The EAHP EU Monitor is a regular round up of news relevant to hospital pharmacy in Europe.

You can subscribe to receive the EAHP EU Monitor by email ***HERE*** *[1]. [1]*

EAHP 2018 Medicines Shortages Survey – share your experience!

Since mid-March the European Association of Hospital Pharmacists (EAHP) has been mobilising its members to gather up-to-date information on the current shortage situation in European hospitals. By participating in the 2018 Medicines Shortage Survey hospital pharmacists can help to improve patient outcomes by sharing data on the prevalence of shortages, types of shortages and length of shortages.

For a number of years, the EAHP has been actively advocating on the issue of medicines shortages and its threat to patient care in hospitals. In 2013 the association released data about the growing problem of medicines shortages [2] experienced by its members. A year thereafter an in-depth analysis of the medicines supply shortage in the hospital sector followed via the publication of results from the first European-wide survey [3] conducted to address the issue of medicines shortages.

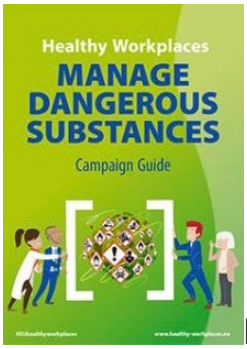
Since up-to-date data on the medicines shortage situation in European hospitals is lacking, EAHP saw a need to gather new information, similar to the one collected by the 2014 Shortage Survey. The current survey activity is looking at

- the nature of medicines shortages problems in Europe, including their prevalence;
- the most common types of shortages;
- their impact on patient care and hospital pharmacy services;
- existing national mechanisms for dealing with or monitoring shortages;
- how hospital pharmacists typically manage the problems shortages cause; and,
- hospital pharmacist views on proposed policy solutions.

With less than 5 weeks left to complete the 2018 Shortage Survey, EAHP would like to encourage all European hospital pharmacists to share their experience by 11th June 2018 via the following LINK [4]!

More information about the 2018 Shortage Survey HERE [5]

More about EAHP's advocacy work on medicines shortages HERE [6]



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 work place.

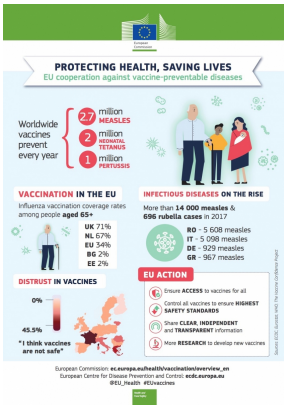
In April 2018, the European Commission released a proposal to amend the Carcinogens and Mutagens Directive [7]. The amendment aims at improving workers' health protection by reducing occupational exposure to five carcinogenic chemical agents, namely cadmium and its inorganic compounds; beryllium and inorganic beryllium compounds; arsenic acid and its salts, as well as inorganic arsenic compounds; formaldehyde; 4,4'-methylene-bis(2-chloroaniline) (MOCA). 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 the 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 [8] and by taking part in the European Weeks for Safety and Health at Work [9] which is organised in October each year (calendar week 43).

More about the proposal to amend the Carcinogens and Mutagens Directive HERE [7]

More information on the healthy workplace campaign of EU-OSHA HERE [10]



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 consultatio [11]n, a factsheet [12], an informative video [13], and a proposal for a Council recommendation [14].

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 the World Health Organisation (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 one 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 sub-optimal vaccine uptake (lower than 95%). The coverage with diphtheria, tetanus, and pertussis vaccines is also sub-optimal, 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.

Read the communication HERE [15]

EJHP - Hands on medicines information

The 'Hands on medicines information' section of the European Journal of Hospital Pharmacy (EJHP) aims at presenting clinical queries arising from medicines information practice, in particular those that are complex or unusual and could be of interest to other hospital pharmacists.

Hospital pharmacists are encouraged to send submissions for this EJHP section. They should present a clearly defined clinical question and answer which should be supported with scientific evidence. The inclusion of patient-specific information and an outcome assessment is strongly encouraged.

Submissions should be structured in the following manner:

- Summary of up to 150 words;
- Introduction, including the case presentation and any clinical or background information relevant to the query;
- Clinical question;
- Recommended answer, including the problem-solving approach used (if applicable);
- Outcome and discussion; and,
- Key message/learning outcome of one sentence.

The article should be no longer than 1500 words, include a maximum of 1 table and/or figure and up to 10 references. It can be uploaded via the 'submit a paper' button on the EJHP website [16].

EMA – 2017 annual report

On the 2nd of May 2018, the European Medicines Agency (EMA) released its 2017 annual report. The report outlines the key achievements and initiatives of the agency, such as evaluation and monitoring of medicines, increased engagement with the public, reallocation of its seat, and regulatory steps taken to facilitate a higher degree of patient safety.

The year 2017 was, alongside Brexit and the agency reallocation process, full of challenges for EMA. In September 2017, the first public hearing was held at the agency, bringing together patients, carers, doctors, pharmacists, and academia. They shared their experience with valproate, and the EU citizens were asked to answer a questionnaire about it with the purpose of complementing the scientific evidence. The new EudraVigilance [17] system was launched in November 2017, to improve the reporting of adverse drug reactions in Europe. The Priority Medicine scheme (PRIME [18]) celebrated its first anniversary, with 34 medicines being included by the end of 2017. Also, scientific advice reached an all-time high in 2017, with 5% of it given jointly with HTA bodies.

In the report, there are plenty of facts and figures available which support the impact of EMA's work. The agency recommended 92 medicines for human use for marketing authorisation, out of which 35 had new active substances. Alongside medicines for human use, the agency also recommended 18 medicines for veterinary use for marketing authorisation, including 7 new active substances and 10 vaccines.

To read more about EMA's activity in the previous year, and for the interviews with various stakeholders and EMA representatives, find the 2017 annual report here [19]. In 2017, EMA also released 181 news releases, all of which can be found on their website [20].

Image not found or type unknown

WHO – Patient Safety Challenge

In spring 2017, the World Health Organisation (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.

Learn more HERE [21]

EJHP – the May edition is out!

May's edition of the EJHP includes an editorial on change blindness as well as original articles on individualised antimicrobial dosing in critically ill patients undergoing continuous renal replacement therapy, on the evaluation of the physicochemical and biological stability of reconstituted and diluted SB2 (infliximab) and on the impact of fampridine on quality of life. More information on the rapid acting fentanyl formulations in breakthrough pain in cancer can be found on the electronic pages of the EJHP May issue.

Read the EJHP May edition HERE [22]

Image not found or type unknown

Consultations

EMA - Questions and answers on Bovine Spongiform Encephalopathies (BSE) and vaccines

The document contains an update of the information in the Public Statement on the Evaluation of Bovine Spongiform Encephalopathies (BSE). Since 2001, understanding of the risks associated with BSE has progressed significantly and a routine review of EMA guidelines identified this document as requiring updating. It includes information on the use of bovine derived materials in vaccine manufacture.

Deadline – 31st July 2018

More information HERE [23]

EMA- Guideline on quality aspects included in the product information for vaccines for human use

The guideline describes the information on the quality aspects to be included in the Product Information of vaccines for human use.

Deadline – 31st July 2018

More information HERE [24]

EMA- Reflection paper on investigation of pharmacokinetics and pharmacodynamics in the obese population

The reflection paper aims at describing how the effects of obesity can be investigated during clinical drug development, providing recommendations on when investigations of the effect of obesity on the PK of a drug should be considered, providing information on specific important considerations for these investigations and discussing how to reflect PK findings in weight/size based dosing recommendations.

Deadline – 31st July 2018

More information HERE [25]

EMA- Draft addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections to address paediatric-specific clinical data requirements

This addendum to the Guideline has been developed to provide specific guidance on paediatric clinical development programmes that are required to support the authorisation of antibacterial agents for treatment of infectious diseases in paediatric patients. This Addendum provides guidance on clinical data requirements to support the approval of an antibacterial agent to treat infectious diseases in paediatric patients, both when extrapolation of efficacy from adults (source population) to paediatric patients (target population) is possible, and when this is not the case.

Deadline – 30th August 2018

More information HERE [26]

EMA- Draft guideline on clinical evaluation of vaccines

This guideline addresses the clinical evaluation of vaccines intended for the prevention of infectious diseases. It includes considerations for trials intended to document the safety, immunogenicity and efficacy of new candidate vaccines and to support changes in the prescribing information of licensed vaccines. It also considers the need for and use of vaccine effectiveness studies.

Deadline – 30th October 2018

More information HERE [27]

9 May 2018

Links
[1] http://www.eahp.eu/newsletter/subscribe [2] http://www.eahp.eu/sites/default/files/files/EAHPdeplMedicineHR2f.pdf [3] http://www.eahp.eu/sites/default/files/shortages_report05online.pdf [4] https://www.surveymonkey.com/r/EAHPshortagesurvey2018 [5] http://www.eahp.eu/content/2018-medicines-shortage-survey [6] http://www.eahp.eu/practice-and-policy/medicines-shortages [7] http://ec.europa.eu/social/BlobServlet?docId=19271&langId=en [8] https://healthy-workplaces.eu/en/good-practice-awards [9] https://healthy-workplaces.eu/en/european-week-safety-and-health-work [10] https://healthy-workplaces.eu/en [11] https://ec.europa.eu/health/vaccination/consultations/cooperation_vaccinepreventablediseases_en [12] https://ec.europa.eu/health/sites/health/files/vaccination/docs/2018_factsheet_en.pdf [13] http://ec.europa.eu/avservices/video/player.cfm?ref=I154315&sitelang=en&lg=EN [14] https://ec.europa.eu/health/sites/health/files/vaccination/docs/com2018_2442_en.pdf [15] https://ec.europa.eu/health/sites/health/files/vaccination/docs/com2018_2452_en.pdf [16] http://ejhp.bmj.com/ [17] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000679.jsp&mid=WC [18] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000660.jsp&mid=WC

[19] http://www.ema.europa.eu/docs/en_GB/document_library/Annual_report/2018/04/WC500248201.pdf
[20] http://www.ema.europa.eu/ema/ [21] http://www.who.int/patientsafety/medication-safety/en/ [22]
http://ejhp.bmj.com/content/25/3 [23]
http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=W
[24]
http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=W
[25]
http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=W
[26]
http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=W
[27]
http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=W