

**Briefing note: Antibiotic Resistance Coalition positions
November 2018**

Future AMR Governance

Principle	Recommendations	Examples / Explanations
Safeguards against conflict of interest are needed	<p>Safeguards against conflict of interest must extend to how the policy dialogue is constructed. It would be logically incoherent to place actors with financial conflict of interest right in the middle of the governance structure.</p> <p>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.</p>	<p>Multi-stakeholder agreement where Member States are decision-makers.</p>
	<p>Safeguards are needed to prevent regulatory capture. There should be support and an enabling policy environment for civil society to bring about concerted public pressure and mobilize consumer demand to leverage procurement practices to effect changes in the supply chain.</p>	<p>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.</p>
<p>Transparency and openness of the policy process are key to ensuring monitoring for accountability to the public's interest</p>	<p>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.</p> <p>Both the inputs as well as the outputs of the intergovernmental process of shaping AMR governance decisions requires a</p>	<p>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.</p>

	<p>commitment to transparency, while understandably preventing those with financial conflict of interest from unduly influencing the outcomes of such deliberations.</p>	
<p>Fairness of representation, particularly of LMIC concerns</p>	<p>Representation of low- and middle-income countries in the deliberative, policy process is key.</p> <p>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.</p>	<p>The representation of LMIC institutions on boards of international organizations, the country coordinating process used by the Global Fund to Fight AIDS, Tuberculosis and Malaria, and consultations held in LMICs are ways in which the public interest voice from these countries can be more effectively captured.</p>
<p>A strong system for monitoring and accountability is needed for effective governance</p>	<p>There should be mandates by governments to collect and share data on antibiotic use in both human and animal sectors. Data collection and sharing are the foundation for ensuring effective monitoring of progress toward meeting targets, and therefore accountability.</p> <p>While the Tripartite efforts to put together a Monitoring & Evaluation Framework are a useful start, the IACG should make a recommendation that ensures an effective framework across Member States for reporting such information. Civil society can also use data, which must be made transparent, to benchmark stakeholder performance against targets and create comparison scorecards.</p> <p>Monitoring and transparency for</p>	<p>The Yellow Card Initiative led by the Danish Veterinary and Food Administration (DVFA) incentivizes pig farmers to adhere to antibiotic consumption reduction targets by setting thresholds against which to benchmark and profile pig farmers.</p> <p>Indicators could be designed with measurement approaches tiered to the stage of development or level of resources in different country settings. By tiering, indicators might be tracked differently depending on the country's existing resources or data collection capabilities. A tiered approach might enable broader participation among less well-resourced countries and provide steppingstones to deeper engagement as local infrastructure</p>

	<p>accountability will be necessary to ensure that R&D, access and stewardship principles are operationalized. External stakeholders such as governments, civil society and the public should have access to open data to be able to conduct the evaluation of progress of government and company benchmarking.</p>	<p>and capacity grow.</p>
<p>Mobilized resources must be commensurate to the targets set in the monitoring by governments and intergovernmental agencies.</p>	<p>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.</p>	<p>A staged approach to ensuring countries have the resources and the technical capacity of implementing global norms requires attention in this global governance arrangement.</p>
<p>A needs-driven, coordinated response to AMR is required</p>	<p>It is important that there be policy coherence between the IACG process and the current work led by WHO, FAO and OIE along with UN Environment.</p> <p>There is a need for a redesigned governance approach that is Member State driven and that can address policy incoherence at its roots.</p>	<p>Lessons from successes and challenges from previous efforts, such as the Committee on World Food Security, might inform the IACG's formulation of a governance structure for AMR policy making.</p>

Optimize use of antibiotics

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<p>Mainstreaming AMR into other development programs and the SDGs is essential</p>	<p>Tackling AMR is a priority that can and should be addressed in SDG2, but also in SDG12, thereby considering reduction of food waste and changes in the food production model.</p>	<p>AMR-specific indicators, both in healthcare and food production systems, should be integrated with the Sustainable Development Goals.</p>
	<p>The contribution of development programs, from vaccination strategies to WASH interventions, to tackling AMR should be aligned to supporting these shared aims and measured.</p>	<p>A model has projected that nearly half of the antibiotic treatment days of children under age 5 would be averted if universal pneumococcal vaccination were achieved in LMICs that fall short of 80% vaccination levels.</p>
	<p>The connection and complementarity between AMR-sensitive interventions and AMR-specific interventions are key to explore.</p>	<p>Conditions of clean water, sanitation and hygiene influence the burden of disease faced by the healthcare delivery system. WASH activities can focus on the potable water supply for communities or the need for sourcing water in health facilities. The IACG might consider how WASH efforts might amplify the response to AMR and what country-level guidance in targeting such initiatives might be offered.</p>
<p>Create an enabling environment for policy and behavior change</p>	<p>The best practices for cultivating, harvesting and disseminating guidelines and behavior change interventions ought to be a focus for IACG review.</p> <p>Supporting collaboratives for mobilizing key constituencies, such as professional societies.</p>	<p>The Institute for Healthcare Improvement’s Breakthrough Collaborative brought together like-minded institutions to review evidence and share best practices. As in the 100,000 Lives and 5 Million Lives Campaigns, these efforts can also lead to campaigns whereby a community of such institutions sets targets for improvement.</p>

Antimicrobial stewardship must also include the food production system	A “Leapfrog Fund” should be established to help small-scale farmers make the necessary transition to achieve a more sustainable food production approach, to become less reliant on antibiotics, and to abide by efforts to ban medically important antibiotics in farming.	Small-scale producers and resource-limited facilities should be supported technically and financially in making the transition to more sustainable antibiotic use practices.
	Routine mass administration of antibiotics to food-producing animals for growth promotion and disease prevention should be banned.	The WHO guidelines on the use of medically important antibiotics in food-producing animals call for a ban on the use of these antibiotics for growth promotion and disease prevention. The European Parliament approved new legislation to end the overuse of antibiotics in farming by banning the preventative mass medication of groups of healthy animals.
Both the healthcare delivery and food production systems generate antibiotic pollution into the environment	Antimicrobial contamination of the environment occurs across the value chain. Targets and standards must be set for all contributors, notably not just pharmaceutical production plants, but also farms, sewage treatment plants and hospitals. The predominant source of antibiotic pollution likely comes from where antibiotics are used, not where they are manufactured.	Benchmarks to lower antibiotic pollution can be (a) set through Good Manufacturing Practice (GMP) standards, (b) incorporated into the National Action Plan, and (c) entered into criteria set by procurement and credentialing agencies. However, their implementation must not disrupt the fragile supply chain of needed antibiotics for the healthcare delivery system.
	Procurement and supply chain policies must include environmentally preferable purchasing criteria to guide manufacturers, producers, suppliers, and distributors to be accountable to responsible antimicrobial use and associated pollution.	As an example within the healthcare sector, Health Care Without Harm has shown how a virtual global network of hospitals and health systems can work to achieve measurable improvements in greening the practices of these institutions through the “Global Green and Healthy Hospitals” project.

R&D and Access

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<p>All R&D efforts should be needs-driven, evidence-based and guided by the key principles of affordability, effectiveness and efficiency, and equity</p>	<p>This will require an end-to-end approach, whereby these principles are an integral part of the target product profiles, public financing of R&D and licensing of these products, not an afterthought upon market entry.</p>	<p>The Global Framework for Development and Stewardship to Combat AMR will be a critical instrument to steer the design and coordination of an end-to-end approach to supporting R&D, including incentive mechanisms.</p> <p>The Tripartite should continue to insist that Member States sustain their support for these important principles in all current and future relevant initiatives, including in the recent TB High Level Political Declaration and in the establishment of R&D Hub by the G20.</p>
<p>Mechanisms to safeguard affordability of products are needed</p>	<p>Target product profiles set by the public sector can play an important role in better channeling R&D funding, ensuring that technology products reflect concerns of affordability and adaptation to resource-limited settings, and coordinating R&D efforts globally.</p> <p>A key component to sustainable access and financing of antimicrobials is affordable pricing, and a key player in keeping the pressure up for continued funding was civil society.</p> <p>Establishing a Challenge Facility could engage civil society and promote sustainable access and financing.</p>	<p>Product development partnerships such as the Drugs for Neglected Diseases Initiative and Medicines for Malaria Venture include target price points for products they develop.</p> <p>The Stop TB Partnership provides support to civil society groups working at the country level through its Challenge Facility for Civil Society. Funding agencies like the Global Fund dedicate seats on their governance boards to civil society representation. Foundations have also supported such concerted civil society action, but not thus far in antimicrobial resistance.</p>

<p>Innovation of both technologies and of practice in the human healthcare delivery, food production and environment sector should be prioritized.</p>	<p>Supporting collaboratives for mobilizing key constituencies, such as professional societies, that can promote and implement innovation in practice.</p>	<p>The Institute for Healthcare Improvement’s Breakthrough Collaborative brought together like-minded institutions to review evidence and share best practices. As in the 100,000 Lives and 5 Million Lives Campaigns, these efforts can also lead to campaigns whereby a community of such institutions sets targets for improvement.</p>
<p>Only the innovation of technologies for human health care has received significant attention in recent years.</p>	<p>A “Leapfrog Fund” should be established to help small-scale farmers implement innovation of practice and make the necessary transition to achieve a more sustainable food production approach.</p>	<p>Small-scale producers and resource-limited facilities should be supported technically and financially in making the transition to more sustainable antibiotic use practices.</p>
	<p>Support for product development partnerships that might bring forward new vaccine for animal health or aquaculture.</p>	<p>The product development partnership model, as reflected in DNDi’s approach with treatments for neglected diseases and through GARDP, is one that might be emulated for innovation of diagnostics and vaccines in the animal health sector.</p>
	<p>Beyond the various prizes established for bringing a new point-of-care diagnostic forward for AMR, there needs to be greater attention to enhancing the innovation of novel diagnostics suited for resource-limited settings. It is, however, not enough to develop new diagnostics. A strategy for their implementation should be considered and coupled with improvements in care or antibiotic stewardship.</p>	<p>The development of a rapid diagnostic test for bacterial pneumonia suited for use where there is minimal infrastructure could save more than 405,000 lives each year, much of it by reducing overtreatment with Antibiotics. A test for acute lower respiratory infections could save more than 400,000 lives each year. The development of and affordable access to diagnostics suitable for use in developing countries and improved laboratory capacity in LMICs is therefore a top</p>

		priority.
	Pooling the building blocks for enabling R&D into these health technologies is another key investment approach to transforming the innovation ecosystem.	The Medicines Patent Pool has importantly shown its value in pooling the licenses of end-products that might be used in combination, notably for AIDS, TB and hepatitis C. Pooling of reagents, research tools, innovation platform technologies and compound libraries also could play an important role in lowering the barrier to new entrants to R&D or to allowing other companies to take the risks of breakthrough innovation.
Mechanisms assuring access to product are essential	The functions of a pooled procurement facility for novel and existing antibiotics, including those in short supply, are critical to support at the global level. A procurement facility has the potential of shaping the upstream R&D pipeline and also the downstream delivery system for such antibiotics. Such a procurement mechanism could build on the experience of the Global Drug Facility.	The fragility of the supply chain, particularly for antibiotics with smaller markets (both new drugs for multi-drug resistant infections and old antibiotics needed once again to provide a last-line defense against such infections) requires 1) a sentinel warning system when existing suppliers might exit, 2) demand forecasting and pooling procurement so that suppliers can reliably count on year-to-year sales, and 3) a financing mechanism that can boost reimbursement when margins are too thin, support entry of generic suppliers to meet GMP requirements, and provide wider margins on international procurement tenders.