EMA
EUROPEAN MEDICINES AGENCY

HMA
Heads of Medicines Agencies

POLAND25.EU

Theme 4: Antimicrobial resistance and other health threats

Preparing the EU for potential threats including antimicrobial resistance

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Theme 4 – general considerations

Potential changes to the goals, objectives or narrative of the strategy

- Explicit reference to terms of the marketing authorization in context of objective for developing additional options for guiding prescribing practices (objective 2)
- Include the example of vaccines as an alternative to use of antimicrobials (objective 6)

Theme 4 – Goal 1 (responsible use of antimicrobials)

Contribute to responsible use of antimicrobials and effective antimicrobial stewardship using a One Health approach

1. Continue to implement the requirements for the mandatory collection and reporting of sales and use data for antimicrobials in animals and for improving access to information and data and communicating the findings
2. Modernise the product information of existing antibiotics for veterinary use and consider additional options for guiding prescribing practices. For human medicines, take account of ongoing initiatives, while incorporating relevant new provisions in the new pharmaceutical legislation
3. In collaboration with relevant EU bodies, define a roadmap for point-of-care diagnostics to support the development of improved diagnostic tests
4. Develop, update, and promote regulatory guidance on antimicrobial use in animals to guarantee therapeutic options and minimise the impact of antimicrobial resistance while also supporting the development, implementation and uptake of guidance for human medicines

Theme 4 – Goal 1 (responsible use of antimicrobials)

To be considered in implementation actions

- Align efforts with stewardship plans and the One Health approach
- Focus on the linkage between environment and health
- Enhance data collection and reporting of sales and use of antibiotics for animals
- Ensure access to data and information, maintain transparency
- Enhance surveillance systems to monitor disease and AMR burden patterns

Other comments

- Prevent, restrict or ban the (preventive) (over)use of antibiotics in agriculture or food producing animals – legal framework already in place

Theme 4 – Goal 2 (development of new agents)

Support development of new antimicrobial agents and alternatives to the use of antimicrobials in collaboration with international partners

5. Provide guidance on regulatory pathways for phages and other innovative products in human and veterinary medicine, engaging with relevant stakeholders

6. Engage stakeholders in pipeline discussions with a view to facilitating the development and eventual authorisation of relevant products

7. Provide systematic support to developers of new antimicrobials, including antibacterials and alternatives to the use of antimicrobials, mainly through the ETF, and for veterinary medicines through the Innovation Task Force (ITF) and veterinary medicines Scientific Advice Working Party

8. Support the European Commission and Member States in the implementation of new business models for antimicrobials (particularly antibiotics), including eligibility assessment

Theme 4 – Goal 2 (development of new agents)

To be considered in implementation actions

- Communicate clearly about the prudent use of treatments, especially for AMR
- Better training for healthcare professionals on the prescription and dispensation of antimicrobials/ health literacy training
- Role of Agency on eligibility of medicinal products for voucher/pull incentives
- Technical support to additional pull incentives to be piloted such as subscription mechanisms
- Interaction with HTA bodies on defining value of new antibacterial agents

Other comments

- Transferable voucher already covered
- Standardise regulatory requirements and support to developers is already covered
- Role of ePI mentioned regularly and covered in other theme areas
- New antibiotics for veterinary use

Theme 4 – Goal 3 (preparedness for health threats)

9. Refine regulatory activities to increase preparedness and harmonise approaches for investigating medicinal products during emergencies, including for conducting timely clinical trials during emergencies

10. Respond to health threats that could be related to climate and environmental changes, using the One Health approach, as defined by OHHLEP, when applicable and in close collaboration with other Union agencies

11. Expand the international alignment on regulatory requirements from quadrilateral (US FDA-Health Canada-PMDA -EMA) agreements to achieve more global consensus

12. Adopt necessary regulatory flexibilities to support the development and authorisation of countermeasures for use in emergencies, including those caused by chemical, biological, radiation and nuclear threats

13. Explore ways to better inform the public about medicines for health threats to engender trust in the medicines and the regulatory system

Theme 4 – Goal 3 (preparedness for health threats)

To be considered in implementation actions

- Support to possible incentives for vaccine development.
- Ensure clear communication to inform the public about the role of vaccines.
- Invest in strategies to ensure accurate information is shared with the general public in order to counteract false information, especially during emergencies
- Foster establishment of clinical trial networks
- Streamline regulatory pathways in emergencies and in preparedness
- Awareness of AMR in package and product leaflet

Comments outside the remit of medicines agencies

- Work towards common solutions on depolluting the environment from pharmaceutical products (consider all factors to climate change)