European Commission opens consultation on orphan medicine regulation

Richard Price

The European Commission has opened a public consultation to gain views from stakeholders on proposed revisions to EU regulation on orphan medicines, especially in respect of how the concept of 'similar medicinal product' is understood. **The consultation closes on 4th November 2016.**

A short four-page document explains the rationale for the proposed changes. Fifteen years after EU regulations on orphan medicines were put in place, changes in science, technology and the pharmaceutical market has caused a rethink in how the concept of 'similar medicinal product' is understood when it comes to applying the various incentives provided by designation of a product as 'orphan' (ie, intended for treatment for rare conditions). Developments in respect to biological medicines and Advanced Therapy Medicinal Products (ATMPs) are particularly cited as giving rise to reconsideration of the term's meaning.

New texts for understanding the meaning of terms within EU orphan medicine regulation, such as 'similar active substance', are proposed. All views and comments on these are welcomed.

UNITED NATIONS GENERAL ASSEMBLY COMMITS TO ACTION ON ANTIMICROBIAL RESISTANCE

The 71st session of the United Nations (UN) General Assembly (GA) has made new global commitments to tackling antimicrobial resistance (AMR), only the fourth time a health issue has been taken up by the UN GA (the others being HIV, non-communicable diseases, and Ebola).

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Member countries of the United Nations reaffirmed their commitment to developing national action plans on AMR, based on the 'Global Action Plan on Antimicrobial Resistance'—the blueprint for tackling AMR developed in 2015 by WHO in coordination with the Food and Agriculture Organization of the United Nations (FAO) and the World Organisation for Animal Health (OIE).

National leaders recognised the need for stronger systems to monitor drug-resistant infections and the volume of antimicrobials used in humans, animals, and crops, as well as increased international cooperation and funding. They pledged to strengthen regulation of antimicrobials, improve knowledge and awareness, and promote best practices—as well as to foster innovative approaches using alternatives to antimicrobials and new technologies for diagnosis and vaccines.

Leaders at the UN meeting also called on WHO, FAO and OIE, in collaboration with development banks such the World Bank and other relevant stakeholders, to coordinate their planning and actions and to report back to the UN General Assembly in September 2018.

Market failures were also highlighted, alongside calls for new incentives for investment in research and development of new, effective and affordable medicines, rapid diagnostic tests, and other important therapies to replace those that are losing their power.

UN SECRETARY-GENERAL REPORT CALLS FOR BOLD GLOBAL ACTION TO CHANGE THE MEDICINES ACCESS LANDSCAPE

A High-Level Panel convened to advise the UN Secretary-General about improving

access to medicines has issued its final report urging bold new global approaches to health technology innovation to ensure more people benefit from medical advances.

The report calls for governments to negotiate global agreements on the coordination, financing and development of health technologies to complement existing innovation models, including a binding Research & Development (R&D) Convention that delinks the costs of R&D from end prices.

The Panel suggests that global governments should form a working group to begin negotiating a Code of Principles for Biomedical R&D, and report annually on their progress in negotiating and implementing the Code in preparation for negotiating the Convention.

The Panel also recommended requiring manufacturers and distributors of health technologies to disclose these costs and the details of any public funding received in the development of health technologies, including tax credits, subsidies, and grants.

The Panel recommended that the UN General Assembly convene a Special Session 'no later than 2018 on health technology innovation and access to agree on strategies and an accountability framework that will accelerate efforts towards promoting innovation and ensuring access in line with the 2030 Agenda for Sustainable Development'.

EAHP Statement 6: Education and Research

Competing interests None.

Provenance and peer review Commissioned; internally peer reviewed.

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To cite Price R. *Eur J Hosp Pharm* 2016;**23**:368.

Eur J Hosp Pharm 2016;**23**:368.
doi:10.1136/ehjpharm-2016-001126