European Directorate for the Quality of Medicines: automatic drugs dispensing report

Stephanie Kohl

The European Directorate for the Quality of Medicines (EDQM) released automated dose dispensing (ADD) guidelines. Their content was agreed on during an open consultation involving stakeholders, which was held this past year and concluded on February 2017. Overall, the ADD guidelines aim at harmonising the standards and approaches to ADD across Europe for the safe supply of medicines to patients.

The ADD guidelines, published this year, have been developed by a working group of experts from industry, academia, pharmacy and government from across the region of the Council of Europe. These guidelines harmonise the standards and approaches to automated dose dispensing across Europe and are intended to be used by pharmacies and manufacturers involved in automated dose dispensing, as well as by national authorities in countries where this service is provided. They include standards regarding the ADD sites and operations, as well as patient care activities associated with the ADD process.

The guidelines include detailed instructions on issues such as product liability and ADD suitability information from manufacturers, responsibility and training of personnel, traceability of medicinal products, suitable packaging materials for ADD, stability of medicinal products, automated dose dispensing process and many other aspects related to ADD. Finally, the report encourages national governments to establish legal frameworks and develop standards or guidance to support the regulation of ADD.

NEW EUROPEAN COMMISSION'S DIRECTORATE GENERAL FOR HEALTH AND FOOD SAFETY STUDY CAPITALISING ON EXISTING INITIATIVES FOR COOPERATION IN CROSS-BORDER REGIONS

The European Commission's Directorate General for Health and Food Safety has

released a study mapping the state of play and optimal ways forward for building cooperation in cross-border healthcare (CBHC). It maps EU-funded cooperation projects for the period 2007–2017 in EU and EEA countries and Switzerland; provides insight into opportunities and challenges for cross-border cooperation in healthcare and offers guidance to local and regional authorities and other parties who are interested in starting a health-related cooperation project. The findings will provide input into the report on the operation of the Cross-border Healthcare Directive, which will be published later this year.

Based on the data analysed, the study gives some recommendations for those interested in starting a health-related cooperation project. These include economically supporting key players in order to reduce transaction costs, taking into account the limitations of regional networks and understanding that high-cost capital investments and emergency care tend to have more discernible economic and social benefits, but require more formalised terms of cooperation. The report also points out that the top categories of CBHC initiatives that have received EU funding over the past 10 years are knowledge-sharing and management, shared treatment and diagnosis of patients.

WHO: WORLD LEADERS JOIN NEW DRIVE TO BEAT NON-COMMUNICABLE DISEASES

WHO has announced the constitution of a new high-level commission comprising the heads of state and ministers, leaders in health and development and entrepreneurs, with the objective of finding innovative solutions for the prevention and control of non-communicable diseases (NCDs), such as heart and lung disease, cancers and diabetes.

According to WHO, NCDs are the world's leading avoidable killers, accounting to 7 out of 10 deaths, and >15 million between the ages of 30 and 70 years die from NCDs every year. This shows not enough is being done to

prevent and control them, as for the first time in history, more people are dying of NCDs than from infectious diseases. In combating NCDs, the World Health Assembly has endorsed WHO cost-effective interventions to prevent or delay most premature NCD deaths, with the objective of scaling up these actions in countries while raising awareness.

The high-level commission will run until October 2019 and will provide actionable recommendations to contribute to the Third United Nations General Assembly High-level Meeting on NCDs scheduled for the second half of 2018. The first report on the proceedings will be published in June 2018.

EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL, EUROPEAN FOOD SAFETY AUTHORITY REPORT: ANTIMICROBIAL RESISTANCE IN ZOONOTIC BACTERIA STILL HIGH IN HUMANS, ANIMALS AND FOOD

The European Centre for Disease Prevention and Control and the European Food Safety Authority have published a summary report on antimicrobial resistance in zoonotic bacteria. The report which touches on humans, animals and food highlights emerging issues and confirms the threat that antimicrobial resistance poses to public health.

Zoonoses infections are transmissible between animals and humans, via direct infection from animals or ingestion of contaminated food. The report focuses on antimicrobial resistance of *Salmonella*, *Escherichia coli* and methicillin-resistant *Staphylococcus aureus*, and provides details on multidrug resistance, as well as complete susceptibility and combined resistance patterns in both human and animal isolates at the EU level and country level.

The findings of the report highlight that *Salmonella* bacteria cause one out of four infections in humans, which show resistance to three or more antimicrobials commonly used in human and animal medicine. The resistance levels of *Campylobacter* bacteria, which are responsible for the most common food-borne disease in the EU, also increased in two of the three analysed antibiotics. Extended-spectrum β -lactamase (ESBL)-producing *Salmonella* Kentucky with high resistance to ciprofloxacin—that cannot be treated with critically important antibiotics—was found for the first time in four countries.

According to Directive 2003/99/EC on the monitoring of zoonoses and zoonotic

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agents, Member States (MSs) are obliged to monitor and report antimicrobial resistance (AMR) in *Salmonella* and *Campylobacter* isolates obtained from healthy food-producing animals and from food. Commission Implementing Decision 2013/652/EU of 12 November 2013 sets up priorities for the monitoring of AMR from a public health perspective, drafts a list of combinations of bacterial species, food-producing animal populations and foodstuffs and lays down detailed requirements on the harmonised monitoring and reporting of AMR.

WHO: 12 EUROPEAN COUNTRIES COMMIT TO GREATER EFFORTS TO PROTECT PEOPLE FROM VACCINE-PREVENTABLE DISEASES

On 20 February 2018, health ministries from 12 south-eastern European countries met in Podgorica, Montenegro to endorse the need to speed up progress towards the goals and strategic objectives of the European Vaccine Action Plan 2015–2020 (EVAP). The EVAP was made to complement the Global Vaccine Action Plan on a European level, parallel to Health 2020 and other regional health strategies and policies. It sets goals for immunisation and control of vaccine-preventable diseases.

The health ministries agreed to a tailored roadmap focusing on common challenges and opportunities to increase individual and community protection against diseases like measles, rubella, diphtheria and others. They also called on WHO to: propose options for the joint procurement of vaccines, support capacity-building on resource mobilisation for sustained financing of immunisation programmes, establish a subregional centre on vaccine demand and strengthen the role and responsibilities of the National Immunization Technical Advisory Groups. Additionally, the ministerial meeting focused on priority topics for south-eastern Europe, such as integrating immunisation programmes into strong health systems by coordinating with other programmes, the private sector, partners and communities.

The outcomes from the Montenegro meeting will feed into the discussion on the mid-term progress review of the EVAP, to be held at the 68th session of the WHO Regional Committee for Europe in September 2018.

There is an ongoing public consultation by the European Commission on strengthened cooperation against vaccine preventable diseases, which is open for input until

15 March 2018. Citizens, administrations, associations and other organisations with an interest in vaccination and health policy can participate in this consultation. Its results will feed into the Council Recommendation on Strengthened Cooperation against Vaccine Preventable Diseases.

COMMISSION SYNOPSIS REPORT: 'TRANSFORMATION HEALTH AND CARE IN THE DIGITAL SINGLE MARKET'

The European Commission has released the summary results of the consultation on the transformation of health and care in the Digital Single Market. The public consultation on transformation of health and care in the Digital Single Market investigated the need for policy measures that will promote digital innovation for better health and care in Europe. The results will feed into a new policy Communication by the European Commission.

A total of 1400 people participated in the consultation, and their overwhelming response, with over 93% of respondents agreeing, was that they would like patients to be able to manage their own health-related data. Also, 83% of respondents believe the interoperability of data throughout the EU MSs and digital innovation would improve patient safety.

The main obstacles to the realisation of this cooperation, according to the respondents, are the risks regarding privacy breaches, cybersecurity risks, lack of infrastructure, lack of awareness and legal restrictions within MSs. As a way to overcome these barriers, many respondents believe it is important to support health-care professionals, and 64% expressed their support for developing cross border infrastructure in order to pool access to health data and scientific expertise across the EU.

On the basis of the responses received as well as from input gathered through the eHealth Network, the Council Conclusions on Health in the Digital Society, eHealth Stakeholder Group, the Workshop on GDPR implementation and health data, the European Commission drew five conclusions. In accordance with these conclusions, the European Commission should work on:

1. Enabling citizens to use and have access to data concerning health across borders;
2. Ensuring that data security and privacy remains a key concern;
3. Lowering barriers, such as the lack of interoperability and the lack of heterogeneity of electronic health record (EHR) systems;

4. Developing actions to minimise barriers relating to health data access and sharing;
5. Addressing the low level of adoption of digital health solutions in healthcare.

COMMISSION EXPERT PANEL PUBLISHES THREE OPINIONS TO HELP GUIDE POLICY MAKERS

The expert panel on effective ways of investing in health of the European Commission has adopted three opinions related to access to healthcare, innovative payment models for high-cost innovative medicines and performance of primary care. The expert panel provides advice in the form of opinions in response to questions submitted by the European Commission, with the aim of supporting EU countries in delivering high-quality care and making their health systems more effective, accessible and resilient.

The *opinion on innovative payment models for high-cost innovative medicines* explores possible new ways of setting prices for specialty medicines by improving access, setting out some broad principles to guide the definition of specific payment models. These include greater price and cost transparency, looking at patent law and market exclusivity rules to promote and reward high-value innovations and developing and using methods to measure the social value of pharmaceutical products, such as in the context of health technology assessment (HTA).

The *opinion on benchmarking access to healthcare in the EU* is based on the data from the EU annual Survey of Income and Living Conditions, drawing attention to evidence of relatively high rates of unmet healthcare needs in some EU countries. The panel proposes a mechanism for setting an ambitious but achievable target for unmet needs based on the median achievements of the best performing MSs and advises on how to identify the distribution of unmet needs and how to address challenges by mobilising resources available at national and European level.

The *opinion on tools and methodologies for assessing the performance of primary care* translates multiple dimensions into comparative key indicators, and descriptive additional indicators, related to the 10 identified domains of primary care. It also sets out some procedural steps necessary for a performance assessment system, including multidimensionality, shared design, evidence-based benchmarking of results, timeliness and transparent disclosure. Finally, it recommends some criteria to ensure relevant performance indicators

are selected, for example, alignment of indicators with objectives of the health system, ability to routinely collect the indicator, the validity and reliability of information. The opinion will feed into the work of the MSs' group on Health Systems Performance Assessment on primary care, which will publish in the first quarter of 2018 a report on measuring primary care.

FALSIFIED MEDICINES DIRECTIVE: THE 1-YEAR COUNTDOWN HAS STARTED

The European Commission released a report on the transposition of part of the Falsified Medicines Directive (FMD) (2011/62/EU) as well as an updated version of the question and answer (Q&A) document on safety features concerning falsified medicines. The report analyses how MSs have implemented the article, which mandates the adoption of proportionate, effective and dissuasive penalties for those involved in the production and circulation of falsified medicines.

The FMD strengthens good distribution practices and requirements for wholesale distributors, reinforces rules on importation, controls and inspections of active substances and their manufacturers and establishes an EU-wide logo to allow the identification of legal online retailers of medicines. Part of these provisions have been applicable since 2013. In addition, the FMD introduces mandatory safety features on prescription medicines. Details on the rules for the safety features appearing on the packaging of medicinal products for human use have been laid down in a Delegated Regulation (2016/161), which will be applicable from 9 February 2019 onwards.

The report of the Commission indicates that MSs have adopted a wide variety of penalties, ranging from 1 year (Sweden, Finland and Greece) to 15 years (Austria, Slovenia and Slovakia). Similarly, also the levels of fines differ from country to country, starting at €4300 in Lithuania and going as high as an unlimited amount in the UK. The report deems the measures adopted by MSs satisfactory. Nonetheless, it suggested to consider the introduction of additional criminal penalties or administrative sanctions in relation to falsified medicines, active substances or excipients to strengthen the overall effectiveness of the measures taken.

Moreover, the European Commission has published an updated version of the Q&A on safety features concerning falsified medicines. Version 9 of the Q&A document addresses in addition to general questions, enquiries relating to the

technical specifications of the unique identifier, verification and decommissioning activities and the repository system.

To assist hospital pharmacists and hospitals with the implementation of the Delegated Regulation the European Association of Hospital Pharmacists (EAHP), the European Hospital and Healthcare Federation and the European Medicines Verification Organisation have set up a hospital platform on European level that looks into the development of communication strategies and the collection and sharing of best practices in order to better understand and solve common issues in the hospital sector.

COST: ARTICLE ON PREVENTIVE AND MITIGATING MEASURES FOR DRUG SHORTAGES

A recent research article published by members of the European Cooperation in Science and Technology (COST) Action 15105 titled 'Systemic Measures and Legislative and Organizational Frameworks Aimed at Preventing or Mitigating Drug Shortages in 28 European and Western Asian Countries' signals the need for developing specific definitions of drug shortages, along with methodologies for their monitoring and evaluation. The article points out that WHO and the European Medicines Agency should take the lead in this endeavour, involving pharmaceutical policy researchers and professionals in order to reach an agreed definition, to be used on an international scale.

The article has been produced by members of the COST Action CA 15105 on European Medicines Shortages Research Network—addressing supply problems to patients. COST is the longest-running European framework supporting transnational cooperation among researchers, engineers and scholars across Europe. COST Actions are bottom-up science and technology networks, open to researchers and stakeholders with a duration of 4 years. They are active through a range of networking tools, such as workshops, conferences, training schools, short-term scientific missions and dissemination activities.

The report analyses worldwide experiences and studies on medicine shortages, drawing comparisons from case studies and conducting a survey regarding the general characteristics of drug shortages, alertness and information systems linked to drug shortages, public service obligations and regulations associated with the problem of drug shortages. It

presents innovative initiatives and identifies lingering obstacles in addressing supply problems to patients, while encouraging information-sharing and research as the way forward.

WHO: MEDICATION WITHOUT HARM CHALLENGE

WHO is working on a global initiative with the aim of reducing severe, avoidable medication-associated harm worldwide by 50% over the next 5 years. Medication errors can result from health worker fatigue, overcrowding, staff shortages, poor training and the wrong information being given to patients.

The Global Patient Safety Challenge on Medication Safety campaign aims to engage key stakeholders in the development and implementation of strategies for medication safety, following the call for action 'Know. Check. Ask'. The campaign encourages both patients and healthcare professionals (eg, nurses, physicians, (hospital) pharmacists) to take an active role in ensuring safer medication practices and medication use processes including prescription, preparation, dispensing, administration and monitoring.

The actions planned in the Challenge address four themes: patients and the public; healthcare professionals; medicines as products and systems and practices of medication.

This challenge is WHO's third global patient safety challenge, following the Clean Care is Safe Care challenge on hand hygiene in 2005 and the Safe Surgery Saves Lives challenge in 2008.

EUROPEAN COMMISSION: LEGISLATIVE PROPOSAL FOR HEALTH TECHNOLOGY ASSESSMENT

The European Commission has issued a legislative proposal for HTA, in order to optimise the use of resources by MSs and reduce the administrative burden for health technology developers. Under the proposal, a pan-European body will be created, funded by the EU budget, which will coordinate national HTA work beyond 2020.

HTA measures the added value of a new health technology compared with existing ones. Examples of health technologies include medicinal products, medical equipment, diagnostic and treatment methods, rehabilitation and prevention methods.

The proposed Regulation on HTA aims to ensure a better functioning of the internal market, by improving business predictability and reducing the

duplication of efforts. It also tries to heighten the human protection level by improving the availability of innovative health technologies for EU patients and promoting the convergence of HTA tools, procedures and methodologies, thus ensuring long-term sustainability of EU HTA cooperation. The scope of the proposal applies to new medicines and certain new medical devices. Four main areas of cooperation are:

1. Joint clinical assessments focusing on the most innovative health technologies with the most potential impact for patients;
2. Joint scientific consultations, whereby developers can seek advice from HTA authorities;
3. Identification of emerging health technologies to identify promising technologies early;
4. Continuing voluntary cooperation in other areas are mentioned by the proposed Regulation.

The proposal will now be discussed by the European Parliament and the Council of Ministers. After its adoption and entry into force, the new rules would be slowly phased-in over a 3-year period. On the

one hand, this would allow MSs to adapt to the new processes. On the other hand, it would be ensured that the implementation of the Regulation on HTA does not interfere with the implementation of the Regulations on medical devices and in vitro diagnostic medical devices.

WHO: HIGH LEVELS OF ANTIBIOTIC RESISTANCE FOUND WORLDWIDE, NEW DATA SHOW

New surveillance data on antibiotic resistance has revealed high levels of resistance to various bacterial infections in both high-income and low-income countries. The WHO's new Global Antimicrobial Surveillance System (GLASS) signals a widespread occurrence of antibiotic resistance among half a million people with suspected bacterial infections across 22 countries. To date, 52 countries are participating in the GLASS (25 high-income, 20 middle-income and 7 low-income countries). There are some obstacles in obtaining data, as some of the participating countries face major challenges in building their national surveillance systems, including a lack of personnel, funds and infrastructure.

However, WHO is supporting more countries to set up national antimicrobial resistance surveillance systems that can produce reliable, meaningful data. GLASS is helping to standardise the way that countries collect data and enable a more complete picture about antimicrobial resistance patterns and trends.

Dr Tedros Adhanom Ghebreyesus, WHO's Director-General, is aiming to make antimicrobial resistance one of WHO's top priorities by bringing together experts working on this issue under a newly created strategic initiatives cluster.

Section 6 Education and Research

Competing interests None declared.

Provenance and peer review Commissioned; internally peer reviewed.

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To cite Kohl S. *Eur J Hosp Pharm* 2018;**25**:169–172.

Eur J Hosp Pharm 2018;**25**:169–172.
doi:10.1136/ejhp-2018-001585