

Implementing the EU AMR Action Plan

Recommendations from the medical technology industry

In June 2017, the European Commission published a "One-Health EU Action Plan" to tackle Antimicrobial Resistance (AMR). This plan includes, among others, actions on *(1) surveillance, (2) infection prevention and (3) novel diagnostics.* These three areas can have a significant impact on the goal of tackling the global burden of AMR. This paper aims at making recommendations on how they can be meaningfully implemented.

1. One Health surveillance and reporting of AMR and antimicrobial use (Section 2.1 of the EU AMR Action Plan)

Measures to strengthen "One Health" surveillance and reporting

According to the World Health Organisation (WHO)¹, "surveillance findings are needed to inform clinical therapy decisions, to guide policy recommendations, and to assess the impact of resistance containment interventions". The following key actions can ensure a comprehensive surveillance of AMR:

1. Widen the scope of surveillance activities (National and EU level)

Enlarging surveillance activities helps to make sure that outbreaks are identified quickly and that appropriate measures can be put in place to prevent such events. The latter can be done by **integrating more human pathogens** (e.g. carbapenemase-producing enterobacteriaceae) **and care sites** (e.g. community care facilities, non-hospital clinics etc.) in local, regional, national and European surveillance programmes.

Furthermore, setting up inclusive **One-Health surveillance programmes** that integrate human, animal, food and environmental data will help better understand the transmission of AMR.

2. Set up target ranges (National/EU level)

A set of outcome indicators for the surveillance of resistance and antibiotic consumption published ² on the request of the European Commission is a first step to assess progress in reducing AMR. To facilitate implementation, we recommend the Commission to establish **target ranges for these indicators**. Based on these, Member States could decide on the concrete targets they would like to take up in their national AMR Action Plans based on their local context.

¹ http://www.who.int/medicines/areas/rational_use/AMR_Surveillance/en/

² https://www.efsa.europa.eu/en/efsajournal/pub/5017



3. Publish infection rates in hospitals and healthcare settings (Local level)

Transparency about infection rates can enable better monitoring and prevention mechanisms to be put in place, while providing key information about patient safety.

4. Screen Healthcare Professionals and patients

Screening for resistant microbes can help monitor development and spread of AMR. Both points 3 and 4 should be part of a comprehensive surveillance plan within a healthcare Institution.

2. Strengthening infection prevention and control measures (Section 2.3 of the EU AMR Action Plan)

Infection prevention in hospital and healthcare settings is diverse and ranges from simple hand disinfection to education of healthcare professionals and establishing infection prevention programmes. Medical technologies can enable efforts for better prevention of infections, through:

- As outlined in the WHO Guidelines (2016)³ on the prevention of Surgical Site Infections (SSIs), the use of specific **medical devices** (e.g. drapes, patient warming device, antibiotic-coated sutures or wound protector devices) can prevent infections and resistance to develop in the first place.
- According to the WHO Guidelines⁴ (2016) on core components of infection prevention and control programmes at the national and acute health care facility level, high-quality microbiology laboratory support is a critical factor for an effective Infection Prevention and Control programme. This is because diagnostic tests help identify pathogens and based on the information collected from such tests, comprehensive plans can be put in place.

Overall, we see the need for the following concrete steps to be taken to ensure proper infection prevention and control programmes to be implemented:

1. Use existing evidence-based infection prevention protocols

Many evidence-based guidelines are already in place in either local (SF2H, KRINKO, NICE) or global (WHO) settings. The EU and national governments should encourage Member States to implement these evidence based protocols in healthcare settings to enable better infection prevention as well as monitoring.

2. Reshape incentives in hospital/healthcare settings

Firstly, incentives for hospital management should be reshaped to encourage better outcomes in terms of infection prevention and AMR rates. For example, using **funding models** that reward adherence to standardised protocols and that are based on HAI/AMR indicators, would incentivise clinical practice to address AMR reduction/management goals. Secondly, the way products are procured by hospitals should

³ http://www.who.int/gpsc/ssi-guidelines/en/

⁴ http://www.who.int/gpsc/ipc-components/en/



also be re-thought. Implementing a **value-based procurement** approach could for example enable the healthcare organisation to include AMR/infection reduction as one of their key criteria for value. This way, tenders for products would have to demonstrate the value they would bring to meet this goal. In turn, this would lead to purchasing of appropriate medical technologies (see above in WHO Guidelines for the prevention of SSIs) which can help fight resistance and increase patient safety in the hospital setting overall.

3. Educate healthcare professionals (clinicians and non-clinicians)

During **medical training**, education about AMR prevention, diagnosis and treatment options available would enable HCPs to avoid overuse and misuse of antibiotics and to prevent infections as effectively as possible. **Continuous education** on this subject throughout the medical career would allow professionals to remain up to date on technological and research developments in the field.

4. Support the concept of "Antimicrobial Stewardship"

The concept of "**Antimicrobial stewardship**" is an essential component to infection prevention. This refers to coordinated interventions designed to improve and measure the appropriate use of antimicrobials by promoting the selection of the optimal antimicrobial drug regimen, dose, duration of therapy, and route of administration⁵. Antimicrobial stewardship seeks to achieve optimal clinical outcomes related to antimicrobial use, minimize toxicity and other adverse events, reduce the costs of health care for infections, and limit the selection for antimicrobial resistant strains. In The Netherlands, such programmes are mandatory for every hospital. A pilot study at the University Medical Centre Groningen ⁶ has shown >10% reduction in antimicrobial prescribing (more than 50% of all antimicrobial prescriptions were modified) and >40 000 \in cost-savings yearly. The economic evaluation strongly indicates cost-effectiveness of antimicrobial stewardship which can lead to a positive return on investment, even shortly after implementation. Therefore, MedTech Europe recommends to:

- **Define essential elements of a solid antimicrobial stewardship programme** and help Member States exchanging **best practices.**
- Support the **broad implementation** of antimicrobial stewardship programmes across all health care settings.

⁵ Infectious Diseases Society of America

⁶ Cost-Effectiveness of Policies to Limit Antimicrobial Resistance in Dutch Healthcare Organisations



3. Measures to enhance the deployment and adoption of diagnostics (Section 3.4 of the EU AMR Action plan)

Diagnostics can play a key role in limiting the spread of resistant bacteria, they:

- **Distinguish between bacterial and viral infections.** They provide information to the doctor whether or not an antibiotic should be prescribed.
- **Rapidly identify specific pathogens** including multidrug resistant organisms like MRSA or CRE (Carabapenems Resistant Enterobacteriaceae). This helps to assign correct treatment and isolation if needed.
- **Characterise antibiotic susceptibility**. Specific tests can provide information on the susceptibility of a certain bacteria to a given antibiotic (i.e. which bacteria will react to which antibiotic treatment). This helps to guide antibiotic prescription and avoid the use of broad-spectrum antibiotics in favour of a more targeted treatment.
- Ensure right duration of treatment. Specific biomarkers can be used to guide antibiotic therapy and this approach has been shown to be cost effective⁷. Outcome of this includes shorter hospital length of stay and/ or reduction in duration of treatment with no adverse outcome.
- **Monitor resistance patterns**. Hospital and healthcare facilities can compile data from diagnostic tests to track antimicrobial resistance patterns (e.g. peaks, outbreaks of a certain organism). This information can be useful in early outbreak detection as well as outbreak management, and it is also vital for the effective implementation of antibiotic stewardship programmes.
- Help new antibiotic drug development by supporting the recruitment of appropriate patients for clinical trials.

MedTech Europe therefore recommends the use of diagnostic tools to encourage the appropriate use of antibiotics. We suggest the following implementation points to make the best use of these technologies:

1. Develop new business models

Incentives and appropriate reimbursement which reflect the medical and economic value that these technologies provide would help to make them more accessible to healthcare professionals and patients.

2. Conduct gap analysis and horizon scanning

A clear analysis of unmet medical needs can be helpful to guide R&D activities related to medical technologies in the right direction.

⁷ <u>https://www.ncbi.nlm.nih.gov/pubmed/26105574</u>

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3351898/

https://ccforum.biomedcentral.com/articles/10.1186/s13054-018-2234-3

https://www.ncbi.nlm.nih.gov/pubmed/30235108



3. Enable the use of rapid diagnostics in the community setting

By being able to quickly distinguish between a bacterial infection from a viral one through a rapid test, community pharmacists would be able to either refer patients to a doctor for further investigation for a bacterial infection or provide over the counter advice and treatment for symptoms for self-limiting viral infections such as the common cold.

Contact & more information:

Timea Rezi-Kato (<u>t.rezi-kato@medtecheurope.org</u>), Manager Government Affairs & Public Policy. More examples of the role of medtech & AMR: <u>http://amr.medtecheurope.org/</u>

ABOUT MEDTECH EUROPE

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There are more than 500,000 products, services and solutions currently made available by the medical technology industry. These range from bandages, blood tests and hearing aids to cancer screening tests, pacemakers and glucose monitors.

Our sector employs more than 675,000 people. There are more than 27,000 medical technology companies in Europe, of which 95% are SMEs.