EU NEWS

European Parliament adopts report on medicines shortages

Stephanie Kohl

During the September plenary session, more than 90% of the Members of the European Parliament supported the ‘Resolution on the shortage of medicines – how to address an emerging problem’, calling for a more self-sufficient Union when it comes to medicines and medical equipment and the provision of affordable treatments for all European patients.

Together with the Association of European Cancer Leagues (ECL), the European Public Health Alliance (EPHA), France Assos Santé and Prescrire, EAHP has put together a common note to remind European policy makers that

shortages of medicines entail considerable risks for the health and safety of patients, the interests of whom must always come first in any policy aimed at fighting this global threat. Given the richness of the European Parliament Resolution, EAHP and the other four organisations picked up on a number of important points that should be prioritised, including but not limited to carrying out a European study on the impact of shortages on patient care; clarifying the supply and notification obligations for market authorisation holders and wholesalers under Directive 2001/83/EC and imposing dissuasive and proportionate sanctions in the event of non-compliance with these legal obligations; setting up a centralised digital platform for declaring available stocks

in the EU and for reporting shortages, including real-time communication to healthcare professionals and patients as well as encouraging the implementation of procurement procedures that award a contract to multiple winners.

Aida Batista, EAHP Vice President and Board lead responsible for the topic of medicines shortages, welcomed the adoption of the Resolution on 17 September by the European Parliament and highlighted the importance of this initiative for patients and healthcare professionals. She stressed that “Unlike mentioned in the title of the report, the problem of shortages is not an emerging problem. It has grown for over 10 years and significantly impacts patient care. For EAHP it is thus of uttermost importance that the calls to action raised in the ‘Resolution on the shortage of medicines – how to address an emerging problem’ are implemented in a timely manner. EAHP and its members are committed to continue their work linked to medicines shortages and support European action on this issue”.

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WORLD ANTIMICROBIAL AWARENESS WEEK IS APPROACHING

In mid-November, the WHO will be celebrating the World Antimicrobial Awareness Week. The 2020 edition will be held from 18 to 24 November to increase awareness of global antimicrobial resistance (AMR) and to encourage best practices exchange among the general public, health workers and policy makers to avoid the further emergence and spread of drug-resistant infections. The European Antibiotic Awareness Day (EAAD) falls within this week and will be celebrated, like every year, on 18 November.

Following a stakeholder consultation meeting in May 2020 organised by the Tripartite Organisations, comprised out of the Food and Agriculture Organisation of the United Nations (FAO), the World Organisation for Animal Health (OIE) and WHO, the scope of the week was expanded from antibiotics to antimicrobials. With this change in scope WHO hopes to facilitate a more inclusive global response to AMR and to support a multisectoral One Health Approach with increased stakeholder engagement. The slogan for the World Antimicrobial Awareness Week in 2020 will be “Antimicrobials: handle with care” and the theme for the human health sector will be “United to preserve antimicrobials”. The European Centre for Disease Prevention and Control (ECDC) is currently preparing for the 2020 edition of the EAAD and will release further information in the coming weeks.

NEW EP RESOLUTION TO TACKLE PHARMACEUTICAL POLLUTION

During the plenary session in September, the European Parliament approved a Resolution on a strategic approach to pharmaceuticals in the environment. The document comments on the serious delay in sharing concrete actions after the publication of a European Commission Communication on a European Union Strategic Approach to Pharmaceuticals in the Environment in spring 2019 and calls for the more careful use of medicines, the development of greener manufacturing and better waste management in the EU.

The Members of the European Parliament acknowledged in their Resolution that pharmaceutical products both harm ecosystems and reduce their future effectiveness, in particular by causing antibiotic resistance. Due to concerns on the ever-growing overall consumption of medication per capita in the EU, they call on the EU Member States to share best practices in limiting preventive use of antibiotics and in disposing of

unused medicines. They encourage pharmacists, doctors and veterinarians to provide information on how to properly dispose of unused medicines. The resolution also underlines the need for further development of “greener pharmaceuticals”, which are as effective for patients, but less harmful to the environment.

EMA PUBLISHES BIG DATA STEERING GROUP WORKPLAN FOR 2020–21

The European Medicines Agency (EMA) announced in mid-September the publication of the workplan for the Big Data Steering Group which has been set up by EMA and the Heads of Medicines Agencies (HMA). It sets out actions to be delivered in 2020–21.

With the European Medicines Regulatory Network focused on the response to the COVID-19 pandemic, the workplan aims to progress evolution to data-driven regulation through smart working, leveraging collaboration with stakeholders and the use of remote expert workshops. In the past 3 years, EMA and HMA have led a thorough assessment of the challenges and opportunities posed by big data in medicines regulation. This culminated in January 2020 with the publication of recommendations for regulators to evolve their approach to data use and evidence generation. Following this preparatory work, the Big Data Steering Group was established in February 2020 to advise the EMA Management Board and HMA on implementing ten priority recommendations. Its first workplan aims to increase the utility of big data in regulation from the quality of data through study methods to assessment and decision-making. It foresees closely involving patients and is guided by advances in science and technology. Other stakeholders will also be involved and the workplan intends to leverage international collaboration. Stakeholders will have the opportunity to discuss the workplan and its implementation in the context of a virtual multi-stakeholder forum scheduled for late 2020.

Big data are extremely large, rapidly accumulating datasets captured across multiple settings and devices, for example through wearable devices and electronic health records. Coupled to rapidly developing technology, big data can complement the evidence from clinical trials and fill knowledge gaps on a medicine, and help to better characterise diseases, treatments and the performance of medicines in individual healthcare systems. The rapidly changing data landscape forces regulators to evolve and change the way they

access, manage and analyse data and to keep pace with the rapid advances in science and technology.

The work carried out by the Big Data Steering Group builds on the Regulatory Science Strategy to 2025, published in March 2020, and will support the European Medicines Agencies Network Strategy to 2025, currently under development. Since the European Medicines Regulatory Network has to prioritise the unprecedented public health challenge of the COVID-19 pandemic, the implementation of the Big Data Steering Group workplan will need to be flexible and certain actions may need to be re-scheduled depending on the development of the pandemic.

WEBINAR: PRACTICAL EXAMPLES OF CLINICAL AND HOSPITAL PHARMACY SERVICES FOR COVID-19 PATIENTS

Earlier this year, EAHP and the European Society of Clinical Pharmacy (ESCP) collected inspiring examples of clinical and hospital pharmacy services for COVID-19 patients (read more about this initiative in the EU Monitor of 26 May). On 29 October, selected examples were presented in a webinar focusing on COVID-19 pharmaceutical care delivered in hospitals. The webinar is part of series hosted by ESCP, also including two other online events covering biosimilars and DOACs. The latter one will be held on 19 November 2020.

QUESTIONNAIRE ABOUT THE WORKING SITUATION FOR HEALTHCARE PROFESSIONALS AND TREATMENT EFFECTS OF THE PANDEMIC IN DIFFERENT COUNTRIES

EAHP has teamed up with its colleagues from the European Society of Oncology Pharmacy (ESOP) to gain more insights on the situation of cancer patients during the COVID-19 pandemic. Building on the success of its weekly surveys, which were completed by pharmacists from 63 countries, ESOP has put together a structured approach to collect further perceptions and facts about the pandemic on a monthly basis.

In April, ESOP had started to put together weekly member situation reports focusing on the number of COVID-19 patients, shortages experienced and the impact on cancer treatments. Over the summer these weekly updates were transformed into a monthly survey exercise that will be carried out between September 2020 and February 2021. The questionnaire is available in German, English, French, Spanish, Russian, Italian and Bosnian. Hospital pharmacists are encouraged to contribute.

CELEBRATION OF THE WORLD PHARMACIST DAY

Every year on 25 September, the pharmacy community brings attention to the positive benefits offered by pharmacists around the globe when it comes to health. Established by the International Pharmaceutical Federation (FIP), the World Pharmacist Day boosts the organisation of activities that promote and advocate for the role of the pharmacist linked to this year's theme "Transforming global health". EAHP encouraged its member organisations to participate actively by communicating how hospital pharmacists are transforming health through a variety of health services.

ONLINE DEBATE: PATIENT SAFETY AND THE IMPLEMENTATION OF FMD IN THE HOSPITAL ENVIRONMENT

On 30 September the European Alliance for Access to Safe Medicines (EAASM), in collaboration with the European Union of Private Hospitals (UEHP) and the European Health Management Association (EHMA), organised a virtual event on "Patient safety and the implementation of the Falsified Medicines Directive in the hospital environment". András Süle, EAHP's President-Elect, shared the Association's views on the implementation of the Falsified Medicine Directive (FMD). Hosted by Member of the European Parliament Manuel Pizarro, the 2 hour online event brought together representatives from the European Medicines Verification Organisation (EMVO), Be4ward, the Finnish Medicines Verification Organisation, the East and North Hertfordshire NHS Trust in the UK and the pharmacy of the Rouen University Hospital in France who exchanged on FMD implementation and its impact on patient safety.

UPDATES FROM THE EUROPEAN MEDICINES AGENCY

The European Medicines Agency (EMA) published new communications on the revocation of the marketing authorisation of ulipristal acetate for uterine fibroids and the use of dexamethasone in COVID-19 patients on oxygen or mechanical ventilation.

PRAC recommends revoking marketing authorisation of ulipristal acetate for uterine fibroids

A review by EMA's safety committee (PRAC) has confirmed that 5 mg ulipristal acetate (Esmya and generic medicines) used for the treatment of symptoms of uterine fibroids can cause liver injury, including the need for liver transplantation. The

PRAC has therefore recommended the revocation of the marketing authorisation of these medicines.

The PRAC considered all the available evidence in its review, including reported cases of serious liver injury. Patient and healthcare professional representatives, including experts in gynaecology, were also consulted. Since it was not possible to identify which patients were most at risk or measures that could reduce the risk, the PRAC concluded that the risks of these medicines outweighed their benefits and that they should not be marketed in the EU.

The use of 5 mg ulipristal acetate medicines for uterine fibroids had already been suspended as a precautionary measure while awaiting the outcome of this review. Ulipristal acetate is also authorised as a single-dose medicine for emergency contraception. This recommendation does not affect the single-dose ulipristal acetate emergency contraceptive (ellaOne and other trade names) and there is no concern about liver injury with these medicines. The PRAC recommendation will now be forwarded to EMA's human medicines committee (CHMP), which will adopt the Agency's opinion.

EMA endorses the use of dexamethasone in COVID-19 patients on oxygen or mechanical ventilation

EMA's human medicines committee (CHMP) has completed its review of results from the RECOVERY study arm that involved the use of the corticosteroid medicine dexamethasone in the treatment of patients with COVID-19 admitted to hospital, and has concluded that dexamethasone can be considered a treatment option for patients who require oxygen therapy (from supplemental oxygen to mechanical ventilation).

Based on the review of available data, EMA is endorsing the use of dexamethasone in adults and adolescents (from 12 years of age and weighing at least 40 kg) who require supplemental oxygen therapy. Dexamethasone can be taken by mouth or given as an injection or infusion (drip) into a vein. In all cases, the recommended dose in adults and adolescents is six milligrams once a day for up to 10 days.

Published data from the RECOVERY study show that, in patients on invasive mechanical ventilation, 29% of those treated with dexamethasone died within 28 days of starting dexamethasone treatment compared with 41% of patients receiving usual care, with a relative reduction of about 35%. In patients receiving oxygen without mechanical ventilation, the figures were 23% with dexamethasone

and 26% with usual care, with a relative reduction of about 20%. No reduction in the risk of death occurred in patients who were not receiving oxygen therapy or mechanical ventilation. These results were supported by additional published data, including a meta-analysis conducted by the WHO which looked at data from seven clinical studies investigating the use of corticosteroids for the treatment of patients with COVID-19. Companies that market dexamethasone medicines can request this new use to be added to their product's license by submitting an application to national medicines agencies or to EMA.

For more information please visit EMA's website at <https://www.ema.europa.eu>.

WHO'S EUROPEAN PROGRAMME OF WORK ADOPTED

In mid-September, the WHO's European Region shared its 5 year vision with ministers and public health officials from over 50 European countries. All endorsed the ambitious plan for "United Action for Better Health in Europe" which is aligned with the Sustainable Development Goals and the WHO's general programme of work for 2019 to 2023.

The European Programme of Work (EPW) was developed in close collaboration with all countries of the region and takes into account the impact that the COVID-19 crisis had and still has on the health systems across Europe. Its core priorities will focus on

- ▶ guaranteeing the right to universal access to quality care without fear of financial hardship;
- ▶ protecting against health emergencies; and
- ▶ building healthy communities, where public health actions and appropriate public policies secure a better life in an economy of well-being.

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