Consultation on a draft Global action plan to address antimicrobial resistance

The questionnaire is divided into four sections. The questions are broadly framed and intended to give you the opportunity to enter into some depth and explain your organization's viewpoint. While only questions marked with * are mandatory, we would appreciate answers to as many as possible. Where a choice of answer needs to be selected please highlight your answer.

Before answering the questions, please refer to our list of supporting documents.


About you

1. Name of individual respondent*

Magdalena Kalata

2. Email address* (preference for official email addresses)

m.kalata@edma-ivd.eu

3. Are you authorised to represent your organization or interest group?* Y _x_ N ___

4. Organization Name*

MedTech Europe

5. Address of the organization*

Rue Joseph II, 40, 1000 Brussels, Belgium

6. Organization website (if available)

http://www.medtecheurope.org

7. Country*

Belgium

8. Type of Organization*

• Government department, ministry or agency

• Development or aid agency, foundation, trust or other funding authority

• International developmental organization

• Academic institution
• Civil society
• Private sector
• Other non-governmental organization (NGO)

Other (please specify) – Non-profit organisation

Non-profit organisation

9. Main sector of interest

Human health
• Animal health
• Finance/economics
• Agriculture or food
• Environment
• Communication, education and community
• Other (please specify)

10. Would you like to be added to our mailing list to receive updates on the development of the global action plan?* Y  N

General questions

1. From the perspective of your organization, what are the most important areas of concern in AMR?

The roots of antimicrobial resistance are widespread and span a number of areas that must all be addressed in order to help combat its further spread, including:

• Rise of multi-drug resistant organisms (MDRO) alongside the drying up of the antibiotic pipeline;

• Sub-optimal manner of antibiotic use (misuse and overuse) and underutilisation of rapid testing technology;

• Inadequate surveillance of antimicrobial resistance patterns at all levels – international, national, local, hospital and ward level – is essential to set up antimicrobial use policies;

• Lack of screening of patients and healthcare workers for MDRO;
• A multifaceted approach for the avoidance of resistance development should include infection control measures (e.g. hand hygiene), environmental controls (e.g. medical devices) and antimicrobial stewardship (e.g. prescriptions), but is currently missing;

• Underuse of diagnostic tests in both animals and humans;

• More provision of solutions for patients in remote areas and linking testing and treatment sites, access to available diagnostic tools and treatment are lacking;

• Overlooking of the impact of wound infections with antibiotic resistant bacteria, which are becoming increasing prevalent with reports of resistant causative isolates across burn\textsuperscript{1, 2, 4}, chronic\textsuperscript{5, 6, 7, 8, 9} and surgical\textsuperscript{10, 11, 12} wounds.

2. Is your organization currently involved in work related to AMR? \_\_Y\_\_N \_\_

If Yes, How?

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\textsuperscript{1} Huang, Y. \textit{et al}. A randomized comparative trial between Acticoat and SD-Ag in the treatment of residual burn wounds, including safety analysis. \textit{Burns} \textbf{33}, 161–6 (2007).

\textsuperscript{2} Mama, M., Abdissa, A. \& Sewunet, T. Antimicrobial susceptibility pattern of bacterial isolates from wound infection and their sensitivity to alternative topical agents at Jimma University Specialized Hospital, South-West Ethiopia. \textit{Ann Clin Microbial Antimicrob} \textbf{13}, 14 (2014).


MedTech Europe, representing the European medical technology industry associations, has been working with EDMA (European Diagnostic Manufacturers Association) and Eucomed (the medical device industry association) member companies in the provision of a variety of tools for the detection, prevention and control of infectious diseases, placing healthcare-associated infection and the rising threat of antimicrobial resistance at the heart of their activities, including:

- Offering a wide range of tests support relevant clinical decisions for optimised patient management, including microbial identification and antibiotic susceptibility testing;
- Solutions for the identification, screening, tracking and preventing of resistance;
- Accounting for the threat posed by antimicrobial resistance in wound care through the development of silver or iodine dressings that have been shown to provide a broad spectrum of activity against multiple antibiotic resistant isolates, including MRSA and VRE, alongside providing a barrier to prevent transmission of bacteria from wounds to the external environment and vice versa;
- Education and awareness-raising initiatives to address major public health issues, including AMR, such as:
  - “Be S.M.A.R.T. with Resistance” - [http://www.biomerieux-besmart.com/](http://www.biomerieux-besmart.com/) - launched in 2010, which focuses on solutions to manage the antimicrobial resistance threat through bi-annual events gathering experts in HAI and AMR, symposia and workshops, education partnerships with educational and professional associations, and research awards for young scientists in relevant fields;
  - Antimicrobial stewardship campaign – Test Target Treat - [http://www.testtargettreat.com/](http://www.testtargettreat.com/) – designed to build awareness and knowledge among healthcare professionals about rapid diagnostic testing strategies, which are available to support prescribing decisions. This global campaign collaborates with antimicrobial resistance based institutions such as the Alliance for the Prudent Use of Antibiotics (APUA) and the British Society of Antimicrobial Chemotherapy to generate educational materials to combat the resistance crisis.
  - Global Point Prevalence Survey of Antimicrobial Consumption and Resistance (Global-PPS) expands a standardised method of data collections that will be used at a global level to monitor rates of antimicrobial prescribing and resistance infections in hospitalised patients;
Publication of practical guides on relevant topics, e.g. antimicrobial stewardship, bacterial resistance, HAIs, extended spectrum beta-lactamases, c. difficile associated diseases, procalcitonin.

Questions about the draft global action plan outline document

Before the WHA resolution was adopted, two WHO AMR Strategic Technical Advisory Group (STAG) meetings were held in anticipation, which included members plus a large number of representatives from other organizations. These meetings identified key issues, concerns and led to the development of a draft outline.

As this consultation progresses and stakeholder meetings are held, the secretariat will harvest and incorporate the input into the draft global action plan.

1. How would you rate your understanding of WHO’s intention in the development of a global action plan to address AMR?
   Very good ___ Good_x___ Fair ___ Poor ___

Additional comments

MedTech Europe welcomes the possibility of submitting comments to the draft global action plan and appreciates the WHO’s effort to explore input from relevant stakeholders.

2. From the perspective of your organization, are the major issues relating to AMR outlined in the draft global action plan? Y ___ N_x___

If No, what additional issues need to be addressed?

While diagnostics are mentioned in the draft global action plan, the emphasis on this critical area could benefit from further development. There are proven diagnostic tools already available from manufacturers, which are utilised in certain countries to great benefit for the improvement of prescription decisions and reduction of the need for antibiotics. These approaches are documented in multiple scientific journals and such success stories should be showcased in the global community as examples of best practice.

The impact of antibiotic resistance on wounds and the possible link to the carriage of antibiotic resistant organisms in wounds should be included within the scope of the global action plan. The activity of antimicrobial wound dressings that contain silver and iodine against such organisms is demonstrated clearly when used outside of the body and is supported by a growing body of clinical evidence as successful treatment for outcomes against infections with MRSA. The cost-effectiveness of such topical antimicrobial dressings in wound care has been reported. In addition, a few case studies have already suggested that silver dressing treatment may reduce systemic antibiotic usage to treat wound infections.

Questions on the ‘Building blocks’ described in the draft outline.
You will notice, the global action plan has been constructed around “building blocks” in recognition that different countries will have different starting points. In this situation, countries can choose building blocks to concentrate upon. Each building block specified has been identified as a key area where specific attention, planning and work are needed to achieve progress in addressing AMR. Through questions in this section, we would like to hear your opinions on these building blocks in more detail.

I. Building block-1: Increasing awareness and understanding about AMR and of the actions and changes needed

a) What do you consider to be the main issues under this priority?

In order to increase awareness of the value of diagnostics in the continuum of care, added value must also be placed on microbiology laboratories at local level.

Educational initiatives in the context of antimicrobial stewardship should be incorporated into medical training from the very beginning to ensure reinforcement at university and during hospital training that can then be taken to full-time employment. Continual educational actions appropriate for each target group within the healthcare system should also be initiated and tailored to patients, doctors, nurses, pharmacists, administrators, and cleaners. Global collaboration on the crisis is also needed to ensure effectiveness.

b) What are the main actions that needs to be done -- and who are the main actors/stakeholders who need to take action -- to go beyond the status quo?

- Development of homogenous communicating through partnerships with relevant stakeholders, including the diagnostics industry.
- Reinforce trainings, medical education and lab capacities at local level, including a continuum of education (e.g. training for trainers).
- Elimination of over-the-counter sales and self-medication of antibiotics;
- Address existing incentives in some countries for the prescriptions of antibiotics;
- Prepare a diagnostic tool box to be available at local area or in areas remote from hospitals, along with appropriate implementation guidelines;
- Exchange best practice examples;
- Collaboration among stakeholders – key opinion leaders, reference laboratories, Centres for Disease Control and Prevention (CDC), WHO, FAO, OIE, national governments, industry, donors, programme implementers and association such as the African Society for Laboratory Medicine (ASLM), the European Committee on Antimicrobial Susceptibility Testing (EUCAST), and Clinical and Laboratory Standard Institute (CLSI);
- At national level campaigns to build public awareness are increasing, but need to be built up further;
• Further studies demonstrating the role of silver dressing treatments to reduce or replace systematic antibiotic usage and the possible impact on the reduction of antibiotic resistant organisms.

c) What steps have already been taken to address this priority? (please provide references where possible)

• World Forum on Healthcare Associated Infections and Antimicrobial Resistance (please refer to General Question 2);

• Education initiatives such as on-going collaboration between the Chinese Health Ministry and the Chinese Medical Association (CARE project) to reinforce better use of antibiotics in hospitals, Get Smart week and European Antibiotic Awareness Day are gaining momentum;

• Publication and distribution of educational material on World Antibiotic Awareness Day to healthcare professionals and the general public;

• Development of diagnostic products to prevent resistance and support prudent prescription of antibiotics, such as tests for the screening of MDRO, molecular resistance detection panels, point-of-care and near patient test for rapid identification of pathogens, etc;

• Development of specialties that drive awareness and focus within healthcare, such as antimicrobial pharmacy and epidemiology.

d) What are concrete and measurable indicators of progress for this priority? (Including, for example, global and national goals to be achieved within 2, 5 and 10 years)

Stakeholders involved might consider:

• Mapping of microbiology laboratories, i.e. healthcare settings where testing could take place and that have the capacity to implement microbiology testing;

• Track the number of laboratories involved over a period of time (2, 5, 10 years), alongside the number of resources allocated to fight against AMR and the number of trainings provided;
  o At 2 years – make an assessment;
  o 5 years – control;
  o 10 years – achieve goals, revert the trend as appropriate.

II. Building block-2: Identifying the most important approaches for preventing development of infections and the steps needed to move beyond guidance to more effective implementation of such approaches

a) What do you consider to be the main issues under this priority?

• How containment of dangerous multi-drug resistant pathogens can be achieved in practice;
b) What are the main actions that needs to be done -- and who are the main actors/stakeholders who need to take action -- to go beyond the status quo?

The main actions needed are:

- Reinforcement of microbiology laboratory network and capabilities;
- Collection and consolidation of microbiology data and reporting mechanisms at local, national and global level; and
- Implementation of infection control policies and antimicrobial stewardship programmes.

The stakeholders who should be involved in activities include key opinion leaders, reference laboratories, CDC, WHO/FAO/OIE, national governments, industry (pharmaceutical, diagnostic and mHealth, donors, programme implementers and associations such as ASLM.

c) What significant work has already been done to address this? (please provide references where possible)

- World Forum on Healthcare-Associated Infections and AMR (see General Question 2 for description);
- Global Point Prevalence Survey of Antimicrobial consumption and Resistance (see General Question 2 for description);
- EUCAST methodology standardisation.

d) What are concrete and measurable indicators of progress for this priority? (Including, for example, global and national goals to be achieved within 2, 5 and 10 years)

Stakeholders might consider the following indicators:

- Case reporting – tracking of the number of cases in hospitals and healthcare settings;
  - 2 years – Make an assessment
  - 5 years – Control of assessment
  - 10 years – Achieve the following:
    - 80% of hospital with microbiology capabilities;
Global consolidated surveillance data for resistance and antibiotic use (covering 60% of the population);

Infection control and antimicrobial stewardship programmes implemented in 70% of healthcare facilities.

III. Building block-3: Optimizing the use of existing antimicrobials for human and animal health and in agriculture

a) What do you consider to be the main issues under this priority?

- Lack of common/joint approach to AMR from both veterinary and human medicine, including overuse in both;
- Counterfeit antibiotics;
- Prescription antibiotics (overuse and misuse), both for:
  - Common ailments where they are unlikely to be of benefit, such as respiratory or urinary tract infections; and
  - For broad spectrum agents, for which diagnostic technology exists to define a specific pathogen that might respond to narrow spectrum therapy. Broad-spectrum agents can increase infections such as C. difficile associated disease.
- Delivery of antibiotics (over the counter sales in some countries);
- Underdeveloped worldwide antimicrobial stewardship initiatives;
- National coverage/insurance systems in healthcare systems should facilitate access to diagnostics and treatment.

b) What are the main actions that needs to be done -- and who are the main actors/stakeholders who need to take action -- to go beyond the status quo?

- Concentrated actions between human and veterinary international organisations to provide guidelines and participate in prequalification processes;
- Identification, control and tracking of counterfeit antibiotics;
- Surveillance of resistance;
- Point-of-care testing to be used by physicians to confirm infection and prescribe antibiotics only when necessary;
- Microbiology testing (identification and susceptibility testing) to help prescribe antibiotics wisely;
- Regulation of antibiotic prescription and authorisation of prescription access (e.g. distribution);
Advocacy at national government level to implement appropriate healthcare system mechanisms;

Stakeholder collaboration between CDC, WHO/FAO/OIE, national governments, industry (pharmaceuticals and diagnostics), donors and programme implementers;

Coordination with national actors (e.g. in vitro diagnostic associations, medical device associations, patient groups, etc.) in dissemination and media activities.

c) What steps have already been taken to address this priority? (please provide references where possible)

Educational initiatives (see General Question 2 for details);

Implementation of rapid diagnostic testing for biomarkers to guide antimicrobial decision making in primary care—the setting where the majority of antibiotics are prescribed—has seen a reduction in prescription and resistance rates. This approach drives patient understanding and acceptance that antibiotics should not be received unless there is clear evidence demonstrating its requirement.

d) What are concrete and measurable indicators of progress for this priority? (Including, for example, global and national goals to be achieved within 2, 5 and 10 years)

Implementation of rapid testing for C-reactive Protein (CRP) and procalcitonin in primary care for respiratory tract infections can drive down antibiotic prescription by 20-30%13, 14, 15, 16;

Rapid testing in secondary care for S. pneumonia and Legionella;

Improved public awareness of when antibiotics are at their most useful.

IV. Building block-4: Identifying and closing critical gaps in knowledge needed to address AMR

a) What do you consider to be the main issues under this priority?

Lab capacities and trained microbiologists are missing, especially in resource-limited settings. For example, bioMérieux is implementing providing training and educational material, but the lack of skilled people is often blocking the adoption of diagnostic solutions by the labs.


Criteria for recommendations should be clearly defined and homogenous to avoid creating new or divergent interpretations.

b) What are the main actions that needs to be done -- and who are the main actors/stakeholders who need to take action -- to go beyond the status quo?

- Reinforce lab capacities through training and diagnostic toolbox, e.g. training for trainers, adoption of training at national level;
- Support strengthening of labs with funding opportunities;
- Liaise with the Clinical and Laboratory Standard Institute (CLSI) and the European Committee on Antimicrobial Susceptibility Testing (EUCAST) for homogenous recommendation criteria;
- Provide Guidelines, list of products pre-qualified by WHO and objectives especially for resource limited countries;
- Transversal working groups to consider different syndromes (syndromic approach) and simplified guidelines for limited resource settings and centralised labs (provide different scenarios);
- Stakeholder collaboration is needed between CDC, WHO/FAO/OIE, national governments, industries (drugs and diagnostics), donors, programme implementers.

c) What steps have already been taken to address this priority? (please provide references where possible)

- EUCAST and CLSI guidelines;
- Training and educational material developed by companies such as bioMérieux (see General Question 2 for details)

d) What are concrete and measurable indicators of progress for this priority? (Including, for example, global and national goals to be achieved within 2, 5 and 10 years)

Stakeholders might consider the following actions:

- 2 years - provision of harmonised guidelines and a list of pre-qualified products;
- 5 years – tracking of people trained and the number of labs that have implemented microbiology initiatives

V. Building block-5: Developing an innovative and sustainable approach to develop and distribute critical products and technologies needed to address AMR

a) What do you consider to be the main issues under this priority?

- Inadequate access to quality diagnostics in microbiology, e.g. diagnostic test for CRP at the point-of-care in more countries;
• Difficulty in obtaining funding for affordable and accessible product development and procurement especially for resource limited countries;

• Supply chain management of diagnostic products;

• Patchy links between testing and treatment sites.

b) What are the main actions that needs to be done -- and who are the main actors/stakeholders who need to take action -- to go beyond the status quo?

• Define criteria for quality diagnostics through prequalification processes, quality assured products, and quality assurance systems at local level;

• Routine use at country level of point-of-care CRP testing, including programme implementation, reimbursement, education and guidelines;

• Define Target Product Profiles (e.g. under the Trans-Pacific Partnership [TPP]) to support product development especially for resource limited countries and in decentralised use, and allocate related funding;

• Adapt supply chain management and related funding including provision of supply chain specialists for diagnostics, appropriate storage facilities, cold chain management, anticipated global and local forecasts to avoid out-of-stock situations at local level and ensure manufacturers stock availability;

• Availability of treatment at local level;

• Stakeholder collaboration between CDC, WHO/OIE, national governments, industries (mainly diagnostics), donors, programme implementers, CLSI, EUCAST

c) What steps have already been taken to address this priority? (please provide references where possible)

• Pharmaceutical and in vitro diagnostic companies are working closely to develop new diagnostic methods, including companion diagnostics, to supply the development of effective antibiotics (e.g. antibiotic susceptibility testing);

• Point-of-care CRP test are routinely already used to assist prescription decisions in Norway, Sweden, Finland, Denmark, Switzerland and the Netherlands. Recently, the UK National Institute for Health and Care Excellence (NICE) recommended CRP testing to be considered for pneumonia, also determining it to be cost-effective.

d) What are concrete and measurable indicators of progress for this priority? (Including, for example, global and national goals to be achieved within 2, 5 and 10 years)

• 2 years: Publication of criteria for innovative products, TPP

• 5 years: Track the number of quality assured products and publish implantation guidelines
VI. Building block-6: Assessing the long term economic, developmental and social costs and implications of AMR as a basis for sustainable investment and action

a) What do you consider to be the main issues under this priority?

b) What are the main actions that needs to be done -- and who are the main actors/stakeholders who need to take action -- to go beyond the status quo?

- Evaluation should be implemented to review all of the existing publications related to the cost-benefit of limiting the spread of resistance;
- Implementation of health-economic evaluation;
- Allocation of proper funding for product development and long term implementation;
- Collaboration between CDC, WHO/OIE, national governments, industry (mainly diagnostics) donors and programme implementers.

c) What steps have already been taken to address this priority? (please provide references where possible)

- World Forum on Healthcare-associated Infections and Antimicrobial Resistance (see General Question 2 for details)
- Point Prevalence Survey (PPS) (see General Question 2 for details)

d) What are concrete and measurable indicators of progress for this priority? (Including, for example, global and national goals to be achieved within 2, 5 and 10 years)

- 2 years: Review all publications available for assessment;
- Implement health economic evaluation.

Concluding questions

3. What contribution would your organization be able to make in implementing the global action plan?

The MedTech Europe member associations – EDMA and Eucomed – as well as their members can:

- Develop new and innovative diagnostic products to support the diagnosis and prevention of AMR, including rapid diagnostic tests to guide treatment decisions;
- Sharing of best practice examples;
- Provision of educational content through initiatives such as Test Target Treat;
• Investigate the possibility of surveillance software solutions for global consolidation of resistance data;

• Facilitate the implementation of evaluation (alongside key opinion leaders in various countries);

• Share and highlight diagnostic challenges and solutions (e.g. in development, implementation, etc.) by being part of roundtables and stakeholder meetings;

• Share experiences through the World Forum on Healthcare-associate Infections and Antimicrobial Resistance;

• Support lab capacities by making available training tools (e.g. practical guides);

• Collaboration with relevant stakeholders and organisations working in the sphere of combatting antimicrobial resistance.

4. Additional input that you feel would be facilitate development of the GAP.

• Creation of collaborative and sustainable partnerships involving CLSI, EUCAST, industry (pharmaceuticals, diagnostics, mHealth), donors, implementers, key opinion leaders from different regions;

• Identification of plan implementation needs and preparation of product forecasting to ensure manufacturers will answer the existing and anticipated needs;

• Close collaboration with and guidance for the manufacturers to develop innovative and relevant diagnostic products.