New interagency AMR report calls for urgent action

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The Interagency Coordination Group on antimicrobial resistance (IACG), which includes members from the United Nations (UN), the WHO, the Food and Agriculture Organisation and the World Organisation for Animal Health, released a report containing critical recommendations to combat drug-resistant infections and to prevent the staggering number of deaths caused by antimicrobial resistance each year.

Antimicrobial resistance (AMR) is increasingly becoming a global problem which calls for immediate, coordinated and ambitious action. In line with the European Commission's One Health initiative, also the IACG report calls for a multisectoral 'One Health' approach in order to jointly avert a potentially disastrous drug-resistance crisis.

Recommendations of the IACG are linked to the acceleration of progress, innovation, collaboration, investment into sustainable responses as well as strengthened accountability and global governance. Countries are encouraged:

- ▶ To prioritise national action plans to scale-up financing and capacity-building efforts.
- ▶ To put in place stronger regulatory systems and support awareness programs for responsible and prudent use of antimicrobials by professionals in human, animal and plant health.
- ▶ To invest in ambitious research and development for new technologies to combat antimicrobial resistance.
- ▶ To urgently phase out the use of critically important antimicrobials as growth promoters in agriculture.

The report calls on countries to intensify the efforts and to jointly work together on overcoming AMR which has also been identified as a major barrier to the implementation of the UN's Sustainable Development Goals, in particular those linked to universal health coverage, secure and safe food, sustainable farming systems and clean water and sanitation.

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EUROPEAN COMMISSION LAUNCHED NEW VERSION OF UNION REGISTER

The European Commission has released a new version of its Union Register of Medicinal Products which lists all medicinal products for human and veterinary use that have been authorised through the centralised procedure. At the moment, the register contains information about more than 1300 medicines. In addition, it also covers designation of orphan medicinal products, refused authorisations and reviews related to nationally authorised medicinal products. The update offers a more simplified navigation, greater compatibility with mobile devices and allows users to filter and export functionalities.

UPDATES FROM THE EUROPEAN MEDICINES AGENCY IN MAY 2019

In early May, the European Medicines Agency (EMA) released its 2018 annual report. In addition, the agency shared information on a new long-lasting implant to treat opioid dependence as well as on the re-analysis of data on use of breast cancer medicine Tyverb following treatment with trastuzumab.

EMA 2018 annual report

The annual report provides an overview of EMA's activities in 2018. It includes information on the Brexit preparations, the key milestones as well as facts and figures about achievements in the field of human and veterinary health.

New long-lasting implant to treat opioid dependence

EMA's human medicines committee (CHMP) has recommended granting a marketing authorisation in the EU for Sixmo (buprenorphine) as a substitution treatment for opioid dependence. Sixmo is an implant that releases low levels of buprenorphine into the patient's body for 6 months. It is indicated in clinically stable adult patients who require no more than 8 mg/day of sublingual (ie, administered under the tongue) buprenorphine, within a framework of medical, social and psychological treatment.

The active substance of Sixmo is buprenorphine. It consists of four small

rods that are implanted in the patient's upper arm by a trained physician under local anaesthetic and continuously deliver buprenorphine for 6 months. This new method of administration could enhance adherence to the treatment and reduce the potential for misuse or accidental overdoses in the home, as well as the risk of accidental ingestion of buprenorphine by others, especially children.

The safety and efficacy of Sixmo were studied in three pivotal trials, in a total of 626 adult patients. One of the trials enrolled opioid use disorder adults who were considered clinically stable by their treating physician. The results demonstrated that 96.4% of patients in the Sixmo group responded to treatment, compared with 87.6% of patients treated with sublingual buprenorphine.

The applicant is required to perform an additional study in patients in Europe to further evaluate the risks associated with the insertion and removal of the implants. The opinion adopted by the CHMP is an intermediary step on Sixmo's path to patient access. The opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation. Once the marketing authorisation has been granted, decisions about price and reimbursement will take place at the level of each Member State, taking into account the potential role/use of this medicine in the context of the national health system of that country.

Reanalysis of data on use of breast cancer medicine Tyverb following treatment with trastuzumab

EMA is updating the prescribing information for Tyverb (lapatinib) following detection of errors in results of a study involving postmenopausal women who had 'hormone receptor positive/human epidermal growth factor receptor 2 positive' breast cancer and whose disease had worsened despite previous treatment with trastuzumab. The results had indicated a benefit of Tyverb over trastuzumab when each medicine was used together with an aromatase inhibitor.

The detected errors were included in the prescribing information for Tyverb on 30 July 2018. However, these will now be removed while data are being reanalysed. In the meantime, the prescribing information will be amended to state, as before, that no data are available on the effectiveness of Tyverb compared with trastuzumab in this combination in patients previously treated with trastuzumab.

In the light of this new information, doctors currently treating patients with Tyverb in combination with an aromatase inhibitor, whose disease had worsened despite previous treatment with trastuzumab, should decide whether to continue with the same therapy or consider an alternative treatment.

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

FIRST WHO GUIDELINE ON DIGITAL HEALTH INTERVENTIONS

In mid-April, the WHO released a guideline containing recommendations on digital interventions for health system strengthening. The document includes information on 10 ways that countries can use digital health technology, accessible via mobile phones, tablets and computers, to improve people's health and essential services. It also provides a better understanding of which digital health interventions have an evidence base to address health system needs and targets decision-makers in health ministries, public health practitioners and other stakeholders.

In relation to health workers, the guideline stresses the need for adequate training to boost their motivation to transition towards working more easily with emerging digital technologies. In particular, supportive environments for training, dealing with unstable infrastructure, as well as policies to protect the privacy of individuals need to be provided.

SPECIAL EUROBAROMETER ON VACCINATION

During the 2019 European Immunisation Week, a Special Eurobarometer was released detailing information on Europeans' attitudes towards vaccination. Data gathered shows that 85% of EU citizens believe vaccination is an effective way to prevent infectious diseases and to protect oneself and others. Around half of the EU citizens have been vaccinated in the last 5 years and a large majority (79%) consult and trust a healthcare professional, such as their pharmacist, to get information about vaccinations.

Information gathered via the Special Eurobarometer forms part of an elaborate European Commission initiative which addresses vaccine disinformation and seeks to increase vaccine coverage across the EU. Together with the WHO, the European Commission will be hosting a Global Vaccination Summit in September 2019 in order to give high level visibility

and political endorsement to the topic of vaccination.

MEDICAL DEVICE INFORMATION PORTAL LAUNCHED

The European Commission released its revamped medical device information website which aims at improving the understanding of stakeholders about the differences between the currently applicable Medical Device Directives and the Medical Device Regulations. In addition, the portal provides resources as well as information on the implementation timeline for the transition between these two instruments.

The two new regulations, covering medical devices and in vitro diagnostic medical devices, entered into force in May 2017. They intend to improve the quality and safety of medical devices available in the EU by setting up control mechanisms and processes for the oversight of these devices. In addition, the creation of a new system of unique device identifiers is foreseen in order to increase the identification and traceability of medical devices. Also transparency is being improved by making available summaries of safety and clinical performance for high-risk medical devices via the European database on medical devices. During the transition period, which for the Medical Devices Regulation will last until 26 May 2020 and for the In Vitro Diagnostic Medical Devices Regulation until 26 May 2022, both the regulations and the directives will apply.

ASSESSING THE EFFICIENCY OF HEALTHCARE SERVICES

In mid-April, the European Commission's Expert Group on Health System Performance Assessment (HSPA) published its report titled 'Tools and methodologies to assess the efficiency of healthcare services in Europe: an overview of current approaches and opportunities for improvement'. The document is the result of the work of HSPA which examined the tools and methodologies at the disposal of Europe countries to assess healthcare efficiency.

The findings of HSPA revealed the shortcomings caused by the limited number of tools available to health policymakers. To ensure patient safety and improved efficiency, a first step should be to invest in the development of more instruments targeting the analysis, measurement and assessment of efficiency of care. Only with the help of the correct tools will health policymakers be enabled to correctly detect inefficient practice and design policy

interventions that can enhance efficiency without unintended consequences on the access to quality care. The authors of the report have identified several promising improvement opportunities. Suggestions include increasing the quality and granularity of cost data, improving measurement of health outcomes, expanding the scope for efficiency measurement beyond hospital care and designing communication of results with stakeholders in mind.

EPRESCRIPTION NETWORK CONTINUES TO GROW

In January 2019, the European Commission announced the implementation of its ePrescription initiative which aims at facilitating the exchange of patient between different European countries (see EU Monitor of 24 January 2019). Estonia and Finland were the first countries that started collaborating with each other. This summer, Croatia will join.

Finnish citizens travelling to Croatia will be enabled to obtain their ePrescriptions in Croatia, while Croatians travelling to Estonia can get their ePrescriptions dispensed there. In the past 3 months, 1000 Finnish patients have already benefited from the initiative and retrieved medicines prescribed electronically by their doctor in Finland in pharmacies in Estonia.

In addition to enabling the exchange of ePrescriptions, the European Commission is also fostering the exchange of patient summaries. Two other countries, Czechia and Luxembourg, received the approval from the eHealth Network earlier this year to start exchanging patient summaries of citizens coming from other European countries. Both will start with the practical implementation in the coming months. Croatia will join in as well and allow the access of Czech patient summaries.

Funding This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient consent for publication Not required.

Provenance and peer review Commissioned; internally peer reviewed.

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To cite Kohl S. *Eur J Hosp Pharm* 2019;**26**:233–234.

Eur J Hosp Pharm 2019;**26**:233–234.
doi:10.1136/ehjpharm-2019-002005