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WEEKLY EU HEALTHCARE NEWS UPDATE

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Europe's Beating Cancer Plan: EU issues recommendations to improve and extend cancer screening programmes

On Wednesday (2 March) the EU Commission's Group of Chief Scientific Advisors (GCSA) released a Scientific Opinion on cancer screening in Europe and on how to improve early detection.

It provides guidelines on how to improve the existing screening programmes on breast, colorectal and cervical cancer and advises to extend them to lung and prostate cancer. Advisors also stressed the importance of increasing people's participation to such programmes by making them more accessible.

The opinion is to influence the upcoming legislative proposal of the EU Commission, which will update the 2003 Council Recommendation on cancer screening to ensure that the latest available scientific evidence is reflected.

Moreover, the EU Chief Advisors pinpointed the areas in which further research is required, and as such, may be a contribution to the EU Mission on Cancer.

Full text of the opinion: https://ec.europa.eu/info/files/scientific-opinion-cancer-screening-european-union_en

Reinforcement of the European Medicines Agency

The regulation reinforcing the EMA's role in crisis preparedness and management of medicinal products and devices became applicable as of 1 March, except for the provisions on shortages of critical medical devices which will apply as of 2 February 2023.

As part of its extended mandate, EMA was tasked with the monitoring of events, incl. medicine shortages, as well as with the reporting of shortages during a crisis. The Agency will also coordinate responses of EU countries on shortages of critical medical devices and in vitro diagnostics occurring in crisis situations, after an initial transition period.

EMA will set up and manage a European Shortages Monitoring Platform to facilitate data collection and reporting by companies and EU Member States on shortages, supply and demand of critical medicines (by 2025). The agency will also coordinate twelve EU expert panels to provide advice to national authorities and the Commission on high-risk medical devices and in-vitro diagnostic devices.

Text of the regulation: https://eur-lex.europa.eu/legal content/EN/TXT/PDF/?uri=OJ:L:2022:020:FULL&from=EN

EMA releases scientific advice on antimicrobials reserved for treating humans

On Tuesday (1 March), the European Medicines Agency published scientific advice in the fight against Antimicrobial Resistance (AMR). It contains the experts' recommendations on antimicrobials and groups of antimicrobials that are to be reserved exclusively for treating human infections since the use of antimicrobials in animals contributes to the development of AMR.

This science-based analysis has systematically assessed all types of antimicrobials. It paves the way for the upcoming adoption of a legislation listing the antimicrobials, which will be reserved for humans.

EMA's advice comes at the request of the Commission and has been put together by a panel of leading experts comprising medical doctors, microbiologists and veterinarians. The analysis was already endorsed by the Agency's Committee for Veterinary Medicinal Products (CVMP). Discussions with the Member States on the timely adoption of the antimicrobials list will start soon.

Full document: https://ec.europa.eu/food/system/files/2022-03/ah_vet-med_imp-reg-2019-06_ema-advice_art-37-5.pdf

Commission asks for comments on draft revised rules on horizontal cooperation agreements between companies

The EU Commission launched a public consultation inviting all interested parties to submit comments on two draft revised Horizontal Block Exemption Regulations on Research & Development and Specialisation agreements ('R&D BER' and 'Specialisation BER' respectively, together 'HBERs') and the draft revised Horizontal Guidelines.

As set out in the explanatory note accompanying the draft revised HBERs and Horizontal Guidelines, the proposed changes aim to:

a) the administrative supervision by the Emake it easier for companies to cooperate in areas such as R&D and production,

b) ensure a continued effective protection of competition,

c) include a new chapter on the assessment of horizontal agreements pursuing sustainability objectives as well as new guidance on data sharing, mobile infrastructure sharing agreements and bidding consortia and

d) simplify European Commission and National Competition Authorities by streamlining and updating the general framework of assessment of horizontal cooperation agreements.

Interested parties are invited to submit their comments on the draft rules **by 26 April 2022**.

Thank you for your attention!

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