Civil society advocated for such a governance structure to provide oversight and coordination across UN and intergovernmental agencies when it called for the creation of IACG, but the resulting IACG as a hybrid of part expert commission and part representative body of key agencies (minus UNDP and UNESCO) provides useful lessons. The strengths and limitations of the IACG offer useful insights into how to shape governance. Any governance structure post-IACG must have 1) greater call on technical agency inputs; 2) ability to assess and coordinate inter-agency activities on AMR beyond just the Tripartite and including the environment; 3) a framework to provide guidance to countries on how to prioritize AMR interventions; 4) a framework for monitoring for accountability; and 5) funding and resources commensurate to this charge. The IACG paper on global governance focuses on how a Standing Secretariat, Global Steering Board and High-Level Commission might deliver a global, multi-stakeholder agreement in 10 years. There are certainly various configurations of these structures—defined in such a generic and general way—that might yield the same outcomes.

Equally important, however, would be how the governance structure enables the use of policy levers that strategically could advance an effective response to AMR. Some of these policy levers can be identified from the work of the other IACG subgroups.

Meeting the challenge of antimicrobial resistance: From communication to collective action	AMR Watch
Antimicrobial resistance: national action plans	Prioritization framework for countries to assess return on investment from different AMR interventions
Optimize use of antimicrobials	Leapfrog fund for transitioning agricultural livelihoods
Antimicrobial resistance: invest in innovation and research and boost R&D and access	Procurement facility
Surveillance and monitoring for antimicrobial use and resistance	Monitoring for accountability framework

AMR governance draws upon important norms set by various intergovernmental bodies, including the Tripartite agencies as well as UNEP and Codex Alimentarius Commission. The IACG paper, however, is unclear in how it hopes to ensure policy coherence with these other sources of normative guidance, with ongoing processes like the Global Development and Stewardship Framework for AMR and the Codex standard-setting process, and with the work of the Tripartite agencies (WHO, OIE and FAO). Are there lessons from the standard-setting and priority-setting across treaties in other areas that might inform the approach, particularly in lead up to a proposed treaty?

The IACG might also lay out steppingstones to building the support, particularly among Member States and civil society, towards a lasting governance approach for tackling AMR, perhaps on the road to a treaty. Before global consensus is reached, what are the ways in which a like-minded group of Member States based on clear principles might come together to act decisively and collectively on AMR, without undermining the confidence building that is needed to reach an equitable, multilateral outcome? Defining these approaches might shed insight as to how to build the momentum for a binding global commitment on AMR.

The road to a treaty, however, should not distract or detract from the pace of ongoing efforts to resolve the shortfalls in support of building a surveillance system, rational use, innovation of health technologies, or other measures to address AMR.

1. Defining governance: Moving beyond the institutional boxes

1.1 The rationale outlined for a global forum is a useful start, that is, to:

- Set global standards and targets in human health, agriculture, and the environment
- Conduct surveillance and monitor progress towards goals
- Build norms and public knowledge of the true scale of AMR and the economic consequences
- Finance alternatives and innovations such as new vaccines, diagnostics and therapies for both humans and animals through a pooled fund
- Collaborate with the private sector where possible
- Ensure accountability to consumers and citizens who will be vital drivers of change.

This list in the background paper, of course, captures many of the AMR policy areas worked on in recent years, but neglects key areas, from the innovation of practice, not just technologies, to building the capacity of professional societies and civil society to effect AMR change.

1.2 The "straw man" model devotes too much attention on structure of future global governance of AMR and too little attention to its functions. There are various ways in the institutional boxes in Figure 1 might be arranged, whether they lead to a global, multi-stakeholder agreement or not. More importantly, the IACG should propose a modular approach to governance delivering on key priorities for AMR governance, offering steppingstones to building a global commitment to such governance, and suggesting how like-minded Member States can move this agenda now (bearing in mind the need for clear principles and the need for reaching an equitable, multilateral outcome).

1.3 The "straw man" model is a top-heavy structure that has more appointed officials and committees than clarity of purpose. Perhaps the IACG should consider the potential functions for global governance first and the strategic levers required for effecting such change. These might include modular components such as:

- R&D coordination and financing for innovation of technology and practice, in both human and animal health sectors
- Pooled procurement facility
- Fund for transitioning small-scale food producers and those with agricultural livelihoods at the subsistence level away from production practices reliant on antimicrobial use
- Campaign fund to support communication efforts for collective action, including civil society and professional society mobilization

1.4 ARC supports the broadening of governance beyond the Tripartite agencies to include the UN Environment Programme, but also expects greater engagement by UNICEF, UNDP and other UN and intergovernmental agencies in tackling the challenge of AMR. It should not remain the province of just the technical agencies steeped in One Health issues.

1.5 Reframing the narrative or "pitch" for AMR as a development issue is important, not only for integrating this work within the Sustainable Development Goals, but also to recognize the potential of AMR-sensitive interventions in advancing AMR-specific goals. For example, WASH (water, sanitation and hygiene) and vaccine campaign interventions could lower the overall burden of bacterial infections, thereby averting the need for antibiotic treatment and the selective pressure on these life-saving drugs.

1.6 The consensus building and stakeholder engagement opportunities could better enlist civil society. Yet whether it was establishing the Global Fund for AIDS, Tuberculosis and Malaria or ratifying the Framework Convention on Tobacco Control, it was not industry, but civil society that was the key catalyst in bringing about these changes. Civil society dramatically lowered the price of HIV/AIDS medicines by negotiating generic triple therapy for $350/year. And for the Framework Convention on Tobacco Control, civil society carried forward much of the country-level advocacy in support of the WHO's first use of its public health treaty making authority, in opposition to the tobacco industry and its allies.

While the Leeds Castle meeting of stakeholders organized in April 2018 included a range of experts, including some from academia, civil society representation remained very limited as was the paucity of voices from low- and middle-income countries. Given importance of these groups in driving and effecting lasting change, both should be enlisted more prominently in shaping the model for future AMR global governance.

2. The IACG paper identifies as barriers to a global approach to AMR as "gaps in data, a lack of scientific agreement, private interests with little short-term incentive to alter behaviour or to accept higher regulatory standards; variations in national capacity/capability to participation in a global compact, and other powerful pressures to maintain the status quo." However, it is unclear how the proposed governance structure would address these barriers.

2.1 The discussion of "Antimicrobial use and human healthcare" in the background paper (pages 21-22) focuses on overuse, but fails to acknowledge the challenge of underuse in resource-limited settings. Such an oversight suggests a potential blindspot in governance-

the need to ensure access, not just avert excess in the use of antibiotics. Ensuring access involves secured financing, pooled procurement, and measures that capture access to first and second-line antibiotics, not just stewardship of these drugs.

2.2 The need for striking the right balance between access and stewardship is underscored by the recent update of the WHO's Essential Medicines List that categorizes antibiotics into Access, Watch and Reserve categories (AWaRe). An important instrument of global governance supporting country-level implementation of the AWaRe strategy might be pooled procurement. The experience of the Global Drug Facility in providing access to second-line TB drugs at lower, negotiated prices in exchange for country program assurances of rational use and scale-up might inform this approach.

2.3 The IACG background paper alludes to "other powerful pressures to maintain the status quo" and "private interests with little short-term incentive to alter behaviour or to accept higher regulatory standards." Yet the proposed governance structure does not put in place safeguards to prevent regulatory capture. Regulatory capture refers to the failure of government to act in the public's interest, and instead commercial interests of those the agency is regulating are advanced. Rather representatives of industry are included on the Global Steering Board.

The paper describes a "corporate voluntary code of conduct on AMR" as one of three models that struck the authors "as offering potential." Astonishingly, the description of the "willingness already demonstrated by some parts of industry" ignores how this "willingness" came about as a result of more than a decade of concerted civil society action. This is recounted in the IACG paper on "Meeting the Challenge of Antimicrobial Resistance: From Communication to Collective Action" which describes how civil society organizations across the consumer, environmental and public health fields used a scorecard ranking the top 25 restaurant chains in the United States based on their antibiotic policies. Responding to the Chain Reaction Report, fourteen of these companies have taken steps to improve the sourcing of food animal products without the routine use of antibiotics, up from five companies two years earlier.

Where in this scenario of "industry codes of conduct on AMR" is the support and enabling policy environment needed for civil society to bring about this concerted public pressure? The paper might also have discussed where needed change in AMR might not come from signaling companies by adversely affecting their public reputation or bottom-line through paying markets. Civil society focused its efforts on public-facing brands in the value chain. Why does the analysis fail to recognize not only the incompleteness of these successes, but

the time it has taken to achieve them and the even longer periods yet to implement these voluntary commitments? The authors of the background paper could have also discussed how voluntary corporate commitments may forestall more effective, government mandated monitoring for accountability.

3. **The IACG discussion document as well as the companion background paper calls for a multistakeholder process that sidelines the role that Member States as governments that represent their peoples must play. Key principles for any governance process should include transparency, safeguards against conflict of interest, and fairness of representation.**

The IACG discussion paper on global AMR governance might also be rooted in commitments to key principles of good governance. These include, as repeatedly noted in previous civil society and ARC position statements, a commitment to transparency and an openness of the policy process, safeguards against conflict of interest, and fair representation, particularly of LMIC concerns.

The ARC input to the IACG from May 2018 highlights the importance of "broad participation among countries, particularly low- and middle-income countries" and "avoidance of any conflicts of interest especially among those who might shepherd a global governance process." The ARC input also made the point that effective monitoring and evaluation of progress "requires governments to ensure collection and public transparency of relevant data as well as the complementary efforts of civil society to hold key stakeholders accountable." Similarly, in its briefing to the 2017 WHO Executive Board, ReAct states that the IACG "embrace the principles of transparency, openness and accountability in its operations and enlist the cooperation of other partners, especially civil society."

3.1 By rooting governance in a rights-based approach and placing Member States at the center of the process, the public's interest is better centered in the process, conflicts of interest can be minimized, and governments, held accountable. Too often, calls for "multi-stakeholder processes" fail to keep governance free of undue influence from stakeholders that have financial conflict of interest. A multi-stakeholder process accepts that corporations will be at the table, making financial conflict of interest unavoidable.

In fact, the IACG background paper on governance puts forward the idea that the World Economic Forum, which "now has formal status as an International Organization" (page 19), could host such a multi-stakeholder protocol. The background paper authors' own

engagement with the World Economic Forum (Devi Sridhar on the World Economic Forum Council on the Health Industry and Ngaire Woods as the co-Chair of the World Economic Forum's Global Future Council on Values, Technology and Governance) should have positioned them well to make clearer critique of the shortcomings of such an idea.

3.2 Transparency and openness of the policy process are key to ensuring monitoring for accountability to the public's interest. The need for this transparency begins with collecting and making publicly available the data on antibiotic use, drug resistance patterns, price, and measures of access and stewardship. The principle also extends to the policy process. Both the inputs as well as the outputs of the intergovernmental process of shaping AMR governance decisions requires a commitment to transparency, while understandably preventing those with financial conflict of interest from unduly influencing the outcomes of such deliberations. Though more could be done to engage stakeholders effectively, the IACG's recent efforts to post its meeting minutes and submissions to its public consultation process are examples of what should be considered part and parcel of good governance practices of transparency.

3.3 Safeguards against conflict of interest are important. Specifically, civil society has concerns over the financial conflict of interest posed by monied interests influencing public policy processes. Disclosure of such financial conflicts of interests can serve as a useful starting point, but does not in and of itself rid the governance process from undue influence from such interests.

Safeguards against conflict of interest must extend to how the policy dialogue is constructed. For example, the proposed "High-Level AMR commission would be led by political, industry, and civil society leaders…" and the diagram of global governance of antimicrobial resistance has industry—alongside civil society, regulators, professionals, and academia--bridging between the Standing secretariat and Global steering board. There is an important difference between recruiting input from industry and having industry involved in the public policy decision making process. The former risks regulatory capture and corruption of the policy process; the latter supports informed decision making. Given the background paper's specific acknowledgement of both "private interests with little short-term incentive to alter behaviour or to accept higher regulatory standards…and other powerful pressures to maintain the status quo," it would be logically incoherent to place these very actors with financial conflict of interest right in the middle of the governance structure.

3.4 Fairness of representation in the policy process refers both to how governance bodies are comprised and also how inputs to the governance policy process is enabled. The representation of low- and middle-income countries in the deliberative, policy process is key to addressing this concern.

Fairness also involves protection against donor-dominated processes. If there is going to be Member State buy-in, particularly by those least well-resourced and sometimes in greater need of effecting changes in AMR policy, the process must allow for both perceived and actual fairness in the governance policy process. The IACG governance paper is somewhat silent on how these concerns of fairness in representation might be handled.

And the examples provided from the Global Fund to Fight AIDS, Tuberculosis and Malaria, GAVI and the Joint UN Program on HIV/AIDS suggest lessons, but less so admonishments. The take-away lessons from these case studies fall short of flagging problems that have emerged in these governance structures. For example, GAVI has faced criticism for placing vaccine companies on its board,[1] and this has led to repeated questioning of whether this initiative has effectively negotiated the best prices for affordable vaccines for the countries it serves.

A stronger comparative analysis might have lifted up useful lessons. For example, how has the Country Coordinating mechanism that requires national committees in recipient countries to include representatives from "government, the private sector, technical partners, civil society and communities living with the diseases"[2] better grounded the work of the Global Fund in local realities or not?

4. Ensuring policy coherence across UN and intergovernmental agencies requires aligning the normative guidance and efforts of these groups, yet the workings of the multi-stakeholder process remain poorly defined in this IACG discussion paper.

4.1 The fragmentation of the governance process for AMR across multiple, intergovernmental agencies (Tripartite or Quadripartite) contributes to policy incoherence. Each of these intergovernmental agencies responds to different Ministries within governments. There is a need for a redesigned governance approach that is Member State driven and that can address policy incoherence at its roots. Lessons from the successes and challenges of

[1] Jack A. Conflict of interest fears over vaccine group. *Financial Times,* May 26, 2011. Available at: https://www.ft.com/content/484e8ada-87c2-11e0-a6de-00144feabdc0
[2] The Global Fund to Fight AIDS, Tuberculosis and Malaria, "Country Coordinating Mechanism," available at: https://www.theglobalfund.org/en/country-coordinating-mechanism/

previous efforts, such as the Committee on World Food Security, might inform the IACG's formulation of a governance structure for AMR policy making. Established in 1974, the Committee on World Food Security (CFS) has served as an intergovernmental body and a forum within the UN system on such issues. Its structure includes the CFS Bureau comprised of a Chairperson and twelve Member State countries and an Advisory group, a Plenary, High Level Panel of Experts on Food Security and Nutrition, and a Secretariat housed in the FAO with support from the World Food Programme and the International Fund for Agricultural Development.

4.2 A needs-driven, coordinated response to AMR is required. The process for aligning and reconciling normative guidance across UN and intergovernmental agencies within the global AMR governance structure should be spelled out more clearly. The potential for such discordance in global AMR governance is greater because AMR, as a multisectoral issue, cuts across multiple agencies with overlapping jurisdictions. For example, the World Health Assembly likely draws government representatives from health ministries, whereas the FAO and OIE General Assemblies likely recruit government representatives from other Ministries.

Antibiotic resistance is caused and driven by a wide range of factors, including overuse and misuse of antibiotics in humans and animals--lack of access to infection prevention measures like vaccines and basic health care, poor quality water, sanitation and hygiene, to name a few. The tripartite consisting of the WHO, OIE and FAO is able to cover a wide range of human and animal health issues, but the responsibility to tackle antibiotic resistance stretches far beyond those three UN agencies. A global governance system will need to enable a broader remit of action and be able to influence a wider set of relevant policy agendas including (but not exclusively) those on sustainable development and poverty reduction.

4.3 The effective engagement of non-State actors might benefit from examining and possibly emulating in some respects the work of the Stop TB partnership . Operating within the guidance laid down by FENSA (WHO's Framework of Engagement with Non-State Actors), the Stop TB partnership has supported civil society organizations through the Challenge Facility for Civil Society. Of note, the Stop TB Partnership moved its Secretariat in 2014 from a hosting arrangement by WHO to the UN Office for Project Services (UNOPS). WHO sits on the Partnership's Coordinating Board and Executive Committee. But the arrangement has served to allow the Partnership to "focus its attention and activities on coordinating the global effort against TB and strengthen its advocacy work" while making it "clear to all how WHO and the Partnership will work both in their respective areas and in

collaboration to accelerate the fight against TB. It will allow both institutions to maximise their respective mandates and comparative advantages."[3] The Partnership includes more than 1000 partner organizations from international and technical organizations, government programmes, research and funding agencies, foundations, NGOs, civil society and community groups, and the private sector.

4.4 A staged approach to ensuring countries have the resources and the technical capacity of implementing global norms requires attention in this global governance arrangement. Member States come to the challenge of AMR with varying levels of resource commitments and differing levels of antimicrobial use in their healthcare delivery and food production sectors. How could targets and milestones be linked to the availability of such support?

4.5 A key test as to whether policy coherence can be achieved involves how AMR governance bases policy on scientific evidence. Lessons from the accomplishments and the challenges that have faced the Intergovernmental Panel on Climate Change would be instructive. Ensuring the trustworthiness of the knowledge that backs the policy process is critical. Independent assessment of available evidence and the capacity to invest in gap-filling research are important to the process of AMR governance. The integrity of these efforts relies on the independence of its funding. This should be a public good, backed by public resources.

However, available evidence will face inherent limitations, where randomized controlled clinical trials are either not possible nor ethical to conduct. In such cases, policy decision making has to be made on basis of the best analysis of the available evidence. The precautionary principle supports such an approach by stating, "When activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established."

4.6 At the country level, inter-Ministry alignment might be supported by the approach taken through the example of National AIDS Councils, promoted by UNAIDS (page 41). The Councils often were positioned above the Ministries of Health, thereby perhaps enabling greater intersectoral collaboration and inter-Ministerial alignment.

4.7 The multiple references to private sector and to civil society are often made imprecisely. In many instances, these labels treat groups comprised of heterogeneous stakeholders with one broad brush. The IACG analysis would benefit from a more careful analysis of the

[3] Stop TB Partnership. "The Stop TB Partnership to move its Secretariat from WHO to UNOPS," July 16, 2014. Available at: http://www.stoptb.org/news/stories/2014/ns14_049.asp

differences among these stakeholders, both in the private sector and civil society. Inviting one civil society representative is not tantamount to representing all of civil society. Focusing on the interests of the research-intensive, multinational drug companies is also not synonymous with the perspective of the pharmaceutical industry sector as a whole. And it almost certainly does not capture the concerns of stakeholders in the healthcare delivery system, insurers, agribusiness, or farmers. In proposing public-private partnerships or enhanced role for the private sector, the IACG also should consider how "to fully engage with the private sector" would be handled. Notably, concerns over financial conflict of interest and risk management need to be in place.

5. Effective governance will not happen unless a strong system to monitor for accountability is in place.

5.1 The IACG discussion paper is silent on the need for transparency of key data, the collection and release of which may require a governance structure to mandate. The flow of food products and the use of antibiotics in its production remain hidden by industry, by governments, and by the intergovernmental agencies involved in the data collection.

5.2 There is also a critical need for AMR Watch activities. This is a shared responsibility, particularly by those stakeholders without financial conflict of interest. Governments and intergovernmental agencies have a key role building upon the Tripartite Monitoring and Evaluation Framework, the country self-assessment surveys, and Tripartite agency data collection efforts. But the transparency, the interpretation and analysis, and even the strategic collection of these data sometimes fall short. This is where the efforts, particularly of civil society, can significantly complement global watch efforts.

5.3 Self-regulation should not be regarded as a substitute for the effective exercise of state authority at both the national and international levels.[4] While the report by Sridhar and Woods points out "private interests with little short-term incentive to alter behaviour or to accept higher regulatory standards," it is puzzling that the report places such prominence on the role for self-regulation. Industry self-regulation is not anchored in democratic accountability. At most, it is an imperfect addition to regulation.

The AMR Industry Alliance brings together over 100 companies in the life-sciences industry and makes reference to the shared goals and commitments made in the Declaration on Combatting Antimicrobial Resistance signed in January 2016 at the World Economic Forum.

[4] Vogel D. The Private Regulation of Global Corporate Conduct: Achievements and Limitations *Business & Society* March 2010; 49(1): 68-87. Available at: https://iow.eui.eu/wp-content/uploads/sites/28/2017/04/Beckers-03-Vogel.pdf

Running counter to commitments made on R&D in this Declaration, Sanofi and Novartis recently closed down their research on antibiotics. And only 36 out of 101 Alliance member companies participated in the survey for the Alliance's first progress report.[5]

5.4 Monitoring for accountability on AMR should be integrated with the indicators for the Sustainable Development Goals. AMR-specific indicators, both in healthcare and in food production systems, would be important to place the issue of antimicrobial resistance squarely in the framework of accountability of the Sustainable Development Goals. As UN Country Teams work towards producing a United Nations Development Assistance Framework (UNDAF) to meet the goals of the 2030 Agenda for Sustainable Development, the IACG should consider how the goals of AMR governance might be furthered within UNDAF.

[5] SustainAbility. *Tracking Progress to Address AMR.* Geneva, Switzerland: AMR Industry Alliance, January 2018. Available at: https://www.amrindustryalliance.org/wp-content/uploads/2018/01/AMR_Industry_Alliance_Progress_Report_January2018.pdf