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# WEEKLY EU HEALTHCARE NEWS UPDATE

15 JULY – 21 JULY 2023

# A CONSENSUS ON 'FINANCIAL NEUTRALITY' FOR SOHO DONATIONS

The European Parliament's health committee (ENVI) has approved amendments to enhance safety and quality standards for substances of human origin (SoHO), such as blood, plasma, and corneas, striving to solve the particularly thorny issue of the right to compensation. The revision comes after more than 20 years since the previous regulations were set.

The updated proposal also covers skin, embryo, sperm, and even breast milk and microbiota. It aims to establish a harmonized system for transplants and donations while ensuring the autonomy of the EU's supply of these substances. Additionally, a crucial aspect resolved during the process was the regulation of voluntary unpaid donations (VUD) in the EU.

The ENVI committee's report received overwhelming support, with 59 votes in favor and 4 against, making it a positive outcome for donors, patients, and the European healthcare system. As indicated by the French Christian-Democrat MEP Nathalie Colin-Osterlé, the result is “a win-win deal for donors, patients, and Europe’s health system”. The amendments were reached through cooperation among various political groups, with 874 initial proposals leading to widely adopted final changes.

Source: <https://www.euractiv.com/section/health-consumers/news/eu-parliament-agrees-on-principle-of-financial-neutrality-for-soho-donations/>

# EU TAKES STRONGER MEASURES TO AVERT ANTIBIOTIC SHORTAGES

**The European Commission, in cooperation with the Heads of Medicines Agencies (HMA) and the European Medicines Agency (EMA), is releasing guidelines to prevent shortages of crucial antibiotics utilized in the treatment of respiratory infections for European patients during the upcoming winter season.**

These recommendations were developed through the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) and are intended to complement the establishment of an EU list of essential medicines. The Commission will work closely with EU Member States to implement these guidelines, and if required, explore the possibility of joint procurements to address any potential shortages.

To prepare for the winter season, EMA and HERA propose proactive actions: increasing antibiotic production by working closely with medicine authorization holders, thoroughly monitoring supply and demand with the help of Member States and companies, as well as promoting public awareness of the prudent use of antibiotics to prevent antimicrobial resistance. This is essential, especially taking into account the recent crisis related to medicine shortages in almost all EU Member States.

Source: <https://www.ema.europa.eu/en/news/european-health-union-eu-steps-action-prevent-shortages-antibiotics-next-winter>

# EC TAKES POLAND TO COURT OVER A PHARMACY AD BAN

**The European Commission on July 14, 2023, decided to refer Poland to the EU Court of Justice over the ban on advertising pharmacies and their activities under the Polish Pharmaceutical Law.**

According to the E-commerce Directive, which applies to regulated professions like pharmacists, they should have the freedom to utilize information society services for promoting their services. However, under Polish law, pharmacies are restricted from sharing extensive information with the public about their location and operating hours. As a result, they are prohibited from using the Internet or any electronic and non-electronic means for commercial communication.

The EC believes that Polish law violates the E-commerce Directive, as well as Article 49 and Article 56 of the Treaty on the Functioning of the European Union (TFEU). The complete advertising ban is seen as unjustified and disproportionate in the context of public health concerns. While some restrictions may be necessary to protect public health, a total ban on advertising negatively impacts market competitiveness. In response to this breach, the Commission first issued a letter of formal notice to Poland in January 2019, and later a reasoned opinion in July 2020. Since Poland has not addressed the concerns raised by the Commission, the case is now being referred to the Court of Justice of the European Union.

Source: [https://ec.europa.eu/commission/presscorner/detail/en/ip\\_23\\_3528](https://ec.europa.eu/commission/presscorner/detail/en/ip_23_3528)

# Thank you for your attention!

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