European Commission opens a public consultation on improving the European system of orphan medicine designation

Richard Price

15 years after the passing of landmark European Commission (EU) regulation to encourage orphan medicine development, the EU is now running a public consultation to take views on revised guidance on how the regulation should operate in practice. Amongst the matters being consulted upon is whether a candidate for orphan drug designation should be required to demonstrate 'significant benefit' over not only existing authorised products, but also those prepared in hospital pharmacies. The consultation also seeks views on if, and how, orphan drug designation benefits could be better applied to benefit the development of treatments for low to zero prevalence infectious diseases in Europe that nonetheless pose the potential risk of becoming a serious threat to public health (eg, Ebola).

INTERNATIONAL COMMITTEE OF MEDICAL JOURNAL EDITORS PROPOSES INDIVIDUAL PATIENT DATA SHARING

The International Committee of Medical Journal Editors (ICMJE) is proposing that authors must share the anonymised individual patient data underlying clinical trial results published in its member journals.

On January 20th 2016 the ICMJE published an editorial in 14 major medical journals sharing their proposal, and are inviting feedback until April 18th 2016.

The ICMJE also propose that authors include a plan for data sharing as part of clinical trial registration. To be considered for publication, ICMJE already requires the prospective registration of all clinical trials before enrolment of the first participant.

EUROPEAN PROFESSIONAL CARD AVAILABLE FOR PHARMACISTS FROM 18 JANUARY 2016

The EU has announced the opening of a 'European Professional Card' (EPC) system for pharmacists and four other

professions (general care nurses, physiotherapists, real estate agents and mountain guides) as from 18 January 2016.

The EPC is not a plastic card, but an electronic certificate issued via the first EU-wide fully online procedure for the recognition of qualifications. This digital procedure is based on the well-established Internal Market Information System (IMI) and allows professionals to communicate with the relevant authorities inside a secure network. The IMI also provides for an official, multilingual communication channel between the regulating authorities for professionals in EU countries to facilitate their cooperation and enhance mutual trust.

The EPC does not replace the 'traditional' recognition procedures under the Professional Qualifications Directive, but it does offer an advantageous option for professionals who wish to work either temporarily or permanently in another EU country.

EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES AND HEALTHCARE ANNOUNCE DEVELOPMENTS TOWARDS A EUROPEAN FORMULARY FOR PAEDIATRIC MEDICINES

The European Directorate for the Quality of Medicines and Healthcare (EDQM) has announced the detailed framework of a project for a European Paediatric Formulary. The Formulary is under development by "The European Committee on Pharmaceuticals and Pharmaceutical Care" (CD-P-PH) and the European Pharmacopoeia Commission, with the secretariat provided by EDQM.

The future online publication will give hospital and retail pharmacies across Europe easy access to a formulary for the preparation of unlicensed formulations of paediatric medicines. Although there have been significant efforts to increase the number of available licensed medicines for children, there is still a shortfall—especially of those containing well-known active substances.

Today, national or regional formularies on pharmacy preparations for the

treatment of children still play an important role in paediatrics. Although some individual countries have good approaches, these are not shared across all countries. This leads to the fact that currently, poorly-developed or even inadequate medicines are sometimes used.

A working party under the auspices of the European Pharmacopoeia Commission will start in 2016 to evaluate existing formulas and to initiate the elaboration of first monographs for the European Paediatric Formulary. Draft monographs will in future be published for public consultation in EDQM's online forum Pharmeuropa before final adoption by the two committees.

2015 EURO HEALTH CONSUMER INDEX SHOWS CONTINUED PROGRESS IN EUROPEAN HEALTHCARE

European healthcare is steadily improving, "in spite of alarm bells about financial crisis austerity measures, aging population and migration turmoil" according to the advertised conclusions of the latest Euro Health Consumer Index (EHCI) 2015. The index highlights that survival rates of heart disease, stroke and cancer are all increasing across Europe, while infant mortality continue to decline. The EHCI, started in 2005, is one of the leading comparisons for assessing the performance of national healthcare systems in 35 countries.

The report gives country by country performance breakdowns, and amongst the key points stressed is that, as new indicators are added to the index, no country demonstrates excellence in all assessed measures, showing room for improvement by all.

The Netherlands once again ranked as the top performing health system when all indicators are taken into account, followed by Switzerland, Norway, Finland, Belgium, Luxembourg and Germany in order.

The index report also reveals continuing struggles in the implementation of e-prescription systems across the majority of European countries.

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Correspondence to Richard Price, Department of Policy and Advocacy, European Association of Hospital Pharmacy, 3 Rue Abbe Cuyers, Brussels 1040, Belgium; richard.price@eahp.eu