

# FIP STATEMENT OF POLICY Mitigating antimicrobial resistance through antimicrobial stewardship

#### **Preamble**

The FIP Statement of Policy on the Control of Antimicrobial Resistance (AMR) was revised in 2017. AMR has since been declared a global public health emergency requiring the whole of society to mobilise to address this serious threat. AMR is a normal evolutionary process that is a consequence of selection pressure exerted by both rational and indiscriminate or unregulated (mis)use of antimicrobials in humans, animals, plants and the environment, meaning AMR mitigation thus requires a "One health" approach. This 2023 FIP Statement of Policy on mitigating antimicrobial resistance through antimicrobial stewardship (AMS) is a revision of 2017 FIP Statement of Policy on control of AMR to reflect current issues and make appropriate recommendations.

#### **Background**

AMR is a global public health threat and an escalating challenge to the control of infectious diseases worldwide. AMR results in prolonged illness, greater risk of infection spread, and increased morbidity and mortality rates that are expected to reach up to 10 million by 2050 unless action is taken. The associated increases in healthcare costs may range from USD 300 billion to more than USD 1 trillion per year and push 28 million people into poverty by 2050.

The AMR burden disproportionately affects low- and middle- income countries (LMICs) due to challenges related to limited human resources and regulatory, technical and infrastructural capacities to address AMR. These include, but are not limited to, inadequate surveillance and monitoring of antimicrobial use and resistance, unreliable supply chain and use, sub-optimal medicines regulation and enforcement, and inadequate infection prevention and control as well as poor water, sanitation and hygiene. The nature and the extent of the AMR burden are not fully quantified. Additionally, antimicrobial medicines are among the most reported substandard or falsified medicines<sup>3</sup> and shortages and stockouts are exacerbating the problem, especially in the context of multiple layers of political, social, natural and health crises.

The World Health Assembly endorsed the World Health Organization's (the WHO) Global Action Plan (GAP) on AMR in 2015 and with Resolution A69/24 member states committed to developing national action plans by May 2017<sup>4</sup> with five strategic objectives, namely

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- "(1) improve awareness and understanding of antimicrobial resistance through effective communication, education and training,
- (2) strengthen the knowledge and evidence base through surveillance and research,
- (3) reduce the incidence of infection through effective sanitation, hygiene and infection prevention measures,
- (4) optimise the use of antimicrobial medicines in human and animal health, and
- (5) develop the economic case for sustainable investment that takes account of the needs of all countries".<sup>5</sup>

The overall goal of the GAP is to ensure, for as long as possible, the continued ability to treat and prevent infectious diseases. Therefore, safe, efficacious, quality-assured antimicrobial medicines must be accessible to all who need them, and these should be used responsibly and safely. In the United Nations General Assembly (UNGA)'s political declaration on AMR in September 2016, the GAP as a guide for countries to address AMR was endorsed.<sup>6</sup>

FIP unequivocally supports the UNGA political declaration on AMR, subscribes to the "One health" approach, and strongly endorses the WHO's GAP on AMR as the blueprint to address AMR nationally and globally. FIP also advocates pharmacists' key important role in the education of healthcare professionals and the public. The WHO has published several resources such as the health workers' education and training on AMR curricula guide, the competency framework for healthcare workers' education and training on AMR and the strategic framework for collaboration on AMR, a practical toolkit for AMS in LMICs to lead and support strategies to enhance AMS and therefore mitigate AMR. To this end, FIP established a commission for supporting AMR mitigation efforts and included AMS as one of its development goals.

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# AGAINST THIS BACKGROUND, FIP RECOMMENDS THAT:

A. Governments and policymakers, in collaboration with member organisations, should:

## A1. Establish governance and regulations by:

- Demonstrating political will and commitment by mobilising relevant national ministries and departments to collaboratively improve the capacities of their national systems to address AMR in the "One health" context.
- Establishing infection prevention and control (IPC), and water, sanitation and hygiene (WASH) programmes for effective prevention and containment of infections and ensuring that all communities and healthcare facilities have access to such programmes.
- 3. Developing, funding, implementing, monitoring and evaluating national



- action plans to contain AMR and formally involving all key stakeholders, including healthcare professionals, the private sector, academia and civil society.
- 4. Facilitating the registration of new or existing antimicrobials and providing appropriate economic incentives to encourage their development and commercial availability.
- 5. Strengthening and enforcing legislative and regulatory controls applicable to all sectors in relation to the life cycle of antimicrobial medicines, in particular, authorisations to market, promote, import, export, prescribe, dispense, correctly store, dispose and otherwise supply antimicrobial medicines including via protocols, internet or telecommunications (telemedicine).
- 6. Enforcing regulations preventing the dispensing and sale or supply of antimicrobial medicines without the prescription or order of an authorised prescriber based on the local regulations.
- 7. Advocating international, collective and alternative financial models to incentivise the research and development of new antimicrobials and ensure equitable access to all antimicrobials for those in need.
- 8. Supporting the discovery and development of new cost-effective antimicrobial medicines, alternatives to antimicrobials, and research into improved use of existing antimicrobials, including new combinations.
- Facilitating the registration of new or existing antimicrobials across countries and appropriate economic incentives for transferring technology to other manufacturers to encourage their development and commercial availability.
- 10. Ensuring that all antimicrobials listed in WHO Essential Medicines Lists are always available in sufficient quantity and standard quality.
- 11. Adapting and adopting the WHO Access, Watch, Reserve (AWaRe) categorisation and Antibiotic Book into the country's standard treatment guidelines and essential medicines list.
- 12. Ensuring that essential antimicrobials will be maintained on the market with contingency stock level arrangements and alternative production by pharmacists enabled where necessary.

#### A2. Embrace the "One health" approach through:

- Designing and implementing robust, representative national and international surveillance programmes for monitoring and reporting patterns of antimicrobial medicine use and resistance in humans, animals (livestock and companion), plants and the environment.
- 2. Regulating and monitoring the rational and appropriate consumption of antimicrobials, routes of access and data availability in humans and animals, plants and the environment.<sup>7</sup>
- 3. Developing and implementing AMS programmes for the responsible use and disposal of antimicrobial medicines in humans, animals, plants and the environment.
- 4. Developing appropriate adult, child and (livestock and companion) animal immunisation programmes for diseases that are vaccine-preventable.

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- Supporting the development and implementation of biosecurity and animal husbandry measures to encourage the discontinuation of the use of antimicrobial medicines for growth promotion, prophylaxis and metaphylaxis.
- 6. Supporting the adoption of effective antimicrobial medicines disposal and biosecurity practices to prevent the contamination of soil and water sources with antimicrobial residues and antimicrobial-resistant microorganisms and ensure that all industries and farms have access to such programmes.

#### A3. Monitor antimicrobial use and consumption by:

- Developing and encouraging adoption of best practices guidelines and developing national systems and regulations to ensure appropriate prescribing, dispensing, compounding, and use of antimicrobial medicines in all sectors to limit the development of AMR.
- Ensuring that only authorised channels are used for the procurement and distribution of medicines to minimise the availability of substandard or falsified medicines, implementing, where possible, pharmaceutical trackand-trace systems.
- Promoting the adaptability of antimicrobial (including fixed dose combinations) pack sizes according to their course length and advocate against irrational fixed dose combinations.
- 4. Developing and implementing a "return and disposal" programme for unused or expired antimicrobial medicines.

# A4. Lead education and awareness campaigns through:

- 1. Conducting public health education campaigns that promote the responsible use of antimicrobial medicines and thereby support health literacy.
- 2. Ensuring availability and access to relevant education on antimicrobial use for the whole of society.
- 3. Promoting the inclusion of the concept of AMR, its impact, and measures to reduce its possible emergence and spread in basic education curricula.
- 4. Collaborating with healthcare professionals and veterinary societies and associations to develop and facilitate the implementation of educational and behavioural interventions that will promote appropriate antimicrobial prescribing, raise awareness of AMR and support AMS in hospitals and the community.
- 5. Including AMS in pre- and in-service education and training and promote interprofessional learning and collaboration.

### B. Pharmacists should:

- 1. Recognise and embrace their leadership role in mitigating AMR and advancing AMS.
- 2. Promote evidence-based medicine in antimicrobial treatment that is informed by the current guidelines and by local antibiograms<sup>8</sup> obtained

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- from robust, representative antimicrobial resistance surveillance programmes.
- 3. Throughout the whole patient journey, ensure together with other professionals, that the right antimicrobial medicine is prescribed to the right person for the right duration at the right dose and dosing interval, opting for the narrowest spectrum agents, where possible.
- 4. Optimise antimicrobial therapy by advocating and actively participating in microbiology-informed antimicrobial therapy and diagnostic stewardship.
- Encourage the use of point-of-care diagnostic tools to screen for early signs
  of infectious diseases, differentiate between viral and bacterial infections
  and inform the choice of empirical antimicrobials, where appropriate as
  part of clinical pathways.
- 6. Give appropriate counselling advice and written information when dispensing antimicrobial medicines to support patient safety and improve health literacy.
- 7. Monitor the use of antimicrobials and adherence to treatment regimens by patients (right dose and interval for the entire course).
- 8. As per local regulations, recommend therapies other than antimicrobial medicines, including symptomatic treatment for viral or self-limiting conditions.
- 9. Acquire antimicrobial medicines only from reliable sources to ensure their quality, safety and efficacy.
- 10. Actively discourage self-medication, storage for future use, and use of leftover antimicrobial medicines by the same or other patients.
- 11. Provide information to the patient on the responsible use of antimicrobial medicines and to prescribers on rational and appropriate antimicrobial prescribing, antimicrobial consumption surveillance and the impact thereof.
- 12. Educate other healthcare providers about AMR and encourage interprofessional cooperation within the AMS programmes in hospitals and in communities.
- 13. Ensure that antimicrobial medicines for human use are supplied subject to the prescription or order of a healthcare professional qualified and authorised to dispense these medicines in accordance with country legislation and regulations.
- 14. Ensure that antimicrobial medicines for animal use are supplied in accordance with country legislation and regulations.
- 15. As part of the national professional pharmacy organisations, work with governments to ensure compliance by pharmacists with legislation applicable to the supply of antimicrobial medicines.
- 16. Actively encourage the appropriate use of antimicrobial medicines, wherever possible.
- 17. Provide updated information and implement health education campaigns on AMR, antimicrobial use and consumption, and AMS to prescribers as well as healthcare and veterinary professionals, livestock producers and other stakeholders in the food and agriculture sectors who administer or otherwise influence the use of antimicrobial medicines.
- 18. Be actively involved in WASH and IPC programmes in communities and

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- health care settings, respectively.
- 19. Encourage competent authorities to involve pharmacists in national and local immunisation programmes and support immunisation generally, and especially for vulnerable populations, to help prevent infections, according to national regulations.
- 20. Actively participate in the World Antimicrobial Awareness Week campaign to promote the significant role of pharmacists as trusted sources of information for patients, healthcare professionals and the public on AMS.
- 21. Take responsibility for programmes for the appropriate return and disposal of unused or expired antimicrobial medicines and proactively inform medicine users about the proper disposal of unused antimicrobial medicines.
- 22. Encourage and advocate an environmentally conscious approach and the application of the green pharmacy principle<sup>9</sup> throughout the lifecycle of antibiotics.
- 23. Conduct research on all facets of AMR and AMS and to apply the findings.
- 24. Provide appropriate counselling and safety checks for allergies and chronic conditions as well as collaboratively work with other healthcare professionals documenting in healthcare records.
- 25. Monitor and support patients who have been exposed to antimicrobial-resistant microorganisms.
- 26. Take the lead in the implementation of AMS programmes at local, regional and national levels, where necessary.

# **AGAINST THIS BACKGROUND, FIP COMMITS TO:**

- Collaborate on the development of wider strategies to rationalise antimicrobial use and to increase awareness of AMR and AMS among all stakeholders in human health, food production, and veterinary and environmental health.
- 2. Promote the establishment and strengthening of transparent, sustainable AMR and antimicrobial use or consumption monitoring, reporting and surveillance systems in all public and private health care settings at national, regional and global levels.
- 3. Promote cooperation among countries and professional organisations in the development and use of quality indicators to monitor responsible antimicrobial prescribing, dispensing, use and disposal practices.
- Promote the enhancement of regulatory systems for quality assurance and post-marketing surveillance of antimicrobial medicines to combat substandard and falsified medicines.
- 5. Facilitate and encourage the consideration of AMR information by regulatory agencies during the registration of antimicrobial medicines.
- 6. Develop and support educational campaigns on the responsible use of antimicrobial medicines aimed at the public and those involved in health care and food production, as well as veterinary and environmental health professionals with the use of social media and digital technologies as appropriate.

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- 7. Endorse the termination of use of critically important antimicrobial medicines for humans in animals<sup>10</sup> for growth promotion purposes as well as the reduction of use for prophylaxis and metaphylaxis by advancing biosecurity and good animal husbandry practices.
- Promote the discovery and development of new, cost-effective
  antimicrobial medicines by advocating reform of reimbursement systems
  and novel incentive mechanisms that recognise the value of novel
  antimicrobials and delink access and availability from return on investments
  and profit.
- 9. Encourage the discovery and development of novel infection treatment modalities and vaccines and support the search for non-traditional methods for antimicrobial discovery, including the use of emerging technologies.
- 10. Understand the basic principles of novel approaches for antibiotics discovery, including artificial intelligence, machine learning, deep learning and data science, as well as new genomic tools used in AMR research.
- 11. Promote the role of the pharmacist in patient education, surveillance data generation and sharing, and the sustainable production of, access to and responsible use of antimicrobial medicines, including selection, procurement, distribution, compounding, use and disposal.
- 12. Promote responsible production of antimicrobial substances and antimicrobial medicines for human and veterinary use, including waste disposal and wastewater handling, and encourage the selection and procurement of medicines produced in an environmentally acceptable way in tenders and reimbursement systems.
- 13. Reinforce the principle that antimicrobial medicines for human use are only supplied on the authority of a licensed healthcare professional, and that antimicrobial medicines for either human or animal use are only supplied in accordance with country legislation and regulations.
- 14. Support scientific research and evidence-based information to advance knowledge on the effective, safe, and responsible use of antimicrobials in communities and other healthcare settings.
- 15. Support the development of healthcare workforce through education and continuing professional development on AMR and AMS for AMR championship and advocacy.

Date of adoption: : Adopted by the FIP Council on 24 September 2023

Proposed by: : FIP Antimicrobial Resistance Commission

This Statement replaces the following previous FIP Statement:

International Pharmaceutical Federation. FIP Statement of Policy on Control of Antimicrobial Medicines Resistance. The Hague: FIP, 2017.

This Statement can be quoted as:

International Pharmaceutical Federation. FIP Statement of Policy -Mitigating antimicrobial resistance (AMR) through antimicrobial stewardship (AMS). The Hague: FIP, 2023. Available at:

www.fip.org/statements

This Statement references the following FIP Statements and documents:

International Pharmaceutical Federation. Fighting antimicrobial resistance: The contribution of pharmacists. The Hague: FIP, 2015. Available at: <a href="http://www.fip.org/files/fip/publications/2015-11-Fighting-antimicrobial-resistance.pdf">http://www.fip.org/files/fip/publications/2015-11-Fighting-antimicrobial-resistance.pdf</a>

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#### References

- 1. The "One health" approach was launched in 2021 by the Quadripartite the Food and Agriculture Organization of the United Nations (FAO), the United Nations Environment Programme (UNEP), the World Health Organization (WHO), and the World Organisation for Animal Health (WOAH, founded as OIE) recognising that the health of humans, animals and ecosystems is interconnected. It involves applying a coordinated, collaborative, multidisciplinary and cross-sectoral approach to address potential or existing risks that originate at the animal-human-ecosystems interface.
- The World Bank. Available from: https://www.worldbank.org/en/news/press-release/2016/09/18/by-2050-drug-resistant-infections-could-cause-global-economic-damage-on-par-with-2008-financial-crisis
- WHO Factsheet. Substandard, spurious, falsely labelled, falsified and counterfeit (SSFFC) medical products. Available from: <a href="http://www.who.int/mediacentre/factsheets/fs275/en/">http://www.who.int/mediacentre/factsheets/fs275/en/</a>
- 4. WHO Global action plan on antimicrobial resistance from World Health Assembly. Available from: <a href="http://apps.who.int/gb/ebwha/pdf">http://apps.who.int/gb/ebwha/pdf</a> files/WHA69/A69 24-en.pdf
- 5. WHO Global action plan on antimicrobial resistance. Available from: https://www.who.int/publications/i/item/9789241509763
- 6. UN Global leaders commit to act on antimicrobial resistance. Available from: <a href="https://www.who.int/news/item/21-09-2016-at-un-global-leaders-commit-to-act-on-antimicrobial-resistance">https://www.who.int/news/item/21-09-2016-at-un-global-leaders-commit-to-act-on-antimicrobial-resistance</a>
- 7. By measures such as daily-defined doses (DDD), the population correction unit (PCU), days of therapy (DOT), data related to pharmacoepidemiology, import, procurement and tender.
- 8. Antibiograms are tables showing how susceptible a series of organisms is to different antimicrobials.
- FIP Green pharmacy practice. Available from: <a href="https://www.fip.org/files/fip/publications/2015-12-Green-Pharmacy-Practice.pdf">https://www.fip.org/files/fip/publications/2015-12-Green-Pharmacy-Practice.pdf</a>
- 10. World Health Organization (WHO). Critically important antimicrobials for human medicine. 3rd revision. 2012. ISBN: 9789241504485. Accessible from:

https://apps.who.int/iris/bitstream/handle/10665/77376/9789241504 485 eng.pdf?sequence=1

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