

CLARIFICATION 'PHARMACY' DEFINITION IN THE EUROPEAN HEALTH DATA SPACE REGULATION

AlliancE for the Digitalisation of HosPitAls MediCation Management PaThways

Proposal for a Regulation on the European Health Data Space: Section 2, Article 12 - paragraph 6

Member States shall ensure that **pharmacies** operating on their territories, including **online pharmacies**, are enabled to dispense electronic prescriptions issued by other Member States, under the conditions laid down in Article 11 of <u>Directive 2011/24/EU</u>. The pharmacies shall access and accept electronic prescriptions transmitted to them from other Member States through MyHealth@EU. Following dispensation of medicinal products based on an electronic prescription from another Member State, pharmacies shall report the dispensation to the Member State that issued the prescription, through <u>MyHealth@EU</u>.

Clarification

The EHDS aims to make health data more accessible, portable, secure, and transferable across the EU to ensure high levels of quality and safety in healthcare. In campaigns and communications advocating the advantages of the EHDS for patients and healthcare professionals' emphasis has largely been focused on community pharmacies' ability to dispense medication to individuals travelling across borders within MyHealth@EU.

Now, on behalf of the EPACT Alliance, EHMA is delighted to share the European Commission's clarification that:

'Hospital pharmacies (incl. ambulatory/one-day settings) are covered in the EHDS and the Commission will 'import certain definitions from <u>Directive 2011/24/EU</u> (Cross Border Healthcare Directive), so pharmacists are health professionals, and pharmacies are healthcare providers, independently of the setting'. On the technical level, there may be differences in handling prescriptions in community pharmacies and hospital pharmacies, or even different types of prescriptions could be used by them. These technicalities can be addressed in the implementing acts for the MyHealth@EU specifications. Specifications will take the current <u>eHealth Network guidelines</u> as a starting point.'

For patients accessing care across borders, such as Ukrainian citizens with cancer, the ability to share medication data from healthcare settings is key for consistent, continuous, cross-border care. In the absence of <u>FAIR data</u> the ability to provide safe, quality, care is compromised. Hence, deploying digital tools in hospital and ambulatory care's medication management pathways is essential to implement the EHDS in healthcare settings.

The EPACT Alliance highly welcomes this clarification and continues to call for hospital pharmacies' to be explicitly referenced in the Regulation to remove uncertainty and ensure it is implemented across care continuum. For more information read our position paper here.