Position Paper on the European Union's Reformed Pharmaceutical Legislation
Availability and Shortages of Medicines in Hospital Settings.

The EPACT Alliance for the Digitalisation of Hospitals Medication Management Pathways warmly welcomes the strong emphasis that the reformed pharmaceutical legislation places on tackling the ever-growing problem of medicines shortages in the EU. The objective of the regulation to improve the supply of medicines with the dual goal of protecting human health is warmly applauded. We recognise that this legislation is an important milestone to support the new mandate of the European Medicines Agency (EMA) to mitigate, manage and prevent medication shortages via the European Shortages Monitoring Platform (ESMP).

Like industry, EU hospitals will have new obligations as they will be key stakeholders of the ESMP by providing supply and demand information for medicines. With this position paper, we wish to draw attention to how hospitals' role and contribution to managing and mitigating medication shortages can be enhanced within the proposal of the Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 and the proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use and repealing Directive 2001/83/EC and Directive 2009/35/EC maintain a robust legal framework to protect public health and guarantee the safety of medical products.

LEVERAGE TECHNOLOGY TO ADDRESS MEDICATION SHORTAGES IN HOSPITALS PRACTICAL SOLUTIONS

Even before COVID, medication shortages were on the increase. The 2022 winter tri-demic once again highlighted the urgent impact of medication shortages on health systems. While media attention focused on the impact of shortages on community pharmacists, **shortages of critical and generic medicines equally impact healthcare staff, hospital pharmacists, doctors, and nurses, in hospital settings.** Already one of the highest spending chapters for health budgets, medication shortages have been shown to increase hospital pharmaceutical budgets already on the rise (ASHP, 2023). Increased expenditures because of drug prices rising and paying for more expensive substitutes have been estimated to cost $230 million each year to US hospitals (Mercatus, 2021).

The continuous availability of medicines is required for patient treatment and care. At any one time, hospitals require up to 200 drugs to treat patients (Iqbal, et al., 2017). However, despite high stock levels, and the complex activities carried out by multi-disciplinary teams to manage medication supplies, the use of robotics and automated digital systems to manage medication stocks is low. **33% of hospitals across the EU have no access to pharmacy inventory information systems and 82% do not have robots for inventory management** (ECAMET Alliance, 2022). In critical wards, only 25% of ICUs had Automated Dispensing Cabinets (ADCs) (ECAMET, 2022).

Hospital pharmacies have the best view of medication inventory as the medication is stored in the pharmacy, however, stock visibility decreases significantly when medicines are transferred to dispensing locations. Current hospital medication inventory management consists of mainly manual counting by pharmacists, which is time-consuming and inefficient adding up to 5 hours per week to hospital pharmacists' workloads (EAHP, 2019). Moreover, manual processes contribute to a general lack of full supply chain visibility and may potentially impede the Union's ability to effectively monitor medication stocks in hospitals.

Furthermore, medication shortages trigger the need for resource allocations, while operational and clinical drug management strategies divert time and resources away from clinical care (ASHP, 2023). To manage pressures on staff hospitals, we may create new posts and processes (Miljkovic, 2019), but with healthcare professional shortages on the rise, recruiting and retaining healthcare workers is becoming ever more challenging. **Annual labour costs associated with medication shortages are estimated to be approximately $359** million for US hospitals (Mercatus, 2021; ASHP, 2023). Therefore, hospitals require digital medication management systems to collect real-time information to manage shortages and provide greater transparency along the supply chain.

Valuable time and significant cost savings can be achieved by introducing digital tools, such as automated inventory management systems, to support professionals in tracing unused stock in hospitals. New technological developments can support professionals with stock management to optimise dispensing processes, and redispersing unused medication to alternative locations within hospitals (D'Accolti, et al., 2019). Evidence from Spain demonstrates that **digitalisation of the medication pathway would optimise spending, and drive productivity in EU hospitals.** The introduction of logistics robots resulted in a 26.4% reduction in medication stocks and an 80% reduction in the wastage of drugs with expired dates (Giménez, et al., 2019). EU hospitals must therefore have access to up-to-date technological systems to support staff and reduce costs associated with managing medication shortages.

ENHANCE MEDICATION AVAILABILITY AND TRACEABILITY IN HOSPITALS FOR THE ESMP

Safeguarding access to medicines requires measures both at the EU, the national and hospital levels to improve information-sharing practices to coordinate actions for managing medication shortages across the EU. To achieve this objective, the EMA's new mandate includes setting up, maintaining, and managing an IT platform known as the European Shortages Monitoring Platform (ESMP). The ESMP will facilitate information gathering on medicines supply, demand, and shortages to monitor, prevent, and manage actual or potential shortages of medicines. **Hospitals will be amongst the key stakeholders in the ESMP as they will be required to provide data on medication stock and demand** to National Competent Authorities supporting manufacturers to plan medicine production. EMA's (2021) reflection paper for 'Forecasting demand for medicinal products in the EU' is based on learnings accumulated by EU National Competent authorities during the COVID-19 pandemic when hospitals were particularly affected by shortages of critical care medicines.

According to this paper, supporting medicine production at the national level depended on hospitals providing three key data points including information on current stock levels . Accurate quantification of stock supply and information on consumption in hospitals require management processes (Iqbal, et al., 2017). Quantification of stock supply during the COVID crisis on drug stocks and demand was tracked and shared from hospitals to NCA's in Microsoft Excel or Google Sheets . Counting of stocks was completed by hand which has been shown to be highly prone to errors (Iqbal, et al., 2017) (IG Solutions, n.d.).

To be ready for the next crisis, pharmacies require advanced logistic systems and digital tools that provide accurate, real, or near-time, quantification of stock supply tools to support stock management practices. Such systems will allow hospital pharmacies to share and communicate accurate data electronically on available stocks of critical medicines in hospitals. Digitalisation through integrated technologies along with the employment of global standards, is key to breaking down supply chain silos in hospital supply chains, and need to provide real-time and accurate demand and inventory data from hospitals for the ESMP.

Much emphasis has been placed on the benefits of ePI to boost the availability of medicines between Member States. While the European Union's support of this innovation is a step in the right direction, ePI alone cannot support the transfer of stocks between hospitals and member states when information on stock levels is unavailable. Digital tools, including electronic product information (ePI), inventory robots, automated dispensing cabinets and connected IT systems can provide full visibility of medicine stocks, demand projections, and ordering processes for hospitals. ePI use must be included as part of an overarching connected hospital IT system which incorporates inventory robots and automated dispensing systems. In combination, these systems will improve medicine shortages management and provide accurate and real-time data on medication stocks from hospitals.

UPHOLD HEALTHCARE RIGHTS BY HARNESSING DIGITAL TOOLS FOR MEDICATION AVAILABILITY

Access to medicines is a key element of the fundamental right to health. The right to **access to medicine and patient safety are closely intertwined** as medication shortages increase adverse reactions, including medication errors that can be harmful, and sometimes deadly, to patients (EAHP 2019; European Parliament, 2020;). The recent pandemic highlighted the impact of medication shortages on hospitals as demand surges meant professionals struggled to maintain supplies of antibiotics, antivirals, sedatives and anaesthetics (WHO, 2022). The interdependence of patient safety and medication availability has been demonstrated by a study in France which showed that pharmacovigilance notifications related to drug shortages increased over time and significantly faster than the total number of notifications in the French pharmacovigilance database (Bourneau-Martin et al, 2020).

The alarming rise in medicines shortages and their impact on patient safety is a key concern and a common issue in European health systems. As such, the reformed pharmaceutical legislation is a key opportunity to address high-level, international, calls to set appropriate policies for medication safety by tackling medication shortages. A key objective of the current reform is to ensure access to and the continued supply of medical products, especially during times of crisis, thus the competencies of hospital pharmacists to step in and counteract shortages when they occur, must be supported as a key element of patients right to access to medicines.

During the COVID crisis, hospital pharmacies throughout Europe promptly prepared oral liquids and capsules including dexamethasone, remdesivir, and other potentially promising drugs prescribed off-label (Carvalho & Almeida, 2022). Hospital pharmacies play an important role in providing medicines when manufacturers cannot meet hospitals' supply needs. Thus, we strongly recommend that the time limit contained in Article 1, subparagraph 6 be deleted from the revised Directive to let compounders provide patients with the medicines they need and to ensure the continuity of care during times of crisis.

Patient access to medicinal products across the EU and security of supply are growing concerns for healthcare managers, hospital pharmacists and frontline healthcare professionals. Shortages of medicinal products increase expenditures on hospital pharmaceutical products, contribute to stress and burnout amongst healthcare professionals and simultaneously pose significant risks to patient outcomes. The right to health and the right to access medicines are inseparable from the safety and well-being of patients and healthcare professionals. Optimal medicine use and access in hospitals during times of crisis includes real-time accurate information sharing, stock monitoring, internal redistribution of medicines, and magistral preparations (compounding) of medicines. With, legal and moral, obligations rising on hospitals to ensure access and security of the supply of medicines for patients, we suggest the following recommendations to ensure that medication safety is prioritised in the reformed legislation:

1. **Procurement and supply chains must be strengthened and diversified to ensure sufficient supplies of Active Product Ingredients (APIs). Reliance on specific regions for product supply must be reduced.**

2. **Remove the time limit contained in Article 1, subparagraph 6 in the reformed Directive to ensure continuity of care during times of crisis.**

3. **Support countries and national ministries to invest in digitalisation, data generation and standardisation of hospital medication data to allow hospitals to share information on medication demand and stocks of critical medicinal products with National Competent Authorities for the ESMP.**

4. **Encourage the use of integrated technologies and global standards to provide real-time and accurate demand and inventory data in hospitals.**

(1) The three data points required are: (a) what is needed for treatment; (b) what is needed to restore planned minimum stock levels; (c) what is currently available in the stocks held by e.g. hospitals

(2) Unpublished research by the EPACT Alliance.

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European Alliance for
Access to Safe Medicines

EJD European Junior Doctors Association

EUROPEAN PATIENT SAFETY FOUNDATION

ENSH
European Network for Safer Healthcare

ECAMET
European Collaborative Action on Medication Errors and Traceability

ECHO
European Children's Hospitals Organisation

european cancer ORGANISATION

International Alliance of Patients' Organizations
A global voice for patients

espnic
European Society of Paediatric and Neonatal Intensive Care

EUROPEAN ONCOLOGY NURSING SOCIETY

FEAM
Federation of European Academies of Medicine

ESN
EUROPEAN SPECIALIST NURSES ORGANISATION

E S A IC
European Society of Anaesthesiology and Intensive Care

All.Can

EUROPEAN UNION OF PRIVATE HOSPITALS
Uehp

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ANNEX

Amendments to the proposal of the Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency

Recital 137

ORIGINAL	ADMENDED
To achieve a better security of supply for medicinal products in the internal market and to contribute thereby to a high level of public health protection, it is appropriate to approximate the rules on monitoring and reporting of actual or potential shortages of medicinal products, including the procedures and the respective roles and obligations of concerned entities in this Regulation. It is important to ensure continued supply of medicinal products, which is often taken for granted across Europe. This is especially true for the most critical medicinal products which are essential to ensure the continuity of care, the provision of quality healthcare and guarantee a high level of public health protection in Europe./	To achieve a better security of supply for medicinal products in the internal market and to contribute thereby to a high level of public health protection, it is appropriate to approximate the rules on monitoring and reporting of actual or potential shortages of medicinal products, including the procedures and the respective roles and obligations of concerned entities in this Regulation. It is important to ensure continued supply of medicinal products, which is often taken for granted across Europe. This is especially true for the most critical medicinal products which are essential to ensure the continuity of care, the provision of quality healthcare and guarantee a high level of public health protection in Europe. *To combat certain shortages, medicinal products prepared for individual patients in a pharmacy according to a medical prescription "magistral formula", or according to the pharmacopoeia and intended to be supplied directly to patients served by the pharmacy "officinal formula", may be used.*

Justification:

Compounding, preparing and manufacturing are unique activities of the pharmacy profession. Compounding is essential for patient care since it closes the gap between licensed medicinal products manufactured by the industry and the lack of treatment options for certain patient groups and individual patients with unmet medical conditions or needs. This includes situations where there are shortages. Thus, it should be specified that pharmacy preparations are one of the options to address certain medicine shortages in hospitals.

Article 111 Cooperation with Member States

ORIGINAL	ADMENDED
The Agency and the Member States shall cooperate to continuously develop pharmacovigilance systems capable of achieving high standards of public health protection for all medicinal products, regardless of the routes of marketing authorisation, including the use of collaborative approaches, to maximise use of resources available within the Union.	The Agency and the Member States shall cooperate to continuously develop pharmacovigilance systems, including those that record adverse events including medication errors, processes and standards for medication safety, and implement digital technologies in healthcare settings, capable of achieving high standards of public health protection for all medicinal products, regardless of the routes of marketing authorisation, including the use of collaborative approaches, to maximise use of resources available within the Union.

Chapter X: Availability and security of supply of medicinal products Section 1

Article 121 Role of Competent Authority (addition)

ORIGINAL	ADMENDED
The competent authority of the Member State shall: (a) assess the merits of each confidentiality claim made by the marketing authorisation holder as defined in Article 116(1) in accordance with Article 119(1), point (e), and shall protect information which that competent authority considers to be commercially confidential against unjustified disclosure; (b) publish information on actual shortages of medicinal products, in cases in which that competent authority has assessed the shortage, on a publicly available website; (c) report to the Agency, through the single point of contact working party referred to in Article 3(6) of Regulation (EU) 2022/123, any shortage of a medicinal product that it identifies as a critical shortage in that Member State to the Agency without undue delay.	The competent authority of the Member State shall: (a) assess the merits of each confidentiality claim made by the marketing authorisation holder as defined in Article 116(1) in accordance with Article 119(1), point (e), and shall protect information which that competent authority considers to be commercially confidential against unjustified disclosure; (b) publish information on actual shortages of medicinal products, in cases in which that competent authority has assessed the shortage, on a publicly available website; (c) report to the Agency, through the single point of contact working party referred to in Article 3(6) of Regulation (EU) 2022/123, any shortage of a medicinal product that it identifies as a critical shortage in that Member State to the Agency without undue delay. *(d) shall in order to avert or mitigate an imminent or existing supply shortage relevant to the supply of a medication product request pharmacies supplying hospitals and hospital pharmacies, to communicate electronically data on available stock of the respective medicinal product* *(e) the reporting obligation should only take place in justified cases upon request from the authority.*

Justification:

The new Regulation 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medicinal devices foresees a new role for EMA to monitor and mitigate medicines shortages. To this end EMA will set up a European Shortages Monitoring Platform (ESMP) collecting information on shortages, supply and demand for medicinal products during a PHE and during actual or potential shortages that can lead to a Major event.

As demonstrated during the COVID-19 crisis, hospitals will be a key stakeholder in the mitigation and management of medicines shortages; they will need to share information on demand and supply of medicinal products in-situ to National Competent Authorities to support manufacturers plan production of medicinal products.

However, most of this information will need to be collected manually as the pharmaceutical supply chain of hospitals is not sufficiently digitalised to share real-time accurate information on medicine stocks and demand. In the absence of real-time accurate information, supply chain transparency is reduced while collecting information manually places additional time and workload pressures on hospital pharmacists and financial budgets.

Mirroring the precedent set by the new Act to Combat Shortages of Supply of Off-Patent Medicines and to Improve the Supply of Paediatric Medicines – ALBVVG of the German Bundestag to combat supply bottlenecks for off-patent medicinal products and to improve the supply of Children's Medicines (Act) hospitals should communicate electronically data on available stock of the respective medicinal product to ensure that NCA's provide the ESMP real-time information on medicine demand and supplies in hospitals to enhance the functioning of the ESMP during times of crisis.

Article 122 Role of Agency Concerning Shortages, Subparagraph 4 - addition

ORIGINAL	ADMENDED
4. For the purposes of fulfilling the tasks referred to in Articles 118(1), 123 and 124, the Agency shall ensure the following, in consultation with the working party referred to in Article 121(1), point (c):	4. For the purposes of fulfilling the tasks referred to in Articles 118(1), 123 and 124, the Agency shall ensure the following, in consultation with the working party referred to in Article 121(1), point (c):
(a) set the criteria to adopt and review the list of critical shortages referred to in Article 123(1);	(a) set the criteria to adopt and review the list of critical shortages referred to in Article 123(1);
(b) specify the tools, including the European Shortages Monitoring Platform ('ESMP'), established by Regulation (EU) 2022/123, once the scope is expanded pursuant to paragraph 6, the methods of and criteria for the monitoring and reporting provided for in Articles 119(1), point (a), and 121(2), point (a);	(b) specify the tools, including the European Shortages Monitoring Platform ('ESMP'), established by Regulation (EU) 2022/123, once the scope is expanded pursuant to paragraph 6, the methods of and criteria for the monitoring and reporting provided for in Articles 119(1), point (a), and 121(2), point (a);
(c) draw up guidance to allow marketing authorisation holders as defined in Article 116(1) to put in place the risk assessment of impact of suspension, cessation or withdrawal and the shortage mitigation plan as referred to in Article 118(2);	(c) draw up guidance to allow marketing authorisation holders as defined in Article 116(1) to put in place the risk assessment of impact of suspension, cessation or withdrawal and the shortage mitigation plan as referred to in Article 118(2);
(d) specify the methods for the provision of recommendations referred to in Article 123(4); (e) publish information covered by points (a) to (d) on a dedicated webpage on its web-portal referred to in Article 104	(d) specify the methods for the provision of recommendations referred to in Article 123(4); (e) publish information covered by points (a) to (d) on a dedicated webpage on its web-portal referred to in Article 104
	(f) Specify the systems and procedures to ensure the European Shortages Monitoring Platform (ESMP) includes accurate information on available critical medicinal stocks in legal entities that are authorised or entitled to supply medicinal products to the public including pharmacies supplying hospitals and hospital pharmacies.

Observation:
Today there are no standard processes among member states to collect inventory data on critical medicines from hospitals. Furthermore, hospitals are not digitalised nor have fully interconnected digital systems to provide accurate digital online reports of inventory of critical medicines. The absence of the above leads to the following risks: Data from hospitals is not consolidated meaning data maintained in the ESMP is not accurate rendering the EMA EMSP invalid especially during times of crisis.
Data is collected but not accurate. Member states provide approximations of hospitals estimations, which is not based on accurate data. If this occurs while no systems and processes are in place during a crisis, it would be impossible to properly manage medication shortages during these crisis periods. Again, the value of data of this quality to the ESMP will be negligible.

Chapter X: Availability and security of supply of medicinal products
Section 2 Security of Supply

Article 129 Obligations on other actors - addition

ORIGINAL	ADMENDED
For the purposes of Article 127(4) and Article 130(2), point (c), and Article 130(4), point (c), where relevant, upon request from the competent authority concerned as defined in Article 116(1), entities including other marketing authorisation holders as defined in Article 116(1), importers and manufacturers of medicinal products or active substances and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other persons or legal entities that are authorised or entitled to supply medicinal products to the public shall provide any information requested in a timely manner.	For the purposes of Article 127(4) and Article 130(2), point (c), and Article 130(4), point (c), where relevant, upon request from the competent authority concerned as defined in Article 116(1), entities including other marketing authorisation holders as defined in Article 116(1), importers and manufacturers of medicinal products or active substances and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other persons or legal entities that are authorised or entitled to supply medicinal products to the public, *including hospitals and ambulatory care settings,* shall provide any information requested in a timely manner.

Observation:
One of the main therapeutic activities of hospitals entails the supply, prescribing and dispensing of medication to patients. As demonstrated by the COVID pandemic hospitals are key healthcare institutions that protect public health in times of crisis. Similarly, the unavailability of medicines in hospitals and for hospitals place pressures on the wider health system. As noted in EMA's (2021), Reflection paper on forecasting demand for medicinal products in the EU/EE hospitals are key stakeholders in supply information to NCA's to support the production of medicinal products by manufacturers. Therefore, it should be made clear that hospitals and ambulatory care settings will also be required to share data with their NCA on medication to ensure the security of supply of medicines.

Amendments for the proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use

Chapter I: Subject matter, scope and definitions

Article 1 (6)

ORIGINAL	ADMENDED
Medicinal products referred to paragraph 5, point (a), may be prepared in duly justified cases in advance by a pharmacy serving a hospital, on the basis of the estimated medical prescriptions within that hospital for the following seven days.	Medicinal products referred to paragraph 5, point (a), may be prepared in duly justified cases in advance by a pharmacy serving a hospital, on the basis of the estimated medical prescriptions within that hospital

Observation:
Access to medicines is a key element of the fundamental right to health. A key objective of the current reform is to ensure access to and the continued supply of medical products, especially during times of crisis, thus the competencies of hospital pharmacists to step in and counteract shortages when they occur must be supported as a key element of patients right to access to medicines. During the COVID crisis, hospital pharmacies throughout Europe promptly prepared oral liquids and capsules including dexamethasone, remdesivir, and other potentially promising drugs prescribed off-label (Carvalho & Almeida, 2022). Thus, we strongly recommend that the time limit contained in Article 1, subparagraph 6 be deleted from the revised Directive to let compounders provide patients with the medicines they need and to ensure the continuity of care during times of crisis

Article 3 (1)

ORIGINAL	ADMENDED
1. A Member State may, in order to fulfil special needs, exclude from the scope of this Directive medicinal products supplied in response to a bona fide unsolicited order, prepared in accordance with the specifications of an authorised healthcare professional and for use by an individual patient under their direct personal responsibility. However, in such case Member States shall encourage healthcare professionals and patients to report data on the safety of the use of such products to the competent authority of the Member State in accordance with Article 97. For allergen medicinal products supplied in accordance with this paragraph, the competent authorities of the Member State may request the submission of relevant information in accordance with Annex II.	A Member State may, in order to fulfil special needs, exclude from the scope of this Directive medicinal products supplied in response to a bona fide unsolicited order, *including those* prepared in accordance with the specifications of an authorised healthcare professional and for use by an individual patient under their direct personal responsibility *or prepared in accordance with the specifications of a competent authority.* However, in such case Member States shall encourage healthcare professionals and patients to report data on the safety of the use of such products to the competent authority of the Member State in accordance with Article 97. For allergen medicinal products supplied in accordance with this paragraph, the competent authorities of the Member State may request the submission of relevant information in accordance with Annex II.

Observation:
During the pandemic, hospitals' pharmaceutical departments were authorised to compound medicines in short supply and most urgently needed, eg. ICU medicines. Such needs are not unique to the pandemic and countries may have already taken steps to make this practice possible in duly justified cases, or may find useful to do so. In view of the immense difficulties brought by shortages, it is necessary to allow such a practice, in a well-regulated framework.
A definition should be included for the term "bona fide unsolicited order".

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