Estonian presidency promoting eHealth and mHealth

Stephanie Kohl

The Estonian Council Presidency is due to its focus called a digital presidency. Every aspect of our society is influenced by digital solutions, including our health. Consequently, Estonia will start discussions on the free movement of data in the health sector.

Prior to its presidency, the Government Office of Estonia had commissioned a study 'Mapping out the obstacles of free movement of electronic health records in the EU in light of the digital single market'. The study compares the Estonian eHealth system with five Member States (Finland, Germany, Poland, Sweden and the UK) that were chosen to have a better understanding of the diversity of eHealth systems that are being used in the European Union (EU).

The study mapped the obstacles as well as enablers of movement of health data, including expectations of the population and the patients' possibilities of using their own health data in the surveyed Member States and across borders. In addition, it provided recommendations to overcome the obstacles identified in the study. Overall, the report shows that necessary preconditions for the free and safe movement of health data across the borders of Member States exist in the EU. It concludes that the main barriers for free movement of health data are not information technology (IT) or legislation, but rather so-called soft aspects such as people's attitudes, awareness and cooperation.

Overall, Estonia is of the opinion that calculated use of e-health solutions supports the general targets of the health policies of Member States, so that people will be healthier, and health systems will be sustainable and more manageable. Consequently, its presidency will also focus on eHealth aspects. There are plans to launch a discussion on the promotion of cooperation and coordination on e-health in order to create the necessary preconditions for the wider use and cross-border

movement of health data for the purposes of treatment, research and innovation and to promote data-based innovation in healthcare.

Moreover, it has been acknowledged by the Estonian presidency that due to the increased role of smart devices and mobile applications, a large volume of health and lifestyle data is currently created. An important aspect in this regard is the safe use and the secure sharing of these data. Attention should be paid to the issues of data protection and cybersecurity, so that health data can be used in a safe and secure way and not to be held from use. Estonia is thus planning to discuss eHealth issues with Health ministers at both an informal meeting and at a high-level conference.

'Health in the digital society and the digital society for health' will address how digital technologies and the wider use of health data are changing our lives and also methods of healthcare. Through a combination of educational sessions, interactive workshops and valuable networking opportunities, the conference will showcase already existing digital health solutions and use cases and technologies to demonstrate that citizen-centric health services and systems are genuinely valuable.

It has further been announced that Estonia will be proposing Council Conclusions on digital health for the adoption at the December EPSCO (Employment, Social Policy, Health and Consumer Affairs Council).

FINAL REPORT OF ARNA PROJECT PUBLISHED

The ARNA (antimicrobial resistance and the causes of non-prudent use of antibiotics) project published its final report which estimates that 7% of antibiotics consumed in the EU are taken without a prescription. The report marks the end of the project which overall aimed at assessing the non-prudent use of antibiotics in the EU and encouraging policies that lead to a more prudent use of antibiotics.

The highest rates of non-prescription use of antibiotics were found in Romania (20%) and Greece (16%), while

the use of antibiotics without a prescription increased between 2013 and 2016 in Bulgaria, Cyprus, Croatia, Finland, Germany, Latvia, Lithuania and Poland. Lack of knowledge among patients and pressure on healthcare professionals to provide antibiotics without prescription were highlighted as two key factors contributing to this issue. It was also found that pharmacists in smaller pharmacies seem more likely to dispense antibiotics without a prescription. Countermeasures such as the enforcement of laws banning over the countersales of antibiotics did not seem to always be effective.

The report analysed the non-prescription use of antibiotics and explored good practice initiatives and policy measures enhancing more prudent use of antibiotics. Fourteen EU Member States have already published national action plans addressing antimicrobial resistance (AMR), while 26 have a surveillance system and a set of activities to promote prudent antibiotic use in place. Further efforts to improve patients' education, develop clear guidelines to healthcare professionals and promote a close collaboration between general practitioners and pharmacists are recommended by the report to tackle this issue. In addition, the report calls for multifaceted campaigns implemented at national level as well as better enforcement of laws in EU countries where antibiotics are available over the counter without prescription.

RESPONSES TO CONSULTATION ON EXPERIENCES WITH THE PAEDIATRIC REGULATION RELEASED

Ahead of the 2017 Report on the Paediatric Regulation, the European Commission published the responses to the targeted stakeholder consultation on the experiences acquired with the Paediatric Regulation.

Regulation No 1901/2006 on medicinal products for paediatric use (the Paediatric Regulation) set up a system of requirements, rewards and incentives together with horizontal measures to ensure that medicines are researched, developed and authorised to meet the therapeutic needs of children. It mainly aims at ensuring high-quality research into the development of medicines for children, that the majority of medicines used by children are specifically authorised for such use as well as the availability of high-quality information about medicines used by children. Its text contains an obligation for the European Commission to present reports in 2013 and 2017 to the European Parliament and the Council.

Correspondence to Stephanie Kohl, European Association of Hospital Pharmacists, Boulevard Brand Whitlock 87 Box 11, 1200 Brussels, Belgium; Stephanie.Kohl@eahp.eu

The stakeholder consultation—which was launched in November 2016—aimed at supporting the European Commission in drafting the 2017 Report on the Paediatric Regulation. To this end, the European Commission included several statements reflecting on possible lessons learnt from the application of the Paediatric Regulation in the consultation. These statements built on the 10-year report to the European Commission prepared by the European Medicines Agency (EMA) and its Paediatric Committee, an external study on the Regulation's economic impact, the experience of the European Commission's departments and reflections on the Paediatric Regulation published in the literature and discussed at stakeholder conferences.

Seventy-five stakeholders representing pharmaceutical undertakings, patient organisations, NGOs, as well as public institutions including regulatory agencies and national ministries participated in the consultation. Their responses will now be carefully analysed by the European Commission and considered for the 2017 Report on the Paediatric Regulation. This report will assess the Paediatric Regulation's impact on public health and businesses in order to inform EU decision makers about the experience with the Regulation since its adoption in 2006. European Association of Hospital Pharmacists (EAHP) is among the stakeholders that submitted a response to the consultation.

AMR INITIATIVES ON THE RISE

The launch of the One Health Action Plan by the European Commission coincided with two other developments in the field of AMR, namely the adoption of the first deliverable of the action plan—the EU Guidelines on the prudent use of antimicrobials in human health—and the publication of a study that gives a compelling insight into the current AMR situation in Romania.

EU Guidelines for the prudent use of antimicrobials in human health

The Guidelines for prudent use of antimicrobials in human health issued by the European Commission are based on a proposal prepared by the European Centre for Disease Prevention and Control (ECDC) with input from EU Member States' experts and stakeholders. They complement the guidelines for the prudent use of antimicrobials in veterinary medicine which were released in 2015.

The guidelines aim to reduce inappropriate use and promote prudent use

of antimicrobials in people. They are complementary to infection prevention and control guidelines which may exist at national level. The measures included therein target all actors who are responsible for or play a role in antimicrobial use. Different chapters are addressing national, regional and local governments, healthcare professionals, patients and others who play a role in antimicrobial use. The elements of good practice to be followed by pharmacists include:

- ▶ Dispensing antimicrobials with prescription, unless specific provisions allow for regulated dispensation in specific circumstances;
- ▶ Ensuring that the patient and/or the carer understands the dosage and duration of treatment as this can improve adherence and increase treatment success;
- ▶ Promoting appropriate disposal of leftover antimicrobials;
- ▶ Notifying adverse events related to antimicrobials in accordance with regulations;
- ▶ Participating in local, regional or national public health campaigns promoting the prudent use of antimicrobials;
- ▶ Providing advice to patients and health professionals with regard to contraindications, drug interactions and food–drug interactions.

Besides measures, the guidelines suggest good clinical practices, systems and processes for EU countries to consider when developing and implementing their national strategies. They also include activities that may be taken by international organisations and agencies in support of national strategy development and implementation.

In the red zone

'In the red zone—Antimicrobial Resistance: Lessons from Romania' is a study by the European Public Health Alliance (EPHA) which provides insights into the AMR situation in Romania. It demonstrates the challenges of the Romanian health system in combatting AMR.

The study is based on interviews with experts from healthcare practice and policy in Romania. It discusses how a combination of factors, including inadequate infection control and prevention protocols, lack of human and financial resources for tackling AMR and hospital-acquired infections, and insufficient surveillance data combine to reduce a country's ability to ward off AMR. Bacteria are not contained by borders, therefore AMR is an issue in

Romania and has become a global threat. Consequently, Europe needs to work together in the fight against AMR. Thus, the study also illustrates the urgent need for coordinated, well-resourced and effective EU policy action and programmes to tackle AMR. Based on this report, EPHA makes the following EU policy recommendations:

- ▶ Deploy EU policies and programmes including legislation to reduce drug resistance, reduce excessive antimicrobial use and tackle other causes of AMR across all relevant sectors (human, animal, industrial, environmental);
- ▶ Expand the remit and resources of the ECDC, deepen the country visits and produce tailored targets and recommendations for Member States/regions;
- ▶ Expand ECDC's role in technical cooperation between the EU and Member States on AMR, including the take-up of best practice;
- ▶ Include recommendations in the European Semester as a policy tool to motivate national progress on AMR and healthcare-associated infections (HAI);
- ▶ Design future EU funding opportunities and conditionalities to boost national policy and implementation capacity, improve facilities to tackle AMR and HAIs, for example, use of rapid diagnostic tests, upgrade laboratory equipment, isolation units, and so on;
- ▶ Identify EU experts to train intersectoral 'AMR champions' at national level;
- ▶ Develop a European curriculum for AMR to be integrated into health workers' education programmes.

MEDICINE ACCESS @ POINT OF CARE LAUNCHED

Medicine Access @ Point of Care (MA@POC) is an international, open access, multidisciplinary, peer-reviewed publication targeted mainly to hospital pharmacists, hospital specialists, decision makers and payers dealing with access to medicine in the broadest sense. Due to the high and even increasing global unmet need for access to medicines, the journal will focus on topics dealing with access to medicines in a broad sense including regulatory compliance and counterfeit medicines.

The first issue of MA@POC puts an emphasis on falsified medicines with three articles addressing this topic from different angles. What's in a word? *Falsified/counterfeit/fake medicines—the definition*

debate by Mike Isles attempts to describe the evolution of the definitions of falsified medicine, counterfeit medicine and fake medicine. Moreover, it brings forth the recommendation to form a consensus to describe such medicines that reach the public.

Fighting counterfeit medicines in Europe: the effect on access to medicines by Maarten Van Baelen, Pieter Dylst, Catarina Lopes Pereira, Johan Verhaeghe, Koen Nauwelaerts and Susie Lyddon puts the Falsified Medicines Directive into focus. It addresses the implementation of the Falsified Medicines Directive, and its Delegated Regulation by drawing attention to the benefits and downsides of the European Medicines Verification System. The article highlights the importance of the system for patient safety and raises the question if its implementation could pose a financial burden for manufacturers which in turn may threaten the availability of medicines.

The last article, *Falsified Medicines Directive: are we heading in the right direction?* by EAHP Immediate Past-President Roberto Frontini has a critical look at the topic. It analyses concerns that have arisen from patients regarding the effectiveness of the unique identifier and the antitampering device in terms of safety. In addition, it puts into focus the problems that end-users, such as hospitals and hospital pharmacies, who deal with high amounts of medicines are faced with. As a solution, the paper proposes the endorsement of more Good Procurement Practices and Good Distribution Practices by all pharmacies to prevent falsified medicines from entering into the market.

EMA AND EUNETHTA PRESENT PLAN TO ALIGN DATA REQUIREMENTS

The EMA and the European Network for Health Technology Assessment (EUNETHTA) are stepping up their efforts to provide developers of medicines with simultaneous, coordinated advice on their development plans and facilitate alignment of data requirements. To this end, EMA and EUNETHTA have developed a joint platform which will allow for consultation requests with the EMA and HTA bodies in EU Member States, in both pre and postmarketing research, and will help align evidence requirements among regulators so that companies can generate and deliver a single set of data.

The platform will replace the current framework for seeking parallel scientific

advice which required medicine developers to contact Member States' HTA bodies individually. In accordance with the new procedure, medicine developers will need to inform EMA and EUNETHTA simultaneously of their intention to request parallel advice. The involvement of individual HTA bodies will be coordinated by EUNETHTA after the submission of the request. The main benefits of this new platform will be:

- Increased mutual understanding and problem solving ability through a more structured interaction between EMA and HTA bodies;
- Improved coordination with, and greater participation of, HTA bodies, as a result of the creation of an Early Dialogue Working Party and an Early Dialogue Secretariat at EUNETHTA;
- Streamlined logistics for the requesters.

These advantages are expected to lead to more robust outcomes resulting from the parallel consultation on evidence-generation plans for pharmaceuticals.

COMMISSION RELEASES NEW MEASURES ON AMR

At the end of June, the European Commission published its new One Health Action Plan which provides a framework for future actions against AMR. AMR—the ability of microorganisms to become resistant to an antimicrobial to which they were previously susceptible, rendering the therapy ineffective—has reached alarming levels in many parts of the world. Consequently, the European Commission started taking actions illustrated in the 2001 Communication strategy against AMR and the 2011 Commission Action Plan. The latter ceased to apply at the end of 2016 and will now be replaced by the One Health Action Plan.

The previous action plan, which was evaluated in 2016, acted as a symbol of political commitment, stimulated actions within Member States, strengthened international cooperation and provided a framework to guide and coordinate activities at international level, including monitoring, surveillance as well as research and development. These actions were relevant to address problems identified by the previous action plan in 2011 and still remain relevant today. Consequently, the new Action Plan is built on three main pillars:

- Making the EU a 'best practice region';
- Boosting research, development and innovation on AMR;

► Shaping the global agenda.

The One Health approach taken in the new action plan recognises that human and animal health are interconnected and encompasses the environment.

Each pillar of the One Health Action Plan contains concrete measures that will be undertaken by the European Commission to continue the fight against AMR. By supporting and assisting Member States in the development of national action plans, strengthening the surveillance and monitoring of AMR and increasing public awareness on AMR, the EU should be made a best practice region. Research and innovation will be stimulated by the European Commission through new business models and incentives for sustainable investment. In addition, the One Health Action Plan contains plans for the stimulation of research on new antimicrobial drugs, rapid-diagnostic tests, vaccines and alternatives.

As part of the last pillar, the global presence of the EU should further be heightened by active contributions towards the normative work of the WHO, the World Organisation for Animal Health, and the Food and Agriculture Organisation of the United Nations. Moreover, resources will be invested in the cooperation with developing countries.

Most actions outlined in the new One Health Action Plan can be addressed by adapting and reinforcing existing actions. In addition, the European Commission plans to closely monitor the effectiveness and performance of the key actions taken in accordance with the One Health approach.

The European Commission expressed its confidence in the new Action Plan, as it can make a difference by sharing the EU experience, strategically reinforcing its research agenda and promoting global action. The European Parliament and the Council are invited to endorse this Action Plan. Member States and other actors involved are called on to help ensure that the efforts to counter AMR outlined in the Action Plan are swiftly implemented.

EU COUNCIL PRESIDENCY: THANK YOU MALTA—HELLO ESTONIA

On 1 July, the EU Council Presidency of Malta came to an end and Estonia assumed the Council's rotating presidency. The presidency is responsible for driving forward the Council's work on EU legislation, ensuring the continuity of the EU agenda, orderly legislative processes and cooperation among Member States.

It rotates among the EU Member States every 6 months.

To ensure continuity, Member States holding the presidency work together closely in groups of three, called 'trios'. These trios set long-term goals and a common agenda which stretches over a period of 18 months. A more detailed 6-month programme is prepared by each of the three countries based on the general programme set by the trio. Estonia forms a trio with Bulgaria and Austria. The three countries are planning on 'taking forward the Strategic Agenda'.

The four priorities that are tackled by Estonia centre around an open and innovative European economy, a safe and secure Europe, a digital Europe and the free movement of data as well as an inclusive and sustainable Europe. They fall within Estonia's presidency theme 'unity through balance'. The image on the one hand reflects the need of Europe for unity—in values, ideas and actions. On the other hand, it suggests that a balance must be found between the various opinions, interests and visions of all Member States. The work programme of the incoming presidency that contains information on each of the four priorities focuses largely on driving digital developments forward, in particular those relating to the Digital Single Market.

The work programme does however not contain any details on measures relating to the health sector. Nonetheless, due to the links between the Digital Single Market and eHealth, a high-level conference on health in the digital society and the digital society for health will be organised in October 2017.

The conference will bring together the EU policymakers and Member State ministers responsible for health, patient organisation representatives, national and international IT and healthcare companies, health professionals, healthcare managers, and the research and development sector. Decision makers and stakeholders will be provided with the opportunity to learn about most recent policy and technological developments and to be part of the discussions to shape the roadmap of actions under Digital Single Market strategy in order to achieve full benefits of digital health at the individual and societal levels.

LETTER TO JUNCKER ON THE IMPORTANCE OF EU HEALTH COLLABORATION FOR EUROPE'S FUTURE

On initiative lead by the EPHA and the European Patients Forum, over 30 organisations representing EU health stakeholders joined forces and wrote a letter to Commission President Jean-Claude Juncker highlighting the importance of EU Health Collaboration. The EAHP was among the group of EU health stakeholders that cosigned the letter.

The letter was sent in the context of the European Commission's White Paper that outlines the future of the EU after 2025. It stresses the importance of EU health policies in fostering collaboration on common public health issues within Member States.

The group called for an enhanced EU action in the field of health that brings the EU closer to its citizens, by protecting patients and consumers and improving people's health as well as for EU action on health that fosters cross-country collaboration, integrates the action of Member States and helps them to address the unprecedented challenges we are facing. To achieve this, the authors of the letter are requesting a meeting with Commission President Jean-Claude Juncker to discuss their concerns and ideas regarding a robust EU Health Programme and the leadership of a dedicated Directorate in the European Commission.

COMMISSION WORKING GROUP ON MHEALTH CONCLUDES ITS WORK

The Working Group on mHealth assessment guidelines recently concluded its work with the publication of its final report. The Working Group was established by the European Commission in February 2016 to develop guidelines for assessing the validity and reliability of the data that health apps collect and process. The European Commission selected members representing civil society, research and industry organisations to participate in the group.

Contrary to their mandate, the group could not reach a consensus on a set of guidelines. Difficulties were encountered, since building such a guideline was a much more complex exercise than expected at the beginning of the process. In addition, Group members struggled to determine

criteria that would be fit for purpose for the fast moving and evolving environment in which mHealth is situated. Nonetheless, the Group allowed for valuable exchanges which are captured in its final report summarising the process and the positions from the represented stakeholders. The report outlines on the one hand the different activities undertaken by the Group and highlights on the other hand the different views of the Group members on the criteria for the assessment of apps and data.

Despite the conclusion of the activities of the Working Group on mHealth assessment guidelines, mHealth will remain an important topic in European Commission policy on eHealth, in particular aspects around the validity and reliability of data from mHealth solutions. Thus, the results of the Working Group on mHealth assessment guidelines will be closely associated to the works of the eHealth network subgroup on mHealth which is led by Member States representatives.

In addition, WHO-International Telecommunication Union commenced its activities related to the mHealth Hub, a project funded by the Horizon 2020 programme. The mHealth Hub seeks to develop national mHealth interventions in selected EU Member States to champion the uptake of mHealth and to focus on the foundation and maintenance of a centralised 'Knowledge and Innovations Hub for mHealth' to monitor and enable mHealth adoption and innovation. This should be achieved by fostering research and innovation in mHealth and bolstering policymaking efforts in implementing mHealth strategies tailored to the need of the European countries and regions involved.

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