POSITION PAPER ON DIGITAL MEDICATION TREATMENT DATA IN THE EUROPEAN HEALTH DATA SPACE

by the Alliance for the Digitalisation of Hospitals Medication Management Pathways

The Alliance for the Digitalisation of Hospitals Medication Management Pathways **congratulates the setting up of a European Health Data Space** (EHDS) to provide European citizens with electronic access to their medical records across borders. Its emphasis on patient safety is vital for the true benefit of access to electronic health records to be realised.

This position paper supports the implementation of a EHDS for **quality healthcare continuity** in all health services in the European Member States. However, the draft regulation does not include all healthcare providers across the care continuum[1] to provide medication treatment data into the EHDS. We, therefore, wish to outline that we see a major **opportunity** in the EHDS **to integrate relevant and actionable medication treatment data** in Electronic Health Record (EHR) systems to strengthen the primary and secondary use of electronic health data in the EHDS.

The effective functioning of the EHDS relies on the **widespread adoption of interoperable IT systems across the care continuum** for the attainment of improved **access to and sharing of electronic health data** for the building of a European Health Union.

DIGITAL MEDICATION MANAGEMENT IN HEALTHCARE SETTINGS: A FUNDAMENTAL OPPORTUNITY FOR EHDS IMPLEMENTATION

Medication is the main part of the therapeutic process for hospital patients. Up to 200 medicines are held in healthcare settings at one time to ensure the availability of quality patient treatment and care. Despite high stock levels, and the complex activities carried out by multi-disciplinary teams to manage medication, the digitalisation of medication data is low. This combined with the inefficient manual collection of medication treatment data in many situations compromises medication management. Comprehensive digitalisation of what is known as the medication management pathway is therefore essential for the EHDS. This includes the mandatory use of automation and e-prescriptions, e-preparation and e-administration/dispensation systems in healthcare settings. When this is achieved European citizens and healthcare professionals can access complete EHRs on medication treatments through the EHDS. The Alliance for the Digitalisation of Hospitals' Medication Management Pathways, in their recent white paper, calls for the **inclusion of medication treatment data in the EHDS (from ambulatory care and hospital settings)** as key data to be generated and shared by Member States within the EHDS (EHMA, 2022).

PATIENT SAFETY ACROSS THE CARE CONTINUUM IS ESSENTIAL

To ensure the EHDS delivers on its **commitment to patient safety**, hospitals, patients, and healthcare professionals must have access to medication treatment data from all care settings across the care continuum. Medication is the most common therapeutic intervention for care and treatment; patients are prescribed up to 9 medications, and many times more, during one episode of hospital

[1] The care continuum represents comprehensive, coordinated and integrated health services that improve the quality and value of care across all states of health and care settings (Welcome to the Care Continuum Alliance). In this paper, the services from the healthcare continuum which are excluded from the EHDS are hospitals and ambulatory care/day hospitals.

care (Carroll & Richardson, 2019). **Unintended medication discrepancies affect nearly every patient moving across the care continuum.** Common discrepancies with the highest risk of harm to patients occur during transitions of care and include the wrong medication dose, contraindications, duplications, and failure to communicate medication changes (WHO, 2019). Hospital-acquired medication-related harm costs a total of $54 billion annually (OECD, 2022). To ensure patient safety in care provision and during care transitions within and between Member States, the EHDS must ensure that **professionals have timely access to patient medication data from all care settings.** This is possible only when the medication pathway across the care continuum is digitalised.

INVESTMENTS IN INTEROPERABLE IT INFRASTRUCTURE AND DATA STANDARDISATION ARE NECESSARY

A key principle of the EHDS is to ensure the **secure and free movement of electronic health data across the Union.** The ability to freely move electronic health data depends on the collection, availability, and portability of an EHR which is implemented in all healthcare settings. However, **levels of integrated digital systems** in hospitals' medication management pathways (including e-prescriptions, e-preparation and e-administration/dispensations) **are low** across the Union. A 2019 report showed a drastic need for improvement in hospital adoption in the deployment, availability, and use of eHealth systems (ESPON, 2019). More recent research conducted by the ECAMET Alliance (2022) showed that only one-fifth of 317 surveyed hospitals had e-prescribing systems (otherwise known as CPOEs) integrated with a clinical decision support system. Additionally, approximately half of the hospitals had e-prescription systems in general wards, oncology (ambulatory or one-day hospitals), oncology (on wards), ICU and ambulatory (other than oncology). Furthermore, only 54-63% of oncology, ICU and general wards were integrated with electronic medical records. The availability of infrastructure and software at the level of each healthcare setting is inseparable from the investments needed to ensure the availability and training of the health workforce to use them.

However, implementation of these tools should not lead to additional fatigue for the professionals, but facilitate their work, making the collection of patient medical data more fluid to support the establishment of a diagnosis and/or a treatment plan. Comprehensive standardised health data generation and collection of medication treatment information that is dispensed and administrated to patients need to be compulsory to ensure that health professionals can access complete patient health records and guarantee evidence-based clinical decision-making. **Modern IT infrastructure (hardware and software) for medication treatment data collection and harmonised standardisation must be deployed in all healthcare settings** in all EU member states to provide **complete availability of electronic health data across the care continuum**. In terms of standards, policymakers should duly consider industry best practices in terms of interoperability or promote the development of the same. In this regard, where appropriate and available, internationally recognised harmonised standards should be promoted and used.

MEDICATION DATA IN ALL HEALTHCARE SETTINGS AND NOT SOLELY COMMUNITY RETAIL PHARMACIES IS VITAL.

An EU stakeholder survey revealed that almost 85% of respondents consider a **lack of data portability drives up costs** in healthcare and delays diagnosis and treatment (EHDS, pg 10). Information on medication treatments from hospitals and ambulatory/day hospital settings are not only critical for EU citizens and healthcare professionals; the secondary use of medication data is also crucial to make informed evidence-based decisions for the long-term economic sustainability of the EU's health systems. **Hospital budgets can save up to 15% with better use of health information**

including better use of medication treatment data, yet poor drug management systems in any country result in the waste of 70% of resources (Olesch, 2022; Iqbal, et al., 2017). After human resources, pharmaceutical spending represents the second largest budget item for hospitals. This makes the EHDS a welcome step towards supporting the modernisation and digitalisation of hospitals to deliver economic, and environmental, sustainability in European health systems.

However, Article 5 and 12 of the draft regulation limits patient electronic prescription and dispensation of medicines to retail pharmacies; hospitals and ambulatory care/day hospitals are excluded. The same limitation is true in the case of the Patient summary, line 12 "Current and relevant past medicines", which mainly refers to medicines prescribed and dispensed in retail pharmacies, but not in hospitals and ambulatory care/day hospitals. Cancer and immunotherapy medication treatments, amongst others, **are mostly only** administrated in hospitals or ambulatory care/day hospitals not by retail pharmacies. Furthermore, standardised medication data is vital to move research forward and to support the correct calculation of medication e.g. medication calculations for children and new-borns based on body weight to reduce errors. If this important medication information is not included in the EHDS there will be significant gaps for large cohorts of patients. **Standardised data generation of medication prescribed and dispensed/administrated to patients across the continuum of care, including hospitals and ambulatory care/day hospitals is key** to monitoring and evaluating treatment performance, for the delivery of safe, high-quality healthcare and for informing budgetary decision-making.

To create a **EHDS that meets the needs of European citizens, data on medication prescribed and administrated/dispensed to patients across the continuum of care generated in interoperable, fully connected systems must be included in the Regulation.** In its current reading, the data within the EHDS risks being fragmented. Opportunities to build on integrating medication-related data into the EHDS can strengthen patients' cross-border care. Additionally, ensuring the availability of medication-related data will allow for the meaningful use of primary and secondary electronic health data to leverage the EHDS's full potential. As the continuity of care is of special importance to citizens (e.g. cancer and immunotherapy patients) accessing care across borders and receiving treatment in several healthcare settings, including retail pharmacies, hospitals, and ambulatory care/day hospitals. Where the EHDS is limited to only one aspect of the healthcare system (i.e. community/primary care) in the continuum of care, the benefits for primary and secondary use of health data will not be achieved for patients, healthcare professionals, policymakers or researchers. Moreover, patient safety during care transitions cannot be ensured. Therefore, we suggest the following recommendations to ensure that health data collection and exchange are consistent across the care continuum.

1. Make hospitals and ambulatory care/day hospitals´ medication data provision to the EHDS more explicit in Articles 5 and 12 of the Regulation and in Annexe I of the document to ensure safe, quality care continuity for patients across the Union's health care spectrum.
2. Support countries and national ministries to invest in digitalisation, data generation and standardisation of hospital medication so hospitals can be fully integrated into the EHDS through patient summaries and e-prescriptions and e-dispensations.
3. Empower regional and local healthcare providers and hospitals that play a crucial role in the process of making medication hospital data interoperable.
4. Stimulate implementation and where needed development of data standards.
5. Promote, and communicate, to hospitals and ambulatory care/day hospitals settings internationally accepted harmonised data standards to facilitate interoperable medication data to collect from healthcare settings into the EHDS.

The Alliance for the Digitalisation of Hospitals' Medication Management Pathways was founded in February 2022, by the European Health Management Association [2]. The Alliance consists of NGOs representing patient and healthcare professional organisations to advocate for the implementation and upscaling of digital medication management tools in hospitals' medication management pathways to enhance the quality of patient care, healthcare professionals' well-being and the long-term resilience and economic sustainability of European hospitals.

Disclaimer: *Views and opinions expressed in this paper do not necessarily represent the views of all Alliance members or the members of each signing organisation. The information contained in this position paper is neither exhaustive nor exclusive to all members.*

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LIST OF REFERENCES

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[2] The European Health Management Association is a non-profit membership organisation that focusses on enhancing the capacity and capability of health management to deliver high-quality healthcare.

Annex

Amendments to the proposal for a EHDS - by the Alliance for the Digitalisation of Hospitals Medication Management Pathways

January 2023

Amendment 1, Section 1, Article 1 – paragraph 2 – (d) (addition)

Original	Amended
This Regulation: 1. strengthens the rights of natural persons in relation to the availability and control of their electronic health data; (b) lays down rules for the placing on the market, making available on the market or putting into service of electronic health records systems ('EHR systems') in the Union; (c) lays down rules and mechanisms supporting the secondary use of electronic health data; (d) establishes a mandatory cross-border infrastructure enabling the primary use of electronic health data across the Union; (e) establishes a mandatory cross-border infrastructure for the secondary use of electronic health data.	This Regulation: a) strengthens the rights of natural persons in relation to the availability and control of their electronic health data; b) lays down rules for the placing on the market, making available on the market or putting into service of electronic health records systems ('EHR systems') in the Union; c) lays down rules and mechanisms supporting the secondary use of electronic health data; d) establishes a mandatory cross-border infrastructure enabling the primary use of electronic health data across the **continuum of care in the Union for patient safety, research and policy-making.** (e) establishes a mandatory cross-border infrastructure for the secondary use of electronic health data across the **health care continuum in the Union for patient safety, research and policy-making.**

Justification: To ensure patient safety during transitions of care, healthcare professionals must have timely access to patients' electronic health data from all care settings in order to provide safe, quality patient treatment and avoid any negative consequences that may arise during cross-border episodes of care.

Amendment 2, Section 1, Article 5 – paragraph 1 – point a,b, c (addition)

Original	Amended
Where data is processed in electronic format, Member States shall implement access to and exchange of personal electronic health data for primary use fully or partially falling under the following categories: (a) patient summaries; (b) electronic prescriptions; (c) electronic dispensations; (d) medical images and image reports; (e) laboratory results; (f) discharge reports	Where data is processed in electronic format, Member States shall implement access to and exchange of personal electronic health data for primary use fully or partially falling under the following categories: (a) patient summaries **including medication treatment information at hospital and ambulatory/day hospitals.** (b) electronic prescriptions **across the continuum of care, including hospital and ambulatory/day hospitals**. (c) electronic dispensations **across the continuum of care, including hospital and ambulatory/day care hospital** (d) medical images and image reports; (e) laboratory results; (f) discharge reports

Justification: To ensure data portability and the secure and free movement of data across the Union from all settings in the care continuum, standardised, interoperable, electronic health data must be gathered on a mandatory basis to close gaps in the voluntary provision of data.

Amendment 3, Section 1, Article 6, paragraph 3

Original	Amended
Member States shall ensure that the priority categories of personal electronic health data referred to in Article 5 are issued in the format referred to in paragraph 1 and such data shall be read and accepted by the data recipient	Member States shall ensure that the priority categories of personal electronic health data referred to in Article 5 **are processed in electronic format across the continuum of care and are issued** in the format referred to in paragraph 1 and such data shall be read and accepted by the data recipient

Justification: To ensure that the EHDS meets the needs of European citizens electronic health data from all care settings are required by all healthcare professionals to ensure the delivery of safe, quality, care.

Amendment 4, Section 2, Article 12 – paragraph 5

Original	Amended
Member States shall ensure connection of all healthcare providers to their national contact points for digital health and shall ensure that those connected are enabled to perform two-way exchange of electronic health data with the national contact point for digital health.	Member States shall **support** and ensure connection of all **regional and local** healthcare providers to their national contact points for digital health and shall ensure that those connected are enabled to perform two-way exchange of electronic health data with the national contact point for digital health.

Justification: To ensure that the EHDS has data from all healthcare settings, regional and local healthcare providers will require support to digitalise their operations and medication management pathways so comprehensive patient summaries are fully integrated into the EHDS.

Amendment 5, Section 2, Article 12, paragraph 6

Original	Amended
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 Directive 2011/24/EU. 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 MyHealth@EU.	Member States shall ensure that pharmacies **across the continuum of care** operating on their territories, including online, **hospital and ambulatory/day hospital** pharmacies, are enabled to dispense electronic prescriptions issued by other Member States, under the conditions laid down in Article 11 of Directive 2011/24/EU. 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, **all** pharmacies shall report the dispensation to the Member State that issued the prescription, through MyHealth@EU.

Justification: To reduce the risk of harm arising from the unavailability of data (e.g. medication discrepancies) during transitions of care, a complete comprehensive medication record is required to ensure the provision of safe, quality, care in all healthcare settings in EU Member States.

Amendment 6, Annex 1

Original	Amended
1. Patient summary Electronic health data that includes important clinical facts related to an identified person and that is essential for the provision of safe and efficient healthcare to that person. The following information is part of a patient summary: 1. Personal details 2. Contact information 3. Information on insurance 4. Allergies 5. Medical alerts 6. Vaccination/prophylaxis information, possibly in the form of a vaccination card 7. Current, resolved, closed or inactive problems 8. Textual information related to medical history 9. Medical devices and implants 10. Procedures 11. Functional status 12. Current and relevant past medicines 13. Social history observations related to health 14. Pregnancy history 15. Patient provided data 16. Observation results pertaining to the health condition 17. Plan of care 18. Information on a rare disease such as details about the impact or characteristics of the disease	1. Patient summary Electronic health data that includes important clinical facts related to an identified person and that is essential for the provision of safe and efficient healthcare to that person. The following information is part of a patient summary: 1. Personal details 2. Contact information 3. Information on insurance 4. Allergies 5. Medical alerts 6. Vaccination/prophylaxis information, possibly in the form of a vaccination card 7. Current, resolved, closed or inactive problems 8. Textual information related to medical history 9. Medical devices and implants 10. Procedures 11. Functional status 12. **Prescription, dispensation and administration of current and past medications across the continuum of care, including, hospital and ambulatory/day hospitals.** 13. Social history observations related to health 14. Pregnancy history 15. Patient provided data 16. Observation results pertaining to the health condition 17. Plan of care 18. Information on a rare disease such as details about the impact or characteristics of the disease

Justification: By limiting data collection within the EHDS to only one element of the continuum of care, the benefits for primary and secondary use of health data will not be achieved. In its current form, the EHDS risks mimicking the voluntary nature of data provisions in the Cross Border Health Care Directive and will not solve the problem of uneven access to and data fragmentation between services in the healthcare continuum.