
Technical consultation on safe management of pharmaceutical waste

Session 3: Linking with related efforts

WHO HQ, Geneva

1 October 2024

Panel discussion

Kate Medicott, WHO

Sanitation lead, Water, Sanitation, Hygiene and Health Unit

Lisa Hedman, WHO

Access to Medicines and Health Products

Nada Hanna, UNEP

Pharmaceutical and antimicrobial waste expert

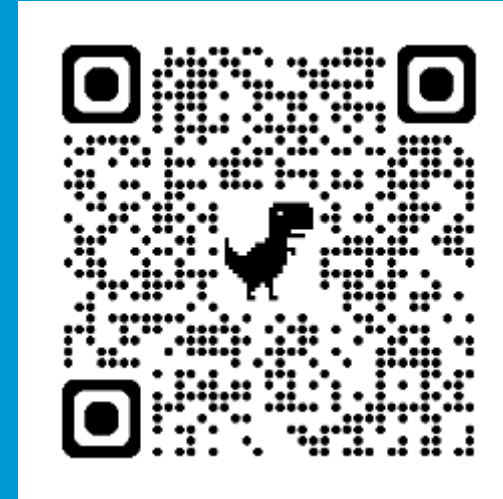
Anand Balachandran, WHO

Unit Health, AMR National Action Plans

Moderation: Maggie Montgomery, WHO

What are key developments, documents and frameworks in your area of work that support safer management of pharmaceutical waste? How can complimentary efforts be better linked and supported, especially at the country level?

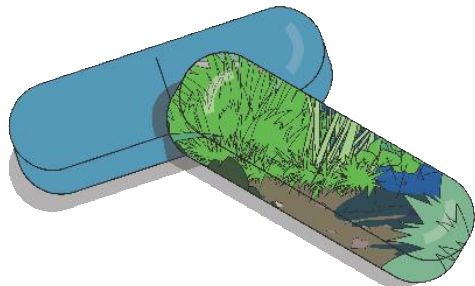
Guidance on wastewater and solid waste management for manufacturing of antibiotics



Landscape of AMR and environment



[Global action plan on AMR](#)



[Technical brief on WASH wastewater and AMR](#)



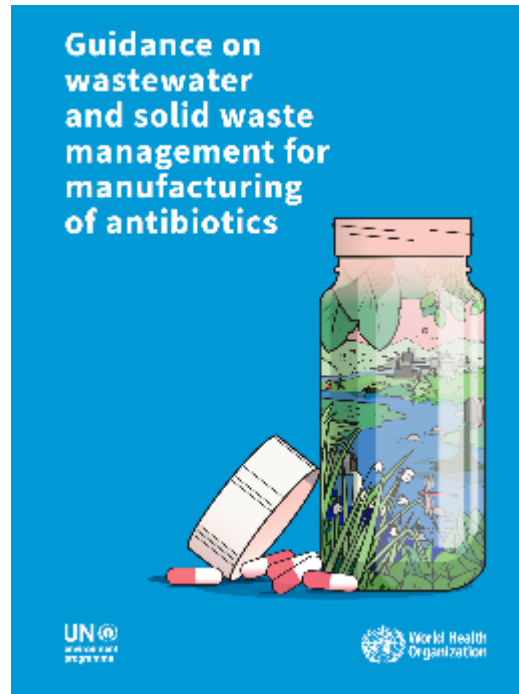
Global Framework on Chemicals



[OpenWHO: AMR in the environment](#)



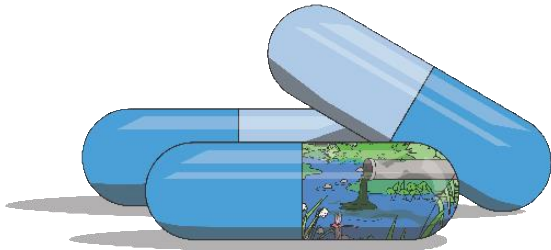
Rationale and purpose



- Currently, antibiotic pollution from manufacturing is **high and largely unregulated** – there is a need to preserve effectiveness of antibiotics
- Called for by myriad international bodies to reduce AMR
- **The purpose of this guidance is to provide an independent scientific basis for inclusion of targets in binding mechanisms of the guidance target audiences.**
- Key principle: **Progressive implementation and improvement to meet targets with a stepwise phase-in to protect the global supply and an affordable, equitable access to antibiotics** especially for vulnerable populations.

Target audiences

- **Regulatory bodies** (national or regional)
 - responsible for the regulation of pharmaceutical manufacturing
 - responsible for wastewater and solid waste where antibiotics are made
- **Procurers** - retail companies, hospitals, regional and national procuring bodies, private sector
- Entities responsible for **generic substitution schemes and reimbursement decisions**
- Third party **inspection schemes and auditors**
- **Industrial actors** in all stages of the production chain of antibiotics, including collective organizations and industry-led initiatives
- **Investors** in the pharmaceutical sector
- **Waste and wastewater management services** that process antibiotic waste



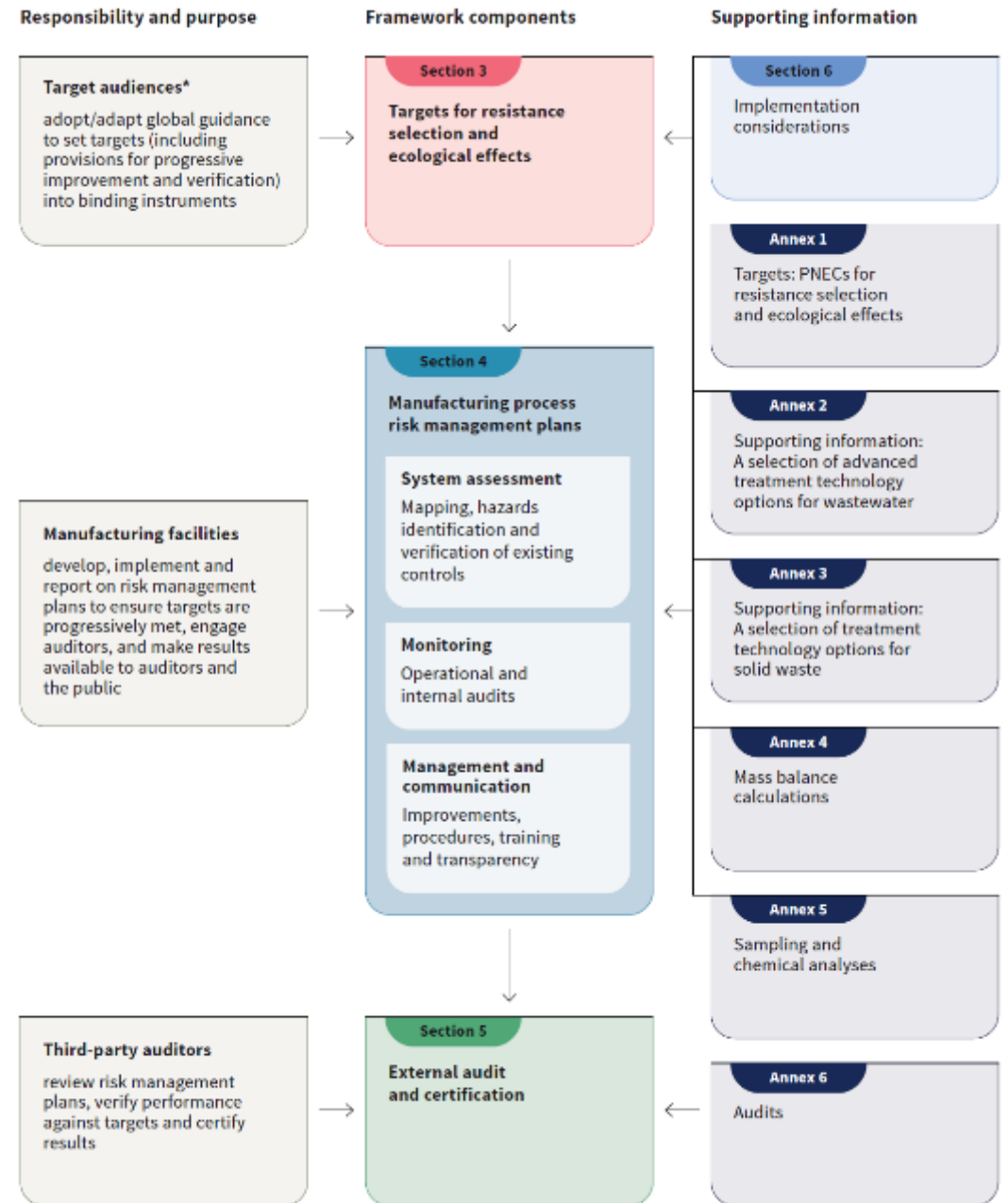
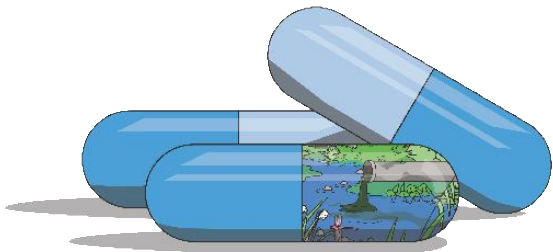
Conceptual framework

Separated roles to:

- Set target
- Implement risk management
- Verify performance

Targets for resistance selection and ecological effects

With supporting information annexed

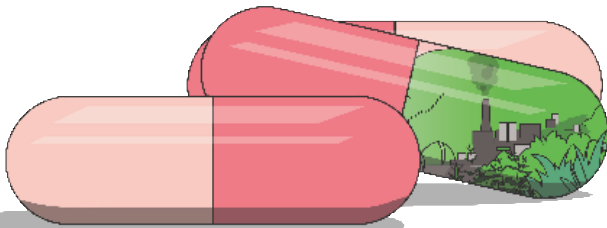


Section 3

Targets for resistance selection and ecological effects

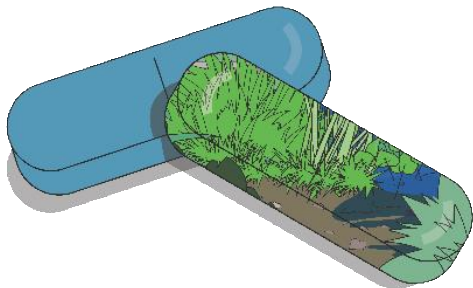
Targets

Target type	For	Targets
Effluent water quality	Antibiotics in liquid effluent	<ul style="list-style-type: none">• PNEsres and PNECeco• Assessment at two levels: Good and Stringent
	Zero liquid discharge or 'not strictly' ZLD	<ul style="list-style-type: none">• None• or same as discharge to water body
Technology	Resistant bacteria in liquid effluent	<ul style="list-style-type: none">• Tertiary or advanced treatment for fermentation• For other, avoid microbial treatment when far in excess of PNECs
	Solid waste	<ul style="list-style-type: none">• Incineration or landfill• If elsewhere, API removal of >99% for fermentation and > 80% for other



Considerations for HCWM

- Technology vs PNEC targets
- Incentives for industry vs HCF as implementors
- Capacity for implementation, progressive improvement and audit
- Co-treatment?



THANK YOU

Full guidance document, WHO news release
and FAQ available at:



Integrating safe waste management of pharmaceutical waste in AMR National Action Plans

Anand Balachandran

Unit Head, AMR National Action
Plans and Monitoring

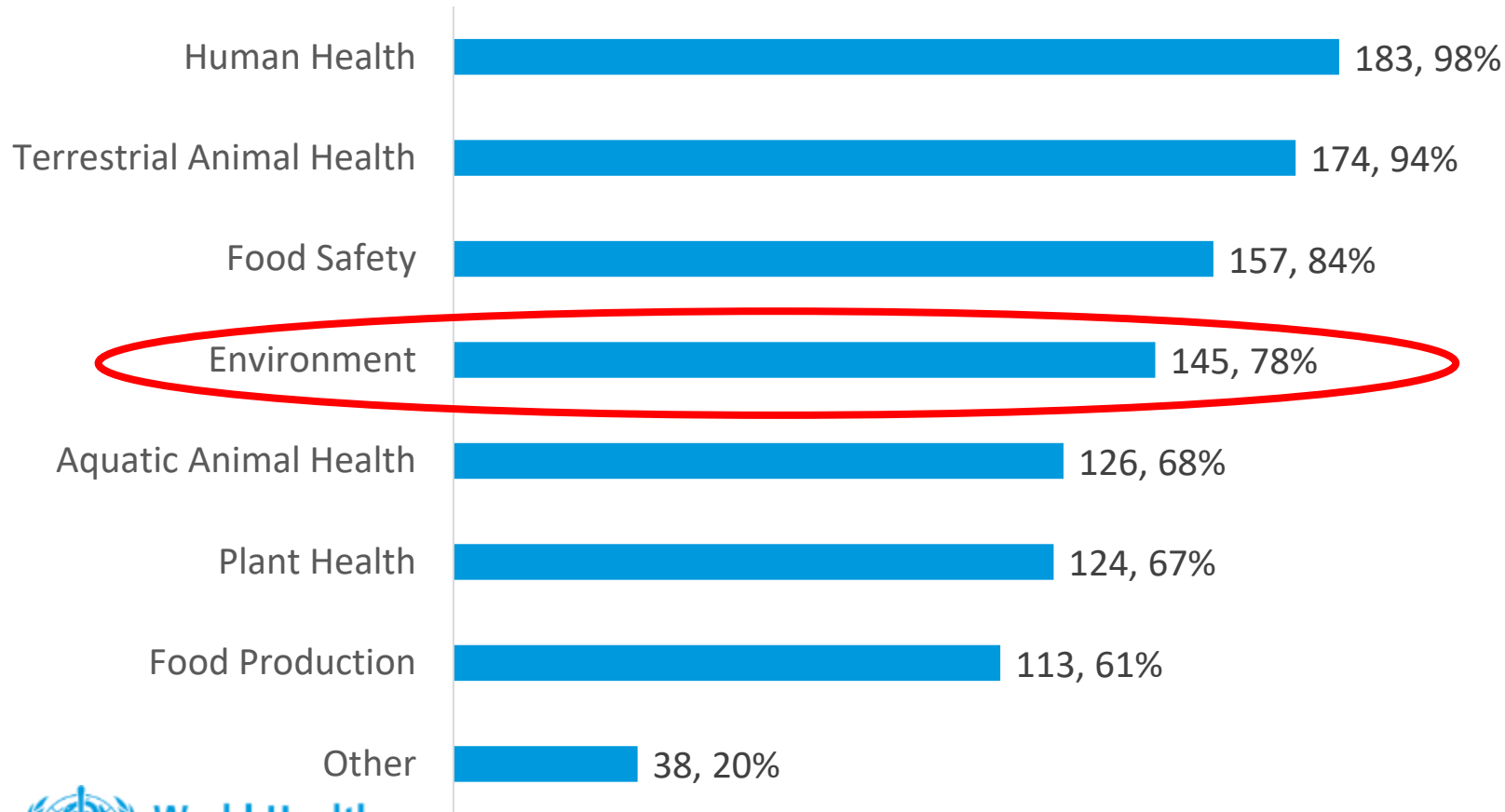
WHO - HQ





AMR Multisector Coordination – sectors involved

TrACSS 2024: Sectors involved in the AMR multisector-coordination mechanism (MCM) (N=186)

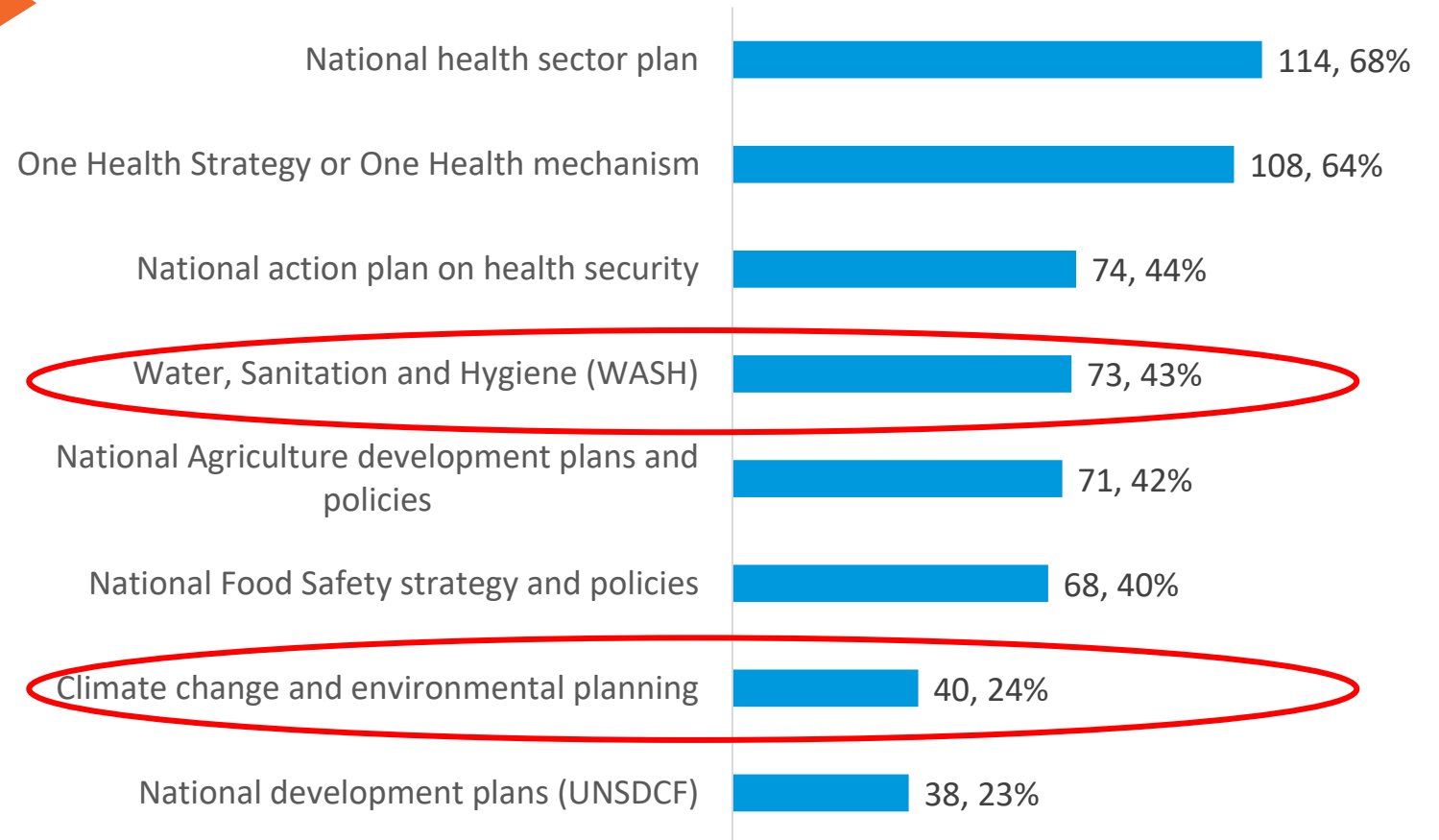
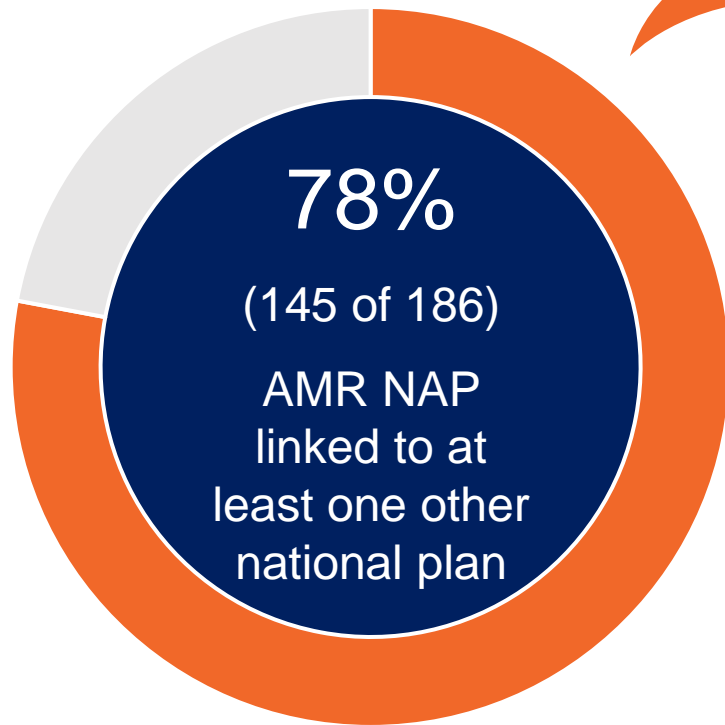


Number & percentage of countries



AMR NAP integration with other national plans

TrACSS 2024: AMR NAP is linked to other existing action plans or strategies (N=186)



Number & percentage of countries

People-centred approach and WHO core package of 13 core interventions

Reduced and slower development of AMR
Reduced mortality and morbidity due to AMR



Pillar 1: Prevention

6. Universal access to WASH and waste management to mitigate AMR
7. Implementation of IPC components to mitigate AMR
8. Access to vaccines and extended immunization to manage AMR expanded



Pillar 2: Access to essential health services

9. AMR diagnosis and management health services are affordable for all
10. Uninterrupted supply of quality-assured, essential antimicrobials and health products for AMR



Pillar 3: Timely, accurate diagnosis

11. Good-quality laboratory system and diagnostic stewardship to ensure clinical bacteriology and mycology testing



Pillar 4: Appropriate, quality-assured treatment

12. Up-to-date evidence-based treatment guidelines and programmes for antimicrobial stewardship
13. Regulation to restrict sales of non-prescription antimicrobials

Foundational step: Strategic information through surveillance and research

3. National AMR surveillance network to generate good-quality data for patient care and action on AMR
4. Surveillance of antimicrobial consumption and use to guide patient care and action on AMR
5. AMR research and innovation including behavioural and implementation science

Foundational step: Effective governance, awareness and education

1. AMR advocacy, governance and accountability in the human health sector, in collaboration with other sectors
2. AMR awareness-raising, education and behaviour change of health workers and communities





Intervention 6:

Universal access to WASH and waste management to mitigate AMR

Priority actions

National and/or subnational level

- Ensure access to WASH and safe waste management in community and health facilities by appropriate planning, budgeting and financing of WASH and safe waste management infrastructure and services.

All health-care levels

- Assess WASH in health care facilities using standardized tools, and improve, maintain and sustain improvements in WASH and safe disposal of health care waste and antimicrobials.

Community

- Ensure clean drinking-water and improve sanitation and personal hygiene (including hand hygiene) through community engagement and community approaches.
- Develop mechanisms to return unused antimicrobials from households for safe disposal.

UNGA HLM on AMR 2024 – Political Declaration

Environment

74. Underscore that environmental factors contribute to the development and spread of antimicrobial resistance and the need for priority actions to prevent and address the discharge of antimicrobials and their metabolites into the environment from a wide range of sectors and services, including sanitation and sewage, waste, wastewater, healthcare, pharmaceutical manufacturing, crop production and terrestrial and aquatic animal production,

Commitments:

78. Address research gaps and promote knowledge generation on the environmental aspects of antimicrobial resistance, including identifying appropriate methods for environmental surveillance, to inform the integration of environmental aspects in the development and implementation of national action plans on antimicrobial resistance as well as priority-setting and policy-making on antimicrobial resistance, including legislation, regulations, and guidance to catalyse preventative and mitigation action to address key pollution sources and prevent contamination of the environment with antimicrobials and their metabolites,

[Link: Letter from President of the General Assembly on AMR final text of the Declaration | General Assembly of the United Nations](#)

Technical consultation on safe management of pharmaceutical waste

Session 4: Supporting effective implementation

WHO HQ, Geneva

1 October 2024

Panel discussion

April Baller, WHO

Unit Head, IPC Emergencies/Health Care Readiness

Marta Kurcharski, WFP

Project Lead

Camilla Agostinho and Atsushi Samura, Global Fund

Specialist, Surveillance and Antimicrobial Resistance

Joos Van Den Noortgate, MSF

Logistics and WASH expert

Ruth Stringer, Health Care Without Harm

Waste expert

Moderator: Nosheen Usman, WHO

From your experience, what are some of the challenges in safely managing pharmaceutical waste? What are some of the implementable solutions? What in particular could be done in emergencies to support best practices?

Health-Related Hazardous Waste

Joos Van Den Noortgate



Pharmaceutical waste



Laboratory waste



Non-Lab Bio-hazardous waste



X-ray related waste



Pesticides (insecticides) & bed nets



Waste Electrical and Electronic Equipment or containing hazardous substances

Batteries



Waste of vehicles et equipment with Internal Combustion Engine



Water treatment related waste



Construction related waste



Contaminated packaging and spills



MSF's Policy on Pharmaceutical Waste Management



- Based on 1999 WHO's Guidelines
- Categorization of wastes' hazardousness:
 - Low-risk hazardous, e.g. large volume parenteral solutions
 - Harmful hazardous, e.g. most medicines
 - High-Risk hazardous, antineoplastics

“All chemical substances can cause harm or kill if encountered at sufficiently large concentrations over crucial periods of time”*

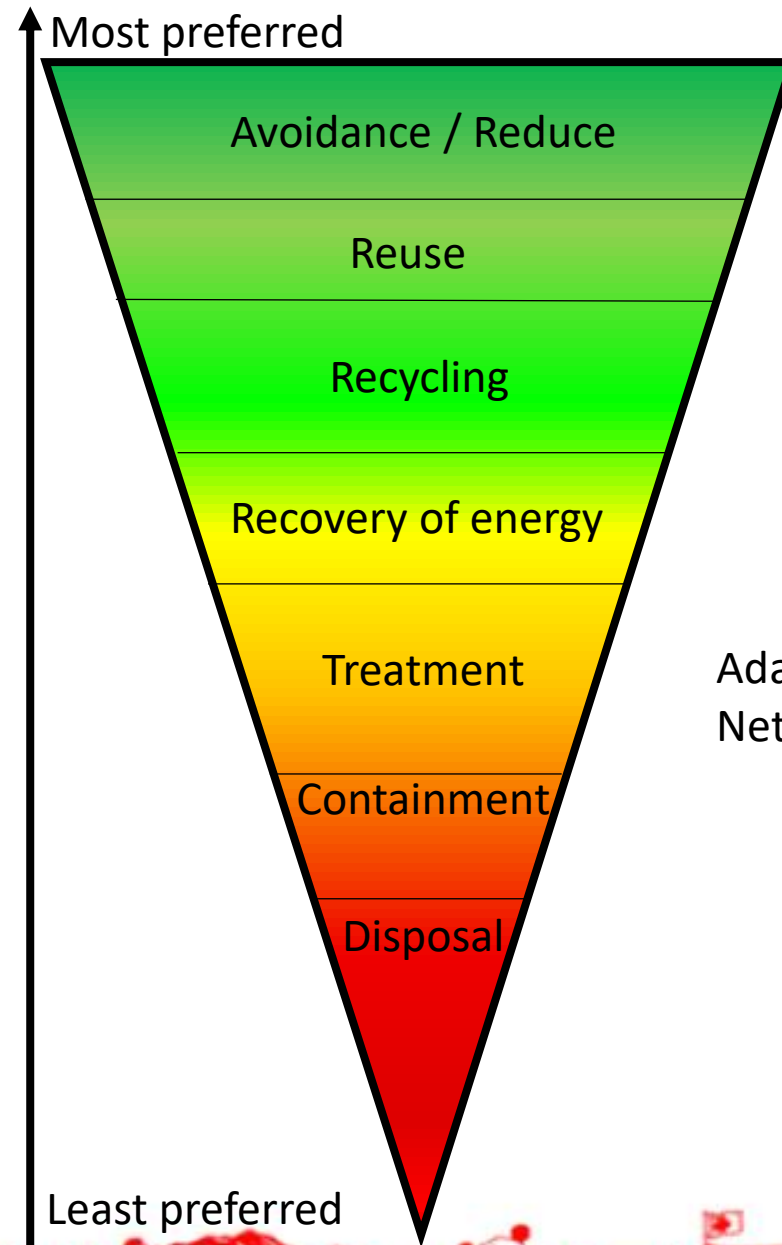
Adapted from Paracelsus

- MSF's Pharma Waste List: since 1999, updated every (2) year(s)
- ***Determination of elimination options***
 - ***Medicines' characteristics:***
 - Category of the API, e.g. anti-infectives, narcotics..
 - Composition: API; and presence of halogen, salt, nitrogen, sulphur, and other toxic elements (arsenic...)
 - Primary packaging (e.g. blister, vial)
 - Potential solubility in water
 - Calorific value
 - ***Known hazardousness from reliable sources***
 - European Waste Catalogue
 - GHS / CLP hazard statements
 - Summary of Product Characteristics (SPC)
 - WHO, EMA, FDA, TGA
 - Others, e.g. Dorosz

MSF's Elimination Options

Allowed methods, by preference and feasibility

- Co-processing (in cement factory):
 - at high temperatures: e.g. kiln
 - at medium temperatures: e.g. pre-calciner
- Incineration Plant:
 - at high temperatures: rare in L(M)IC
 - at medium temperature: e.g. for domestic waste
- Small Scale Dual Chamber Incinerators (5% rule)
 - at high temperatures
 - at medium temperatures
- Inertization: only for certain (semi-)solid medicines
- Dilution: only for certain liquid medicines
- Dissolution: only for certain solid medicines
- Encapsulation: last resort (medicines are not destroyed!)



Adapted from:
Network Waste, UK

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Prohibited methods, incl. in emergencies

- Auto-combustion incinerators:
e.g. De Montfort
- Drum, open surface or pit burning
- Encapsulation at a dumpsite
- Direct burial:
 - in a controlled landfill
 - in an uncontrolled landfill / dumpsite
- **Disproportionately high risk for individual, public, and environmental health**
- **Harm to the most vulnerable communities; it may go undetected/un-indemnified**
- **Risk of further abuses (e.g. “extended” definition of emergency)**

**Do no
harm**



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Session 5: Consolidation and way forward

WHO HQ, Geneva

1 October 2024

Dissemination, capacity building and uptake

- Launch webinar, communications materials, share in various newsletters (Q 1 2025)
- Share document or best practices summary through Health and WASH Clusters
- Develop more detailed module on pharmaceutical waste for Open WHO (and host on other platforms)
- Monitor and fund health care waste management in outbreak/pandemic plans (e.g. Cholera, Monkey Pox, etc)
- Community of practice: check in, every 6-12 months?

Meeting summary and action

- Management of pharmaceutical waste taking on increasing importance with scale and complexity of emergencies, threat of outbreaks, climate change, spread of AMR
- Key areas for action/follow-up
 - **Technical elements of document:** risk-based technology options (alkaline hydrolysis, low temp incinerators, or no pollution control?), waste hazard classification, dilution recs, reverse logistics + storage, emergency considerations, procurement requirements and extender provider responsibility
 - **Systems:** leadership and awareness, regulation and enforcement, logistics and tracking, training and capacity building including on inventory, pre-service, cross sectoral collaboration,
 - **Concrete actions:** short, medium, long-term, indicators to track actions, incentives (procurement policies, regulation and enforcement, requirement of funding, cost/benefits of different options)
- Opportunity to leverage and link with related efforts (e.g. IPC, AMR NAPs, green procurement and low-carbon and climate resilient health care facilities)