



Our time with **ANTIBIOTICS** is running out.

Antibiotics are in danger of losing their effectiveness due to misuse and overuse, and in many cases they aren't even needed.

Always seek the advice of a healthcare professional before taking antibiotics.



Global framework for development and stewardship to combat antimicrobial resistance: state of play

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Goal of consultation

- Present the possible goals, form, structure, content of a possible global AMR framework
- Stimulate discussion among stakeholder and Member States
- Receive feedback to further develop concept and content
- Discuss and define a process to chart a way forward

1st Informal Consultation of Member States and Partners



9-10 November 2017

- Convened by WHO with FAO and OIE
- Focused on the updated draft roadmap of the Framework and next steps

Member States called for the Tripartite to:

- Develop concrete elements of the framework through a stepwise approach
- Employ a One Health approach



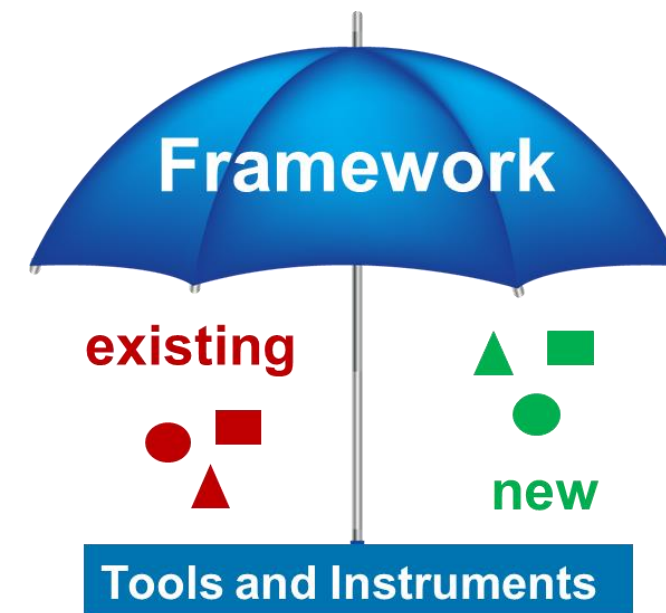
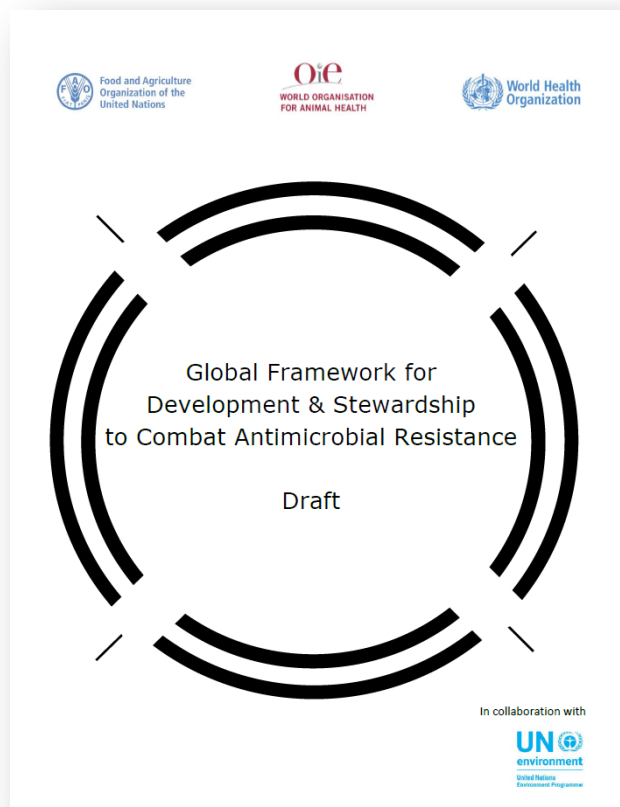
Background

In the *Political Declaration of the High Level Meeting of the General Assembly on Antimicrobial Resistance*, world leaders called on WHO together with FAO and OIE to finalize the Global framework for development and stewardship to combat antimicrobial resistance

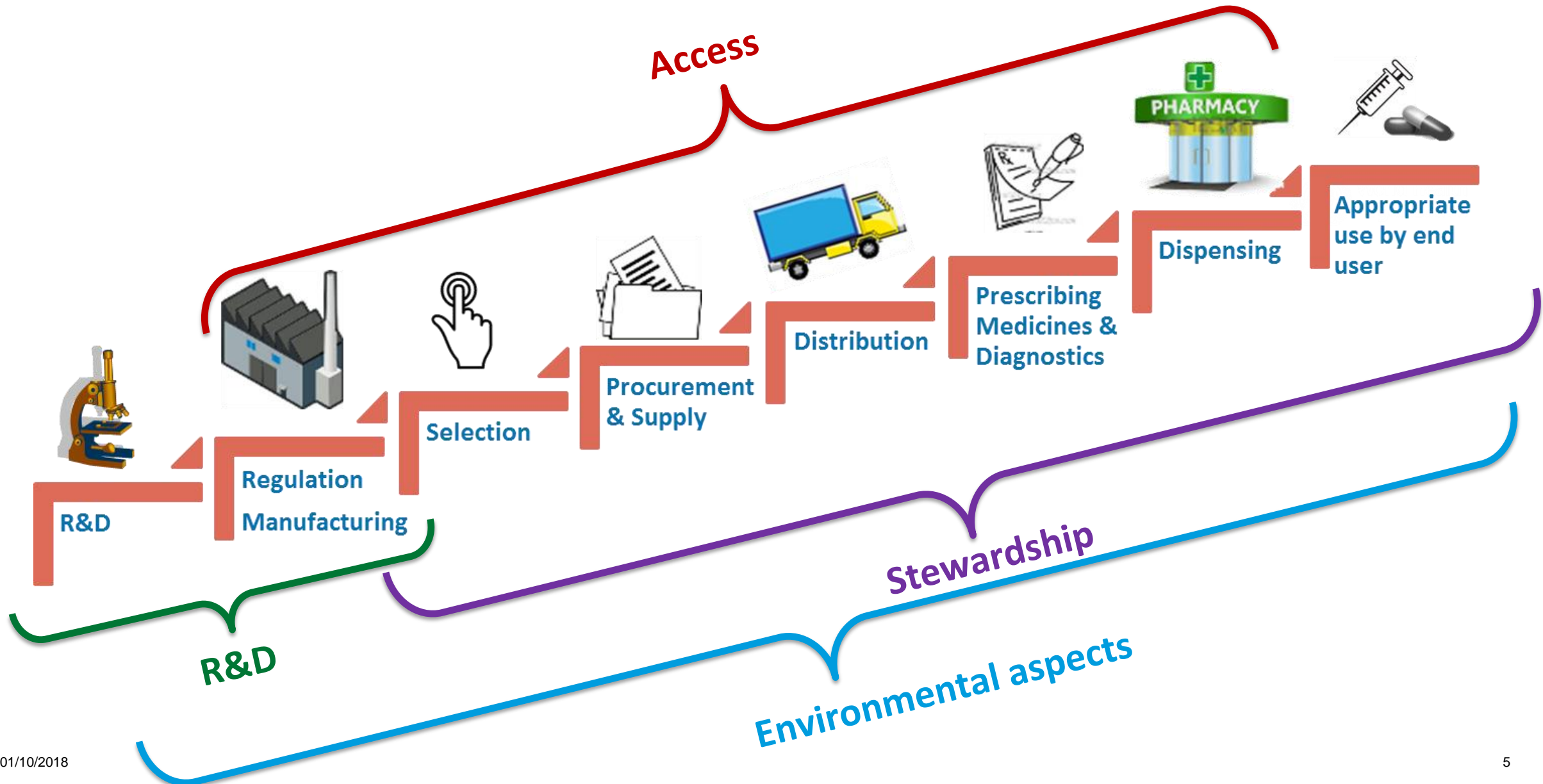
The draft framework:

An umbrella text uniting different tools and instruments that is being developed through a stepwise approach over time

Developed by WHO, FAO, OIE and in collaboration with UN Environment



Covers the whole value chain (of products)



A strong international instrument(s) that drives change at the local, regional, national and global level addressing current gaps in the governance of AMR through defining appropriate goals, standards and targets

10 goals of the Framework

1. Countries set individual long-term/realistic targets with a stepwise implementation plan and timeline to reduce the need and, consequently, the use of antimicrobials in the human, animal and plant sectors.

2. Increase access to and appropriate use of quality-assured first-line antibiotics for human health and limit the use of reserve/last-resort antibiotics by implementing antimicrobial stewardship programmes.

3. Increase access to and reduce shortages of essential and effective antibiotics by ensuring their continued availability.

4. Implement international codes and standards to promote worldwide responsible and prudent use of antimicrobials in animals (terrestrial and aquatic) and plants.

5. Phase out the use of antibiotics for animal growth promotion and plant protection in the absence of risk analysis.

10 goals of the Framework (cont.)

6. Use of fluoroquinolones, third- and fourth-generation cephalosporins, and colistin should be guided by the following considerations:

- Do not use as preventive treatment applied by feed or water.
- Do not use as first-line treatment unless justified.
- Use as second-line treatment should ideally be based on bacteriological tests.
- Extra-label or off-label use should be reserved to instances where no alternatives are available.

7. Increase investment and capacity building in clean water, sanitation and hygiene (WASH), infection prevention and control (IPC), vaccination programmes, and good animal (terrestrial and aquatic) husbandry practices and biosecurity measures where needed to limit the emergence and spread of AMR.

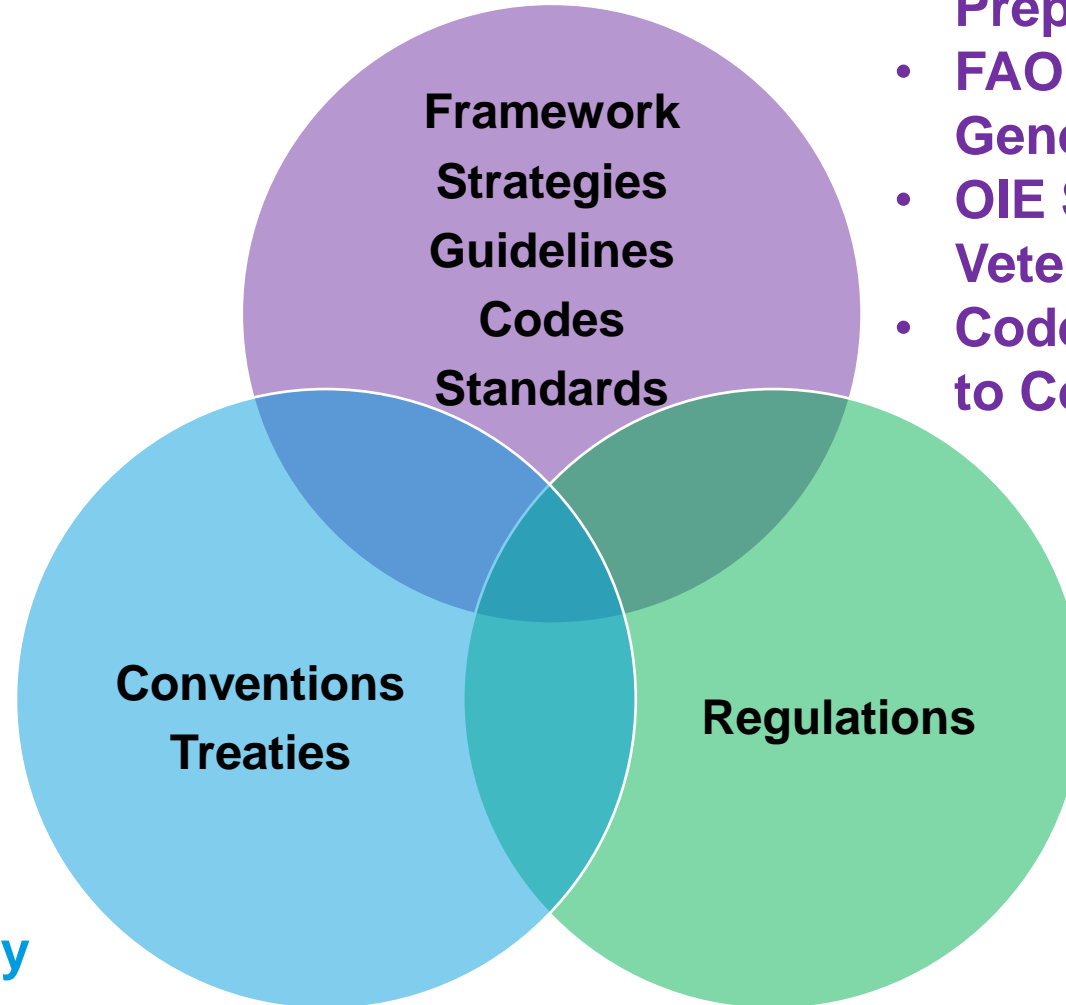
8. Increase investment in developing new antibiotics, alternatives to antibiotics, diagnostics and vaccines for use in humans, animals and plants.

9. Increase investment, research and surveillance of antimicrobials and resistant microorganisms in the environment to better understand the role of the environment in the dynamics of AMR and the relevance of the contributions from anthropogenic sources.

10. Limit the release of active pharmaceutical ingredients into the environment, especially into water, and ensure environmentally sound management of obsolete stocks.

Chapter 2: Legal form

- WHO Framework Convention on Tobacco Control
- FAO International Plant Protection Convention
- Convention on Biological Diversity



- WHO Pandemic Influenza Preparedness Framework
- FAO Global Plan of Action for Animal Genetic Resources
- OIE Standards on the Quality of Veterinary Services
- Codex Alimentarius Code of Practice to Contain and Minimize AMR

- WHO International Health Regulations (2005)

Considerations regarding legal form

- **Different options** with individual strengths and weaknesses ranging from non-binding (code of conduct) to binding (convention, WHO regulation)
- **Binding vs. non-binding not a binary question:** Recent international treaties that are binding, incorporate maximum flexibility (e.g. Paris Convention on Climate Change)
- **Governance** differs depending on instrument
- **Form and method of adoption** should reflect purpose and content of the framework
- Content needs to be further developed to allow identification of ideal form of the instrument(s)



Chapters 3-5

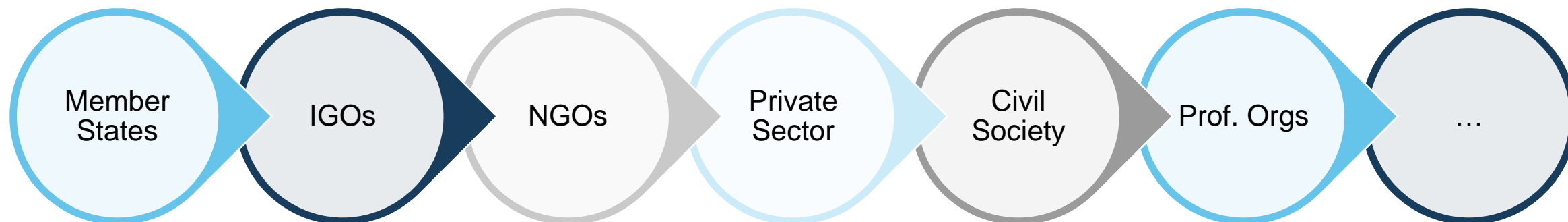
R&D, Access & Stewardship, Environment

Content of the chapters:

- Key challenges and objectives
- Basic principles
- Potential targets
- Responsibilities of the Tripartite and UN Environment

To be developed:

- Responsibilities of Member States and other stakeholders



Chapter 3. R&D to foster access

Basic principles:

- Invest in R&D for new antimicrobials, improvement and reformulation of existing antibiotics, alternatives to antimicrobials, diagnostic tools, vaccines for human, animal and plant health
- R&D should be needs-driven, evidence-based and guided by the principles of affordability, effectiveness and efficiency, equity and appropriate, and prudent use of antimicrobials that need to be considered from the outset
- The cost of investment in R&D on AMR should be de-linked from the price and volume of sales so as to facilitate equitable and affordable access
- ...

Global Targets for R&D



R&D related responsibilities of the Tripartite and UN Environment

Goal	Objectives (outputs)	Responsibilities
3.4.1 R&D coordination	Effective global coordination of R&D activities and financing	Tripartite: Provide support to global coordination of R&D activities (e.g. Global AMR R&D Hub; STAR-IDAZ International Consortium on Animal Health)

Chapter 4. Access & stewardship policies

Basic principles:

- Increase access to and reduce shortages of essential and effective antibiotics by ensuring their continued availability.
- Implement international codes and standards to promote responsible and prudent use of antimicrobials in animals (terrestrial and aquatic) and plants worldwide.
- Phase out the use of antibiotics for animal growth promotion and plant protection in the absence of risk analysis.
- ...

National targets for access and stewardship

Access and Stewardship related responsibilities of the Tripartite and UN Environment



Goal	Objectives (outputs)	Responsibilities
4.4.9 Dispensing and regulation	Strengthening of regulatory aspects for AMR	Tripartite: Develop guidance for countries to analyse and update their national legislation at all stages of the antimicrobial life cycle.

Chapter 5: Environmental aspects of AMR

Developed in close collaboration with UN Environment

Key principles

- Adopt standards, regulations and targets for improving access to and responsible and prudent use of antimicrobials and for emissions into the environment based on national context and needs;
- Apply the precautionary approach set forth in principle 15 of the Rio Declaration on Environment and Development, as well as support and facilitate the regular exchange of evidence and science-based knowledge;
- Limit the release of active pharmaceutical ingredients into the environment, including water, and ensure environmentally sound management of obsolete stocks.

Targets

Environment related responsibilities of the Tripartite and UN Environment

Goal	Objectives (outputs)	Responsibilities
5.4.12 Collection and safe disposal of antibiotics from homes and farms	Raised awareness of the correct disposal of unused and expired antibiotics in homes and farms	Tripartite and UN Environment: Develop awareness and advocacy materials for the safe disposal of unused/expired antibiotics by patients and farmers (e.g. patients and farmers to bring antibiotics to pharmacies) and on take-back schemes.

Annex 1: Selected Financing Mechanisms

Differentiates financial needs for

- the secretariat and governing bodies
- driving change towards better stewardship, appropriate use of and access to
- financing R&D and access for both animal and human health

Reviews different mechanisms

Assessed contributions, replenishment, taxes, bonds, social impact/insurance/other bonds, priority review vouchers, transferable exclusivity rights, multilateral fund

Suggests mixed model:

- Secretariat: Assessed contributions
- Access & stewardship: Multilateral fund modelled after Montreal Protocol
- R&D: Social investor bond model



Annex 2: The current R&D landscape

Initiative	Budget	Role	Products	Stages of development	Geographical scope	Appropriate use & access	Targets specific high-priority medical needs
Multi-lateral							
CARB-X	USD502m (2016-21)	Funding and expert support	Therapeutics, diagnostics, preventatives, devices	Hit-to-lead through end of Phase 1	Global	✓	WHO & CDC
GARDP	€236m (2017-23)	Developer	Therapeutics	Any stage of development	Global	✓	WHO
JPIAMR	€234m (2012-2024)	Public funder	Health products and research on resistance	Discovery research & early stage	Global	X	WHO & national priorities
European Union							
IMI: ND4BB	€700m (2014-18) €200-300m (2018-20)	Financial, in-kind and expertise	Therapeutics, diagnostics	Whole value chain	Global	✓	Priority pathogens including WHO priority list
InnovFin Infectious Diseases	€180m (2015-20) €80m (2018-20)	Loan to be paid back in case of success	Vaccines, drugs, medical & diagnostic devices	Clinical development	EU MS and H2020 associated countries	X	Priority pathogens including WHO priority list
Industry							
Repair impact fund	USD 165m (2018-23)	Convertible loans and royalty-based	Novel therapeutics, companion diagnostics	Lead optimization through end of Phase 1	Europe & U.S.	In progress to be established	WHO&CDC

The way forward

We propose to continue working on the concept and the technical content

- 1) **Develop the draft framework:** further develop the overall concept and legal form based on the feedback
- 2) **Member States involvement:** hold additional informal consultations with Member States on specific aspects of the framework
- 3) **Additional stakeholders:** hold consultations with civil society, the private sector, NGOs, academia and professional organizations
- 4) **Timeline and process:** establish a timeline for completing a draft framework and negotiation process to reach agreement as efficiently as possible



Misuse of **ANTIBIOTICS** puts us all at risk.

Taking antibiotics when you don't need them speeds up antibiotic resistance. Antibiotic resistant infections are more complex and harder to treat. They can affect anyone, of any age, in any country.

Always seek the advice of a healthcare professional before taking antibiotics.

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Link to the draft framework:

http://www.who.int/phi/news/WHO_OIE_FAO_UNEP_Working_paper_of_the_framework_FINAL.pdf?ua=1



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