Commission: communication on the future of digital health

Stephanie Kohl

In a communication that was published at the end of April, the European Commission provided insights on the digital transformation of health and care in the Digital Single Market. Measures identified by the communication aim at increasing the availability of data in the EU and at building on previous initiatives to boost the free flow of non-personal data. This publication basis itself on the result of a public consultation concluded in September 2017.

The initiative by the European Commission, which provides direction for EU-level activities in the field of digital health for the coming years, was welcomed by many stakeholders such as patient and health-care professional associations. Three main areas of action were identified focusing on securing access to health data for citizens, personalised medicine and citizen empowerment with digital tools for user feedback and person-centred care.

Concrete actions for each of the three key areas have been put forward by the European Commission including but not limited to the development of an eHealth Digital Service Infrastructure, the creation of voluntary collaboration mechanisms for health research and clinical practice, the implementation of pilot exercises for rare and infectious diseases as well as the facilitation of the supply and uptake of innovative digital-based solutions for health.

ECDC: TOWARDS ONE HEALTH PREPAREDNESS

The European Centre for Disease Prevention and Control (ECDC) published the results of an expert consultation on One Health preparedness in Europe. The report addresses the challenges of the One Health approach and seeks to identify priority areas for action to help strengthen it. One Health encompasses human and veterinary health as well as the environment.

Consultation participants suggested to reinforce ECDC's role related to information exchange and coordination of surveillance data by improving cooperation

with the European Food Safety Authority (EFSA), supporting the development of One Health action plans at national level, conducting integrated risk assessments and fostering simulation exercises to improve coordination and networking across sectors. A number of additional measures aiming at enhancing the One Health preparedness in Europe were also identified. These recommendations advised to invest into early warning and surveillance and to close research gaps. Moreover, the duplication of efforts should be avoided through better coordination. Communication should be improved to facilitate risk management.

ECDC is currently evaluating how these recommendations can be incorporated in forthcoming actions to encourage cross-sectoral preparedness planning as well as in future annual work plans. Close cooperation with the European Commission, EFSA and WHO is crucial for the implementation of measures that strengthen the One Health preparedness in Europe.

EMA: SUPPORTING MEDICINES FOR CHILDREN IN THE EU

In March 2018, the European Medicines Agency (EMA) conducted a workshop to seek input on the better application of the Paediatric Regulation. This exercise aimed at boosting the development of medicines for children. In the workshop report, EMA summarizes the outcomes of the meeting during which patients and carers, academics, healthcare professionals and pharmaceutical industry representatives as well as clinical trial assessors provided their thoughts about ways to improve the implementation of the Paediatric Regulation.

The workshop participants centred their discussions on five key topics linked to the identification of paediatric medical needs, international cooperation, the timely completion of paediatric investigation plans (PIPs), improving the handling of PIP applications and increasing transparency around paediatric medicines. For each of these topics, different proposals for concrete actions were put forward. The considerations of the workshop participants will be reflected in a new action plan that is currently being developed by the European Commission and EMA. Both institutions plan to share it by mid-2018.

The Paediatric Regulation was adopted to encourage and enable high-quality research into the development of medicines for children. Ten years after its entry into force in 2017, the European Commission conducted a review that showed an increase in medicines for children in many therapeutic areas. The report, however, also revealed that little progress has been made in diseases that only affect children or where the disease shows biological differences between adults and children. For more information on the 10-year report, see the EU Monitor of 7 November 2017.

COST ACTION: SURVEY ON IMPACT OF MEDICINES SHORTAGES ON PATIENTS

European Cooperation in Science and Technology (COST) Action member Darija Kuruc Poje is looking for support to complete her research activity on the impact of medicines shortages on patients for COST Action CA15105—European Medicines Shortages Research Network—addressing supply problems to patients (Medicines Shortages).

Medicines shortages are a global problem that can significantly affect patients. Although the importance of the problem has been identified, no objective data are currently available on the patient's impact. The survey by COST Action CA15105 tries to address this issue by quantifying the impact of medicines shortages at patient level in hospital environment.

Patients are encouraged to share their experience with medicines shortages by completing the short questionnaire via the following link <https://bit.ly/2sRVhFh> by 1 December 2018. Questions in relation to this survey activity can be addressed by email to Darija Kuruc Poje (dakuruc@obkoprivnica.hr).

FIP: PHARMACISTS IN THE SUPPLY CHAIN: THE ROLE OF THE MEDICINES EXPERT IN ENSURING QUALITY AND AVAILABILITY

On 8 May 2018, the International Pharmaceutical Federation (FIP) issued the report 'Pharmacists in the supply chain: the role of the medicines expert in ensuring quality and availability'. In the report, FIP viewed the role of pharmacists in the pharmaceutical supply chains, as inefficient pharmaceutical supply chains were recognised as a contributing factor to the lack of worldwide access to basic life-saving medicines.

The report stresses that the effort to increase the quality and efficacy of supply chains is an important contribution to achieve the United Nations' Sustainable Development Goals and universal health

coverage. The role of pharmacists was analysed with the report providing an overview on the broad and unique competencies of these healthcare professionals that are critical to supply chain integrity. As medicines experts, pharmacists have an essential role to play in the full range of activities of the supply chain.

Furthermore, the report offers a global overview of the roles of pharmacists in different supply chains in low-income, middle-income and high-income countries, and describes their evolution. It does not aim to depict a single system that all countries should strive to incorporate. However, the report highlights the fact that the ultimate goal of all systems should be to ensure efficient supply of quality medicines—offering the right medicine, at the right time, to the right patient. Moreover, it underlines that globalisation has a direct effect on the supply chain itself, adding complexities to that goal. Investments should be made in the education and training of pharmacists to promote their involvement in the supply chain.

Evidence presented in the report was gathered through literature reviews, survey data and case studies of nine countries with different supply chain structures. Next to the recognition of the importance of pharmacists' involvement in the supply chain, a comprehensive and detailed definition of the supply chains together with the integrity of it in relation to global health and descriptions of competencies (both general and pharmacists') are included in the report.

WHO: LIST OF ESSENTIAL DIAGNOSTIC TESTS

WHO published its first ever list of essential diagnostic tests. The document catalogues the 113 most critical categories of diagnostics for common and priority diseases to improve diagnosis and treatment outcomes.

The list of essential diagnostic tests aims at providing guidance and reference to develop and/or update lists of national essential in vitro diagnostics. It was developed through extensive consultation and reviewed by WHO's Strategic Advisory Group of Experts on In-Vitro Diagnostics—a group of 19 experts with global representation. The final document comprises a group of general laboratory tests to be used for common conditions as well as a group of tests designed for the detection, diagnosis and monitoring of 'priority' diseases such as HIV, tuberculosis, malaria, hepatitis B and C, human papillomavirus and syphilis.

Similar to WHO's essential medicines list, which was released in the 1970s and serves

as a reference for health authorities around the world to guide procurement decisions for critical drugs, also the list of essential diagnostic tests will be revised on a regular basis. Future editions of the list of essential diagnostic tests will include antimicrobial resistance, neglected tropical diseases, non-communicable diseases and emerging pathogens. Support will be provided by WHO to countries adapting the list to the local context.

NEWS FROM THE EMA

This month's EMA communications feature recommendations from the Pharmacovigilance Risk Assessment Committee (PRAC) on the suspension of hydroxyethyl starch (HES) solutions for infusion in the EU and measures to minimise risk of rare but serious liver injury with Esmya for fibroids, information about EMA's review of Zinbryta as well as study results on the HIV medicine dolutegravir.

PRAC recommendations

PRAC confirmed the suspension of the marketing authorisations for HES solutions for infusion. This decision was rendered after an additional inquiry by the European Commission following PRAC's initial recommendation issued in January 2018. The European Commission requested PRAC to consider whether suspending the marketing authorisations could result in an unmet medical need. In addition, PRAC was asked to reflect on the feasibility and likely effectiveness of additional risk minimisation measures.

PRAC has completed its review of Esmya (ulipristal acetate), following reports of serious liver injury. After considering all the evidence, it was concluded that the medicine must not be used in women with liver problems and that certain other patients may start new treatment courses provided they have regular liver tests. Temporary recommendations have already been released in February 2018, while the review was still ongoing.

The PRAC's recommendations will now be forwarded to the Committee for Medicinal Products for Human Use for the adoption of EMA's final opinion. After, a final legal decision will be taken by the European Commission.

EMA's review of Zinbryta

PRAC has confirmed that the multiple sclerosis medicine Zinbryta (daclizumab beta) poses a risk of serious and potentially fatal immune reactions affecting the brain, liver and other organs. It is consequently no

longer authorised and has been recalled from hospitals and pharmacies.

Patients could be at risk from the start of treatment and for several months after stopping treatment, and it is not possible to predict which patients will be affected. The PRAC therefore confirmed its previous conclusions that risks of Zinbryta outweigh its benefits for patients with multiple sclerosis. Healthcare professionals should continue monitoring patients who have been treated with Zinbryta in line with recommendations issued in March 2018.

Study results: HIV medicine dolutegravir

The EMA is currently analysing the preliminary results from a study that found four cases of birth defects such as spina bifida (malformed spinal cord) in babies born to mothers who became pregnant while taking dolutegravir. As the evaluation is still ongoing, EMA released the following precautionary advice:

- ▶ Dolutegravir HIV medicines should not be prescribed to women seeking to become pregnant.
- ▶ Women who can become pregnant should use effective contraception while taking dolutegravir medicines.

Women who have been prescribed dolutegravir should not stop taking their medicine without first consulting their doctor. EMA will update the recommendations as necessary when it concludes its assessment.

HAZARDOUS DRUGS: EU EFFORTS FOR THE BETTER PROTECTION OF WORKERS

The better protection of workers from the exposure to hazardous substances is currently high on the European agenda. Initiatives such as the amendment of the Carcinogens and Mutagens Directive and the new campaign of the European Agency for Safety and Health at Work (EU-OSHA) aim at making the EU a safer workplace.

In April 2018, the European Commission released a proposal to amend the Carcinogens and Mutagens Directive. The amendment aims at improving workers' health protection by reducing occupational exposure to five carcinogenic chemical agents, namely cadmium and its inorganic compounds; beryllium and inorganic beryllium compounds; arsenic acid and its salts, as well as inorganic arsenic compounds; formaldehyde; 4,4'-methylene-bis(2-chloroaniline). The Carcinogens and Mutagens Directive contains a number of general provisions to prevent or minimise the exposure for carcinogens and mutagens falling under its scope.

In relation to the proposed amendment, the European Commission highlighted that carcinogenic and mutagenic substances can apart from cancer also cause other important health problems. By putting in place measures to prevent high exposure levels to the five additional substances, the European Commission hopes to address these problems.

The healthy workplace campaign of EU-OSHA, which was also launched in April 2018, aims at tackling the issue of exposure to hazardous substances from a broad angle. The theme of 2018/2019 centres around the management of dangerous substances. During its 2-year operating time, EU-OSHA hopes to draw attention to the issue and to promote the best ways of tackling the risks that dangerous substances pose to workers through a series of events and activities.

The campaign website provides tools and publications that can help to address the exposure to hazardous substances at the workplace. In addition, EU-OSHA encourages the involvement in the campaign through participating in the Healthy Workplaces Good Practice Awards and by taking part in the European Weeks for Safety and Health at Work, which is organised in October each year (calendar week 43).

EUROPEAN COMMISSION COMMUNICATION FOR STRENGTHENED COOPERATION AGAINST VACCINE-PREVENTABLE DISEASES

At the end of April, the European Commission released a communication on strengthened cooperation against vaccine preventable diseases. The communication is covering three pillars—tackling vaccine hesitancy and improving vaccination coverage, sustainable vaccination policies in the EU, and EU coordination and contribution to global health. The communication is only one of the actions the Commission is working on to tackle the issue of decreasing vaccine coverage and trust in vaccines. Other actions include a public consultation, a fact sheet, an informative video and a proposal for a Council recommendation.

The communication issued by the Commission recognises that vaccination has brought immense benefit to the society, as it is one of the most cost-effective public health interventions and the core of prevention programmes all over the world. As per estimations of WHO, today, vaccines save between 1 and

3 million lives every year. In the coming decades, vaccines are projected to save 25 million people more.

However, there are several key challenges to overcome in order to ensure sustainable, equitable and effective vaccination programmes in all member states. One of the biggest ones is vaccine hesitancy, followed by ensuring high vaccine coverage, hindering the spread of vaccine-preventable diseases and more. The need to overcome these challenges is becoming more and more apparent when looking at measles. In 2017, 14 000 cases of measles were recorded in the EU, three times more than in 2016. The root cause of this is a suboptimal vaccine uptake (lower than 95%). The coverage with diphtheria, tetanus and pertussis vaccines is also suboptimal, and fatal diphtheria cases recently reported in the EU have served as a reminder that we are not completely safe from those diseases yet.

The Commission communication also tackles the influenza vaccine, the coverage of which remains below the target of 75% for the population over the age of 65. In older people, influenza can represent a serious threat; however, only one EU Member State has reached the target of coverage.

Each one of the three pillars covered by the Commission communication is split into two sections—key challenges and priority activities. With those, the Commission recognises the key challenges under each pillar, and presents the activities it will take to tackle each of those challenges.

WHO: PATIENT SAFETY CHALLENGE

In spring 2017, the WHO launched a new initiative—the Global Patient Safety Challenge on Medication Safety—seeking to halve avoidable medication-related errors over the next 5 years.

Mistakes in ordering, prescribing, dispensing, preparing, administering or consuming the wrong medicine can be made by both health workers and patients. Such mistakes could however be avoided through systems and procedures which ensure that the right patient receives the right medication at the right dose via the right route at the right time. Consequently, the WHO initiative calls on countries to take early priority action addressing system failures in the way care is organised and coordinated.

The Challenge is coordinated by the WHO Patient Safety and Quality Improvement unit, of the Service Delivery and Safety department, in collaboration with WHO department of Essential Medicines and

Health Products. Support will be provided by WHO in the following 10 key areas:

1. Lead the process of change and take global action to make progress on the domains of the Challenge framework.
2. Facilitate the development and implementation of country programmes.
3. Commission expert reports to provide a starting point for in-country work to develop guidance and action plans in each of the domains of the Challenge.
4. Develop strategies, guidelines, plans and tools to ensure safety of medication practices.
5. Publish a strategy setting out research priorities and mobilise resources for an international research study on hospital admissions due to medication effects.
6. Hold regional launch events in each WHO region following on from the global launch.
7. Create and implement a communications and advocacy strategy and a global campaign and produce promotional and educational materials.
8. As part of the WHO Patients for Patient Safety programme, ensure that patients and families are closely involved in all aspects of the Challenge and develop a tool to help patients protect themselves from harm.
9. Monitor and evaluate impact of the Challenge.
10. Mobilise resources to enable full and successful implementation of the Challenge.

Healthcare professional societies together with other groups, including but not limited to Ministries of health and health system leaders, educational and research institutions, regulatory authorities, patient advocacy groups and the pharmaceutical industry, are encouraged to support the action by acting as catalysts for change.

Section 6: Education and Research

Funding None declared.

Competing interests None declared.

Patient consent Not required.

Provenance and peer review Commissioned; internally peer reviewed.

© European Association of Hospital Pharmacists 2018. No commercial re-use. See rights and permissions. Published by BMJ.

To cite Kohl S. *Eur J Hosp Pharm* 2018;**25**:228–230.

Eur J Hosp Pharm 2018;**25**:228–230.
doi:10.1136/ejhp-2018-001634