FOCUS-EU

HEALTH

December 2019

Overview of EU and global policy developments

BIOSIMILARS: GLOBAL DEVELOPMENTS

New ICH harmonisation activities

The International Council for Harmonisation (ICH) has agreed to work on Bioequivalence for Immediate-Release Solid Oral Dosage Forms (M13). This is the first time that an ICH working group will focus on the global generics and biosimilars regulations. The ICH has also agreed on the revision of the ICH Q9 Guideline on Quality Risk Management and the work on ICH Q3E Guideline Impurity: Assessment and Control of Extractables and Leachables for Pharmaceuticals and Biologics.

Source: https://www.ich.org/2019

Biosimilars in eye therapies

Five years after the first FDA approval of a biosimilar, only 46% of approved products are launched and show a slow market uptake. However the current trend may change with shifting formulary management practices in the United States in favor of less expensive treatments. At least this is what the increasing launches of biosimilars for eye diseases point to. Four months after its launch at risk, Amgen's Mvasi (bevacizumab-awwb), has captured 10% of the Avastin market and gained the advantage of being the first bevacizumab biosimilar available for prescription. Pfizer has confirmed plans to launch its biosimilar bevacizumab, Zirabev, in the US market on December 31, 2019 and Ruxience (rituximab) in January 2020.

Sources: https://www.centerforbiosimilars.com/

https://www.raps.org/biosimilar

European Parliament

Second MDR Corrigendum Targets Class I Devices

A RAPS article by Zachary Brennan on the corrigendum voted by the European Parliament's Committee on the Environment, Public Health and Food Safety. The amendment gives manufacturers of certain low risk Class I devices an additional four years to comply.

Source: https://www.raps.org/EP/medicaldevices

European Commission

New EXPH Panel

The 17 members for the next work cycle of the EXPH Panel will be appointed in December to work on three new mandates.

The Expert Panel on effective ways of investing in health (EXPH) is an interdisciplinary and independent group established by the European Commission in 2012. The Panel provides non-binding advice on matters related to effective, accessible and resilient health systems in support of DG SANTE.

Source: https://ec.europa.eu/EXPH_members

Report on fostering Health Promoting Health Systems

The EXPH has published its report on "Options to foster Health Promoting Health Systems".

Source: https://EXPH_healthpromoting_healthsystems

Dekra's Dutch NB Designated Under MDR

Dekra Certification B.V. has become the third Netherlands-based notified body (NB) to be designated under the Medical Devices Regulation (MDR) and the eighth overall under MDR.
The designation allows Dekra to review different types of active implantable and non-implantable devices, as well as non-active implants and non-active, non-implantable devices, among others. Dekra's German-based NB is also designated under MDR and is one of two NBs designated under the In Vitro Diagnostic Regulation (IVDR).

Sources:
https://ec.europa.eu/growth/tools-databases/NB_43666

https://www.raps.org/number-8-nb-designated-under-mdr

Joining the Dots: Recommendations on digital transformation of health and care

Joining the Dots Conference brought together leading European projects with a focus on better data for person-centred health and care, optimised research and Learning Health Systems. A session was dedicated in identifying good practices, key drivers and inhibitors for large scale deployment of the current EU market of digital solutions for person-centred care. The key conclusions of the session *Boosting digital transformation of health and care: scaling up and evaluation* will feed into the political process and included:

- The EU market of digital solutions for person-centred care is very unstructured and, in many cases, key drivers and inhibitors for large scale deployment are unknown.
- An in-depth analysis of the person-centricity characteristics of existing digital solutions is needed, in order to provoke the desired marked disruption in this business area.
- Pilots, demonstrators and capacity building activities are needed to improve the ability of health and care authorities to deploy innovative solutions at large scale.
- Service innovations need to be adapted and tailored to the specificities and context to the wide range of different health and care systems that exist in Europe.
- Twinnings are a viable and effective tool to promote the scaling up of digital solutions for person-centred care across regions and countries.
- The provision of relevant evidence and know-how to health authorities, health providers and field researchers is essential in order to increase their capacity to prepare investment strategies and access financing.
- The implementation of different evaluation approaches can optimise decision making and boost investments in digital health and care, resulting in innovative cost-effective health care solutions.

Joining the Dots was organised by *i*~HD, the European Institute for Innovation through Health Data. The *i*~HD is an entity arising from the Electronic Health Records for Clinical Research (EHR4CR) and SemanticHealthNet projects, in collaboration with several other European projects and initiatives supported by the European Commission.

i~HD: https://www.i-hd.eu/
For info on projects contributing to recommendations:
https://www.i-hd.eu/index.cfm/

Source:
https://ec.europa.eu/eip/joining-dots-boost-digital-transformation

Eurostat: Cataract surgeries in the EU

Eurostat has published its surgical operations and procedures statistics. The most common surgical operation performed in EU hospitals were cataract surgery. Cataract surgeries were conducted 4.7 million times in 2017 across the EU Member States. In thirteen of the Member States, cataract surgeries were performed 1 000 times or more per 100 000 inhabitants in 2017, peaking at 1 400 times per 100 000 inhabitants in Portugal (2015 data), followed by 1 300 each in Austria, France, Czech Republic and Latvia.
By contrast, cataract surgery was performed fewer than 400 times per 100 000 inhabitants in Romania, Cyprus and Ireland.

Source: https://ec.europa.eu/eurostat/

Across the World

Court Ruling on Device vs Drug

The decision of a USA court has highlighted the limits on the FDA's discretion to classify as drugs products which satisfy both definitions of medical device and drugs. The US District Court for the District of Columbia decided that Vanilla SilQ, a contrast agent drunk by patients before undergoing an X-ray should be treated as a device because Vanilla SilQ products, unlike other contrast agents, do not chemically interact with the body.
The court has also noted that FDA "does not have discretion to regulate all contrast agents uniformly" when administrative decisions run counter to clear statutory meaning: the legislative amendment vesting FDA with the powers "to determine the appropriate regulatory regime . . . when a product satisfies both definitions [medical device and drug]" aimed to facilitate a regulatory track for so-called "combination products".
The impact of this case on the classification of devices remains to be seen as typical costs to market a device are around $60,000, compared to $500,000 for drugs.

Sources: https://ecf.dcd.uscourts.gov/cgi-bin
https://www.raps.org/court-rules-against-device

FDA: Final Rule for Medical Devices

The Food and Drug Administration (FDA) has issued a final rule amending requirements for medical device premarket submissions that replaces paper and multiple copies with requirements for a single submission in electronic format.

The final rule is an amendment by the Food and Drug Administration Safety and Innovation Act (FDASIA) that allows FDA to classify any device from class III to class I or class II (down-classification); or to increase product classification based on new or changing information on device risk.

Source: https://s3.amazonaws.com.pdf

https://www.raps.org/fda-from-paper-to-electronic

FDA: exploring experiences of clinicians globally

The FDA has launched CURE ID, an internet-based repository that will allow the clinical community to report their experiences treating difficult-to-treat infectious diseases with novel uses of existing FDA-approved drugs through a website, a smartphone or other mobile device. The platform enables the crowdsourcing of medical information from health care providers to guide potentially life-saving interventions and facilitate the development of new drugs for neglected diseases. The repository is a collaboration between the FDA and the National Center for Advancing Translational Sciences (NCATS), which is part of the National Institutes of Health (NIH).

Access CURE ID: https://cure.ncats.io/#/introduction

Source:
http://www.ehealthnews.eu/fda-app-for-health-care-professionals

Other

UK patient health data traded to US firms

An EURACTIV article by Samuel Stolton on the sale of health data of the UK National Health Service (NHS) patients to US companies and global pharmaceutical firms.

Source: https://www.euractiv.com/uk-health-data-to-us-firms/

How the data wave in healthcare will help improve patient outcomes

An EURACTIV article by Catherine Estrampes on the increased use of advanced data analytics, connected devices, genomics and AI and the impact on patient outcomes and operational efficiencies in care.

Source: https://www.euractiv.com/data-wave-patient-outcomes/

Clear standards required for development and use of AI in healthcare

An EURACTIV article by Natasha Foote on the ethical concerns in policy circles regarding the use of artificial intelligence in healthcare systems.

Source: https://www.euractiv.com/standards-for-AI-in-healthcare

Calls

ERC Consolidator Grants Call 2020 Open

Deadline: 4 February 2020

The Call for the ERC Consolidator Grants is the last one under Horizon 2020. The ERC Consolidator Grants are for researchers with 7-12 years of research experience after PhD and it is designed to support Principal Investigators at the career stage at which they are consolidating their own independent research team. Up to €2 million are available for projects of up to 5 years duration. Important information on the call is included in the ERC Work Programme 2020 and especially the call-specific Information for Applicants. The proposal templates are available from the EC Funding and tender opportunities portal once having registered for the call.

For eligibility and how to apply: ERC website.

Call for proposals on new infrastructures (ESFRI)

Deadline: 5 May 2020

ESFRI Guide: https://ESFRI-Roadmap2021-Public-Guide.pdf

Health Research Infrastructures: http://esfri

Open Call DT-ICT-12-2020: AI for the smart hospital of the future

Deadline: 22 April 2020

For topic conditions, documents and submission service:
https://ec.europa.eu/fundingdt-ict-12-2020

Open Call SC1-HCC-10-2020: Towards a Health Research and Innovation Cloud: Capitalising on Data Sharing Initiatives in Health Research

Deadline: 7 April 2020

For topic conditions, documents and submission service:
https://ec.europa.eu/sc1-hcc-10-2020

Open Call SC1-BHC-06-2020:
Digital Diagnostics - Developing Tools for Supporting Clinical Decisions by Integrating Various Diagnostic Data
Deadline: 7 April 2020

For topic conditions, documents and submission service:
https://ec.europa.eu//funding-tenders//sc1-bhc-06-2020

Open Call SC1-BHC-20A-2020:
Pre-Commercial Procurement (PCP) for Integrated Care Solutions
Deadline: 7 April 2020

For topic conditions, documents and submission service:
https://ec.europa.eu/funding-tenders/sc1-bhc-20a-2020

Open Call SC1-DTH-12-2020:
Use of Real-World Data to Advance Research on the Management of Complex Chronic Conditions
Deadline: 7 April 2020

For topic conditions, documents and submission service:
https://ec.europa.eu/info/funding-tenders/sc1-dth-12-2020

Open Call SC1-HCO-19-2020:
Reliable and accessible information on cell and gene-based therapies
Deadline: 7 April 2020

For topic conditions, documents and submission service:
https://ec.europa.eu/funding/sc1-hco-19-2020

Open Call SC1-DTH-06-2020:
Accelerating the uptake of computer simulations for testing medicines and medical devices
Deadline: 22 April 2020

For topic conditions, documents and submission service:
https://ec.europa.eu/funding/sc1-dth-06-2020

Consultations & Events

Webinar on innovation procurement calls in health
9 January 2020
The webinar provides information about the new funding of €34 million for innovation procurements in health and care available from the Horizon 2020 programme including how to prepare a proposal.
Overview of 2020 calls in healthcare field:

- Funding for Pre-Commercial Procurement (PCP) actions
  - Digital health & care: 9 M€, deadline 22 April 2020 (see Topic DTH-14)
  - Integrated care: deadline 7 April 2020 (see Topic BHC-20A)
- Funding for Public Procurement of Innovative solutions (PPI) actions:
  - Diagnostics: deadline 7 April 2020 (see Topic BHC-20B)

Indicative budget for BHC-20 A & B together is €25 million.

Source:
https://ec.europa.eu/eip/webinar-innovation-procurement-health

EMA - Population-specific Pharmacovigilance

Deadline: 28 February 2020

EMA has released for public consultation the draft Guideline on good pharmacovigilance practices (GVP)
Product- or Population-Specific Considerations III: Pregnant and breastfeeding women.

Consultation document and template for comments:
https://www.ema/pharmacovigilance-population-specific

WHO - PHARMACEUTICALS

Deadline: 15 January 2020

The World Health Organization (WHO) has drafted a new guideline on data integrity in the production and control of pharmaceuticals.
Contact details for submission in the link below.

Source: https://www.who.int/medicines/data_integrity.pdf

The EU EYE continues to be a partner of the European Innovation Partnership on Active and Healthy Ageing (EIP-AHA) with a commitment to the B3 Action Group on Integrated care accessible at: https://ec.europa.eu/eip/b3/

FOCUS - EU Health | Dime Limited
74 Oxford Road, OXFORD OX4 4PE, UK | info@dimeltd.com
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