EU NEWS

What will the new European Commission deliver in the field of health?

Stephanie Kohl

The Commission of Ursula von der Leyen was supposed to start its work on 1 November 2019. However, due to the rejection of three candidate-Commissioners by Members of the European Parliament, von der Leyen's Commission is picking up its activity with a one-month delay. Unlike some of her fellow Commissioners, Stella Kyriakides the designate for the areas health and food safety has passed her hearing in the European Parliament with flying colours.

Following Kyriakides' hearing on 1 October, the Environment, Public Health and Food Safety (ENVI) Committee of the European Parliament has voiced its agreement with the Cypriot becoming the EU's next Commissioner responsible for Health and Food Safety. During her hearing Kyriakides touched on many points included in her mission letter. In the field of health, she plans to focus her work on:

- ▶ the development of a European Cancer Plan;
- ▶ taking action against the growing threat of antimicrobial resistance; and,
- ▶ addressing the access to safe and affordable medicines with Member States.

Also medicines shortages played a role in the hearing. In relation to tackling this issue Kyriakides mentioned close collaboration with Member States and the need to find a system for the early detection of shortages. Other topics that were brought up included the engagement of civil society and mental health.

LIGHT ON HEALTHCARE WORKERS' KNOWLEDGE AND ATTITUDES ABOUT AMR SHED DURING EAAD 2019

On 18 November the European Centre for Disease Prevention and Control (ECDC) hosted this year's European Antibiotic Awareness Day (EAAD). The 2019 edition brought together healthcare professionals from all over Europe and presented findings of a first-of-its kind survey that looked at the attitudes of healthcare professionals towards antibiotic resistance (AMR).

Overall, the findings of the study, which was carried out earlier in 2019, revealed that knowledge and awareness of AMR and related issues is generally high among healthcare professionals working in the European Union and the European Economic Area. With more than more than 89% of the over 18 000 respondents acknowledging the connection between prescribing, dispensing and administering of antibiotics and the emergence and spread of AMR. However, at the same time the report also highlighted

some significant knowledge gaps on antibiotic resistance related to human health. In addition, the findings in the areas of patient involvement and infection management showed that more investment is needed in producing and disseminating locally adapted guidance, resources and toolkits aimed at healthcare workers.

EU JAMRAI DESIGN CONTEST—SHARE YOUR IDEAS

The Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (EU JAMRAI) used the celebration of this year's EAAD to launch a design contest to find a symbol that can be associated with the fight against AMR. The contest aims at raising awareness. It encourages everyone to take action through giving visibility to the rising public health problem of AMR.

Participants who like science, have a creative mind or want to make a change raising awareness about the global threat of antibiotic resistance are welcomed to enter this contest. Entries will be accepted until the 31st of March 2020, and the winner will be announced next summer. Entries will be judged by a multidisciplinary and multisectoral jury, including representatives from EU-JAMRAI and ECDC, other members of its stakeholder forum, scientists, regulatory bodies and patient organisations.

WHO—ANTIMICROBIAL STEWARDSHIP TOOLKIT

The WHO has released a new toolkit focusing on antimicrobial stewardship programmes in healthcare facilities in low- and middle-income countries. Given the growing threat of antimicrobial resistance (AMR) the toolkit seeks to provides practical guidance to support the implementation of Objective 4 of the Global Action Plan on AMR which is linked

to optimising the use of antimicrobial medicines.

The different sections of the toolkit help healthcare professionals with the implementation of antimicrobial stewardship in their working environment. Interested parties will be assisted with the identification of structures and resources that need to be put in place at the national and healthcare facility level via a step-wise approach that can be applied in low-resource settings.

EUROPEAN MANIFESTO ON INFLUENZA VACCINATION

Influenza season is just around the corner. To raise awareness about the importance of influenza vaccination, EAHP together with more than 200 pan-European, national and international organisations has signed the European Manifesto on Influenza Vaccination. The manifesto calls for more action to increase seasonal influenza coverage rates in Europe to reduce the burden of this disease, and therefore improve citizens' health outcomes and quality of life.

At international level, a Global Influenza Strategy was launched by WHO in spring 2019. The strategy provides a framework for WHO, countries and partners to approach influenza holistically through tailored national programmes for the coming 10 years. It covers actions ranging from surveillance to disease prevention and control, with the goal of strengthening seasonal prevention and control and preparedness for future pandemics.

In addition, to health systems, hospitals and clinics also individuals can take steps to fight influenza. To prepare yourself for the influenza season the WHO released recommendations which include:

- ▶ Getting vaccinated
- ▶ Using good manners when coughing and sneezing
- ▶ Keeping your hands clean

BIOSIMILARS GUIDE FOR HEALTHCARE PROFESSIONALS AVAILABLE IN 23 LANGUAGES

In late October, the collaboration of the European Medicines Agency (EMA) and the European Commission on improving the understanding of biosimilar medicines in the EU reached another milestone. 15 additional language versions of the information guide on biosimilars for healthcare professionals were published, making the guide now available in 23 of the official EU languages.

COMMISSION RELEASES ATMPs GUIDELINE

The European Commission published Guidelines on Good Clinical Practice specific to Advanced Therapy Medicinal Products (ATMPs). These take into account the advances and experience in the field of ATMPs. The guidelines should be read in conjunction with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines on good clinical practice, which are also applicable to ATMPs. To the extent that there is a difference in the requirements, the content of these guidelines prevails. Prior to the adoption of the guidelines, the European Commission conducted a targeted stakeholder consultation between August and October 2018. EAHP inputted to this consultation which collected contributions from 35 stakeholders.

UPDATES FROM THE EUROPEAN MEDICINES AGENCY

The European Medicines Agency (EMA) recently released communications confirming that Xeljanz should be used with caution in patients at high risk of blood clots and on measures to minimise risk of serious side effects of the multiple sclerosis medicine Lemtrada.

Ema confirms Xeljanz to be used with caution in patients at high risk of blood clots

EMA has concluded that Xeljanz (tofacitinib) could increase the risk of blood clots in the lungs and in deep veins in patients who are already at high risk.

EMA is recommending that Xeljanz should be used with caution in all patients at high risk of blood clots. In addition, the maintenance doses of 10mg twice daily should not be used in patients with ulcerative colitis who are at high risk of blood clots unless there is no suitable alternative treatment. Further, EMA is recommending that, due to an increased risk of infections, patients older than 65 years of age should be treated with Xeljanz only when there is no alternative treatment.

These recommendations follow the Agency's review of an ongoing study (study A3921133) in patients with rheumatoid arthritis and an increased risk of cardiovascular disease, plus data from earlier studies and consultation with experts in the field. All data combined showed that the risk of blood clots in deep veins and lungs was higher in patients taking Xeljanz, especially the 10mg twice daily dose, and in those being treated for

an extended period. Results also showed a further increased risk of serious and fatal infections in patients older than 65 years of age.

The recommendations were issued by the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) and have now been endorsed by the Agency's human medicines committee (CHMP). They will replace the measures put in place at the start of the review in May 2019. The changes come into force when the European Commission issues its decision.

Measures to minimise risk of serious side effects of multiple sclerosis medicine Lemtrada

EMA is recommending restriction of the use of the multiple sclerosis medicine Lemtrada (alemtuzumab) due to reports of rare but serious side effects, including deaths. New measures to identify and manage the serious side effects are also recommended. The side effects include cardiovascular disorders (affecting the heart, circulation and bleeding as well as stroke) and immune-related disorders (caused by the body's defence system not working properly).

Lemtrada should now only be used to treat relapsing-remitting multiple sclerosis if the disease is highly active despite treatment with at least one disease-modifying therapy or if the disease is worsening rapidly. Lemtrada must also no longer be used in patients with certain heart, circulation or bleeding disorders or in patients who have autoimmune disorders other than multiple sclerosis.

The medicine should only be given in a hospital with ready access to intensive care facilities and specialists who can manage serious adverse reactions.

EMA has also recommended updating the physician's guide and the patient information pack with advice on minimising the risk of serious cardiovascular disorders, which may occur shortly after a Lemtrada infusion (drip), and immune-related conditions, which may occur many months and possibly years after the last treatment.

These recommendations were issued by the EMA's safety committee (PRAC) and have now been endorsed by the Agency's human medicines committee (CHMP). They will replace the temporary measures introduced in April 2019 while the review of Lemtrada was under way. The changes come into force when the European Commission issues its decision.

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

STUDY ON THE EU'S PUBLIC HEALTH POLICY RELEASED

A study has been released which analyses the state of play as well as the current and future challenges that lie ahead of the European Union's (EU's) public health policy. It puts into focus topics that may shape the agenda of the European Parliament's committee on Environment, Public Health and Food Safety (ENVI Committee) during its current 5 year mandate.

The study was commissioned by the ENVI Committee and describes key public health definitions, principles and concepts. In addition, it discusses the EU's powers to act on health, and presents an overview of health policy developments and challenges. Topics such as for example the implementation of the Medical Device Regulations, action to combat antimicrobial resistance and vaccine hesitancy have been covered in order to provide Members of the European Parliament with a comprehensive overview of health issues that may shape the agenda of the new legislature.

ANNUAL MEETING OF THE HEALTH POLICY PLATFORM HELD

In mid-October, the European Commission organised the annual meeting of its Health Policy Platform, bringing together over 50 stakeholders active in the field of health. The afternoon session of the meeting was dedicated to the presentation of joint statements that have been prepared by different working groups. In addition, ideas for new thematic networks – which will take up their activity in 2020 – were shared.

Four joint statements were shown. These included one mapping and building cross-border and regional cooperation, one focused on improving organ donation and transplantation in the EU, one seeking to ameliorate people-centred healthcare solutions and one identifying common challenges to supporting the health of vulnerable populations. The meeting concluded with the presentation of the five leading proposals for the 2020 Thematic Networks which touched on the following:

- ▶ 'A human rights-based approach to taskshifting: the role of peer workers'
- ▶ 'Colorectal Cancer Screening in the European Union'

- ▶ 'Digital skills for future-proof doctors – Digital Doc'
- ▶ 'Inter-professional Education for Digital Skills'
- ▶ 'Profiling and training the healthcare workers of the future'

Members of the Health Policy Platform were asked to vote online for their favourite topic. The EU Health Policy Platform is an interactive tool to boost discussions about public health concerns, share knowledge and best practices. Via the different thematic networks stakeholders can exchange with each other and prepare joint statements.

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