

Realising the potential of *in vitro* diagnostics and medical devices to prevent and control AMR

Antimicrobial resistance (AMR) is a serious global threat that puts in jeopardy the effective prevention and treatment of an ever increasing range of infections¹. Effective AMR control can only take place through the use of diagnostics and other prevention tools, which are today still not sufficiently implemented in many European countries.

It is important to acknowledge the relation between Healthcare Associated Infections (HAIs) and the development of resistance. HAIs are often caused by resistant bacteria². Preventing and detecting these infections early is essential to reduce antibiotic use in healthcare settings and therefore decreasing the risk of developing resistance.

MedTech Europe encourages policy makers to act together and consider the medical technology industry as a solution-provider and a partner. We recommend the following actions at both EU and Member States (MS) levels:

1. Develop, implement and monitor **a new EU Action Plan** on the fight against AMR
2. The EU should encourage and support Member States to put in place and monitor **national targets and surveillance systems** for the reduction of AMR through holistic action plans under a “One Health approach”
3. Encourage **the implementation of evidence-based guidance on infection control** and share good practice between EU Member States
4. Support the development of **new funding and business models for improved access** to innovative technological solutions that help to prevent and control AMR/HAIs.
5. Foster the **uptake of solutions** to diagnose and prevent AMR/HAIs.
6. Ensure the **implementation of antibiotic stewardship and infection control programmes** in hospitals and healthcare facilities, as well as transparency of infection rates
7. Develop and support **educational programmes** targeting both healthcare professionals and patients

I. AMR: A cross-border challenge

Across the EU, 25 000 people die each year from drug resistant infections³. Worldwide, this number will increase to 10 million by 2050, according to the UK AMR Review⁴. This is 1.8 million more deaths than those attributed to cancer. Not only will this impact patient safety and recovery, but it risks going back to a ‘pre-antibiotic era’, where patients could die from simple bacterial infections and life-saving treatments can no longer be performed safely⁵. AMR also puts a heavy burden on the economy due to loss of income and productivity, as well as informal care requirements. In Europe, the annual extra healthcare costs and productivity losses due to multidrug-resistant bacteria amount to 1.5 billion euros⁶.

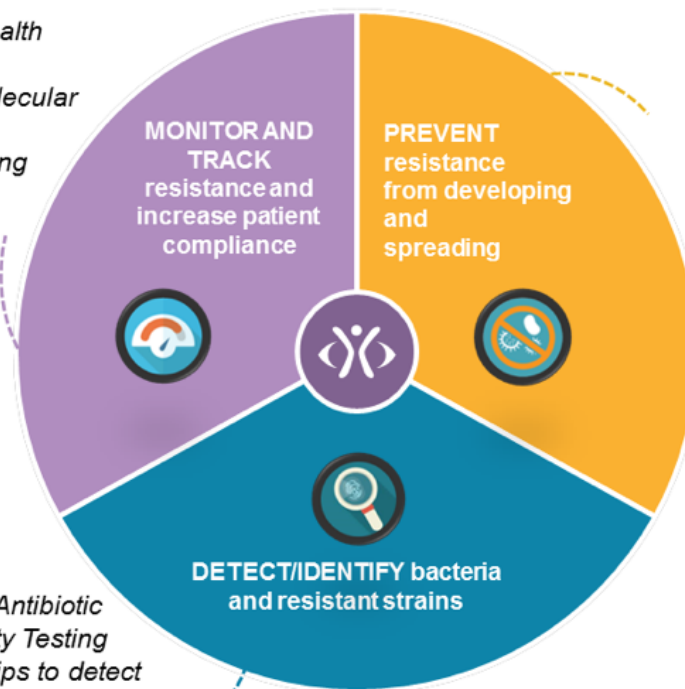
There are multiple challenges to combatting antimicrobial resistance. Not only do we lack new antibiotics but we also overuse- and misuse existing ones in human medicine and animal husbandry⁷. In addition, a lack of public awareness, healthcare system challenges and poor infection prevention in healthcare institutions make effective control of AMR more difficult⁸. HAIs are closely tied to the issue of resistance. HAIs are often caused by resistant bacteria⁹. Infection prevention should therefore play a key role in avoiding resistance in the first place.

II. What can Medtech do?

Medical technologies (medical devices and *in vitro* diagnostics) can help prevent, diagnose and control infections, stopping the spread of resistant bacteria throughout the patient pathway. Preventing and managing HAIs contribute to the control of bacterial resistance, by limiting the transmission of multi-drug resistant organisms, and consequently lowering the need for antibiotic therapy.

Examples:

- eHealth, mHealth solutions
- Real-time molecular technologies
- Drug monitoring
- Etc.



Examples:

- Antimicrobial incise drapes
- Antibacterial sutures and implants
- Antimicrobial dressings for catheter securement
- Body disinfectants
- Surface testing products
- Air control culture media
- Etc.

Examples:

- Automated Antibiotic Susceptibility Testing
- Reagent strips to detect resistant microorganisms
- Mass spectrometry
- Multiplex PCR systems
- Virus/bacteria biomarkers
- Etc.

PREVENT resistance from developing and spreading

- Screening patients (before and during hospitalisation) and healthcare workers with diagnostic technologies for multidrug-resistant organisms helps **mitigate exposure**.
- The adoption of alternative solutions based on antiseptics (antibacterial sutures and implants etc. – see for more examples above) and methods that can **diminish the reliance on antibiotics and thus the development of resistance**.
- Innovative decontamination technologies and processes can also contain resistance, by **avoiding cross-contamination**.

DETECT/IDENTIFY bacteria and resistant strains

- **By differentiating between bacterial and viral infections**, diagnostic tests can play a substantial role in preventing the over-prescription of antibiotics.
- **Identifying resistance and the correct, targeted antibiotic therapy** through diagnostic tests can play a decisive role in patient outcomes.

MONITOR & TRACK resistance and increase patient compliance

- Diagnostic technologies aid the **surveillance of antimicrobial resistance patterns**, helping to control the emergence of resistant bacteria. This data can inform antimicrobial policies and prescribing guidelines at all levels (ward, hospital, local and national).
- **Monitoring patients and their compliance to treatment** through diagnostic, eHealth and mHealth solutions.

Effective use of medical technologies (please see for examples above) can therefore help to fight the two key reasons for the spread of AMR: the overuse- and misuse of antibiotics. Moreover, companion diagnostics can help with patient stratification based on their response to a treatment, and therefore improve patient recruitment for clinical trials of new antibiotic molecules, optimising new antibiotic development.

III. What do we need moving forward?

Given the importance of AMR and the need for coordinated and precise activities, MedTech Europe suggests the following actions to be taken on at national and/or European levels:

- 1. Develop, implement and monitor a new EU Action Plan on the fight against AMR.** With the previous EU Action Plan becoming outdated and given the political momentum, a new Action Plan will be crucial in continuing efforts to fight resistance. When developing new EU guidance, it will be important to reinforce the link between AMR and infection prevention/management.
- 2. The EU should encourage and support Member States to put in place and monitor national targets and surveillance systems for the reduction of AMR through holistic action plans under a “One Health approach”.** Best practice countries in this domain include the French Government (see Case study 1).
- 3. Encourage the implementation of evidence-based guidance on infection control and share good practice between Member States.** Helping to implement such guidelines on a national level will have a positive impact on the levels of infection in hospital and healthcare facilities and therefore lowering the risk of AMR.
- 4. Support the development of new funding and business models for improved access to innovative technological solutions that help to prevent and control AMR/HAIs.** The intrinsic value of available technologies is still not well understood or incentivised by healthcare systems, making them less accessible to patients. To fully utilise the potential of these technologies and ensure their access, structural changes will have to be implemented in a manner that acknowledges the value they provide.
- 5. Foster the uptake of solutions to diagnose and prevent AMR/HAIs.** One key step would be to make sure that they are used to ensure that antibiotic prescription is appropriate and informed by evidence, as suggested by the UK AMR Review¹⁰. Nurture the practical implementation of these technologies as a standard of care, monitored by verified quality indicators.
- 6. Encourage the implementation of antibiotic stewardship and infection control programmes in hospitals and healthcare facilities, as well as transparency of infection rates.** Where these programs already exist, they should be enhanced through technological support, such as electronic surveillance systems. The Netherlands is a good example of successful antibiotic stewardship teams in hospitals (see Case study 2). Publishing hospital and healthcare facility infection rates within the right context and setting annual targets can encourage healthy competition for the reduction of hospital-acquired infections, a high percentage of which, are caused by highly resistant bacteria¹¹.
- 7. Develop and support educational programmes targeting both healthcare professionals and patients.** Behavioural change will be a key factor in improving awareness and understanding around resistance¹².

Complementary actions at EU and Member State levels, which make use of medical technology solutions, can lead to prevention and reduction of AMR. MedTech Europe is ready to engage and partner with stakeholders in the fight against resistance.

1) Factsheet on antimicrobial resistance, WHO, 2016

2) ECDC website: AMR and HAI Programme

3) WHO Europe, Data and statistics on AMR

4) Review on Antimicrobial Resistance – Comparative deaths graph

5) Factsheet for the general public, ECDC

6) European Commission AMR Factsheet, 2016

7) Factsheet on antimicrobial resistance, WHO, 2016

8) Communiqué of Tokyo Meeting of Health Ministers on Antimicrobial Resistance in Asia, 2016

9) ECDC website: AMR and HAI Programme

10) Review on Antimicrobial Resistance: Final report and recommendations (May 2016)

11) CDC: Making Health Care Safer, 2016

12) WHO Global Action Plan on Antimicrobial Resistance

13) Combating Antimicrobial Resistance: Examples of Best Practices of the G7 Countries, 2015

14) The Netherlands EU Presidency: AMR Next Report, 2016

Case study 1.

Did you know...?... that France has a well-established National Action Plan on the prevention of HAIs, which is also in line with their National Plan on antibiotics¹³? 'PROPRIAS' is a prevention focused and patient-centred plan along the whole care pathway. It aims to reinforce control over antibiotic resistance as well as reducing risks of HAIs in invasive procedures. While many EU Member States have National Action Plans, they are rarely implemented, unlike the French one. Another key aspect of the French Action Plan in the concrete and measurable targets set out e.g. the proportion of non-justified antibiotic treatments longer than 7 days should be below 10%.

Case study 2.

Did you know... ?

...that the Dutch Government has made multidisciplinary antimicrobial stewardship teams mandatory for every hospital¹⁴? Their job is to:

- Monitor antimicrobial use and resistance hospital-wide
- Provide tailored feedback on antimicrobial therapy
- Provide continuous education and training to healthcare professionals

Researchers found the impact of the so-called 'A-teams' to be significant in reducing length of hospital stay and required nursing time. Cost savings per hospital totalled 70.000 euros compared to the historical cohort during a 12-month period after implementation.

ABOUT MEDTECH EUROPE

MedTech Europe is an alliance of European medical technology industry associations. The Alliance was founded by EDMA, representing the European in vitro diagnostic industry, and Eucomed, representing the European medical devices industry. Our mission is to make value-based, innovative medical technology available to more people while supporting the transformation of healthcare systems onto a sustainable path. We promote a balanced policy environment that enables the medical technology industry to meet the growing healthcare needs and expectations of its stakeholders. For more information, visit www.medtecheurope.org.

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