EU news

EMA/HMA joint statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU

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In mid-September, the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) issued a joint statement confirming that biosimilar medicines approved in the European Union are interchangeable with their reference medicine or with an equivalent biosimilar. This joint statement brings more clarity for healthcare professionals and consequently will improve patients' access to biological medicines across the EU.

Since 2006, EMA has been at the forefront of biosimilar medicines and so far, has approved 86 of them. EMA's position is based on the experience gained in clinical practice, where it has become common that doctors switch patients between different biological medicinal products. Approved biosimilars have demonstrated similar efficacy, safety and immunogenicity compared with their reference medicines, and analysis of more than one million patient-treatment years of safety data did not raise any safety concerns. Thus, EU experts considered that when a biosimilar is granted approval in the EU, it can be used instead of its reference product (or vice versa) or replaced by another biosimilar of the same reference product. Decisions regarding substitution at pharmacy-level (the practice of dispensing one medicine instead of another without consulting the prescriber) are managed by individual Member States. EMA plans to update its communication materials on biosimilars for patients and healthcare professionals to integrate the new joint statement.

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MEDICAL DEVICE COORDINATION GROUP SHARES ACTIONS SUPPORTING THE AVAILABILITY OF MEDICAL DEVICES

Following concerns raised on notified body capacity and availability of medical devices and in vitro diagnostics by health ministers at the Employment, Social Policy, Health and Consumer Affairs (EPSCO) Council meeting in June, the Medical Device Coordination Group (MDCG) endorsed and published a list of actions. The list of actions contained in the MDCG 2022–14 Position Paper seeks to increase the capacity of notified bodies and the preparedness of manufacturers, in an effort to facilitate the transition to the Medical Devices Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR).

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