

Dear Honourable Members of the European Parliament,

Dear European Commissioner,

**Re: The undersigned members of the Alliance for the digitalisation of hospital medication management pathways call for a European Patient Safety Strategy**

Patient harm is an urgent public health issue and patient safety is a shared European challenge, pertinent to all EU Member States striving towards building a resilient European Health Union. In Europe, 1 in every 10 patients experience harm while receiving services in a hospital<sup>1</sup>, and as many as 4 in 10 patients are estimated to be harmed while receiving care in primary and ambulatory care settings across the OECD countries<sup>2</sup>. More than half of cases of patient harm are preventable; **a European strategy and concerted actions at the European level are needed to reduce the significant burden of harm in healthcare settings**

**Approximately 15% of hospital expenditure and almost 13% of health spending** (amounting to \$606 billion across the OECD) **is attributed to treating patient safety failures** in rich countries<sup>3</sup>. Taking just one of the main causes of patient harm – medication errors, almost 18% of European patients, the equivalent of 80 million people, report experiencing significant harm from a medication error during hospitalisation<sup>4</sup>. **European estimates suggest that 1 person per million dies every day from a medication error**, overshadowing deaths from road traffic accidents, breast cancer or HIV<sup>5</sup>. These statistics are expected to be the tip of the iceberg as reporting medication harm is neither mandatory in all EU Member States nor are all medication errors detected by patients or staff, the annual costs of medication errors could be as high as €43 billion. Additionally, research from Germany demonstrates that medication errors extend hospital stays by up to 8.5 days. For Spain, the cost of errors equates to 3% of national healthcare budgets.<sup>6</sup>

Among different factors, patient safety is significantly impacted by the fatigue of the healthcare worker; lack of sleep can affect the level of vigilance or ability to interpret information or events, as well as the speed and quality of communication and decision-making<sup>7</sup>. For instance, recent studies<sup>8</sup> <sup>9</sup> have confirmed an obvious link between fatigue and patient safety, finding that physicians suffering from burnout are far more likely to be involved in incidents where patients' safety is compromised. With overworked healthcare workers and understaffed teams, the quality of care suffers, leading to medical errors and poor outcomes for patients. Patients may also have to wait longer to be seen and treated, leading to delays in care.

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<sup>1</sup> [https://www.who.int/europe/health-topics/patient-safety#tab=tab\\_2](https://www.who.int/europe/health-topics/patient-safety#tab=tab_2)

<sup>2</sup> Slawomirski L, Aaraaen A, Klazinga N. The economics of patient safety in primary and ambulatory care: flying blind. OECD Health Working Papers No. 106. Paris: Organisation for Economic Co-operation and Development; 2018 (<https://doi.org/10.1787/baf425ad-en>).

<sup>3</sup> OECD (2023) "Advancing Patient Safety Governance in the Covid-19 Response"

<sup>4</sup> EPACT Alliance (2022) 'Digital Medication Management in Healthcare Settings: An Opportunity for the European Union'

<sup>5</sup> EPACT Alliance (2022) 'Digital Medication Management in Healthcare Settings: An Opportunity for the European Union'

<sup>6</sup> All figures cited in this paragraph can be found in the EPACT Alliance White Paper (2022) 'Digital Medication Management in Healthcare Settings: An Opportunity for the European Union'

<sup>7</sup> FATIGUE IN ANAESTHESIOLOGY – CALL FOR A CHANGE OF CULTURE AND REGULATIONS, Nancy Redfern, Federico Bilotta, Igor Abramovich, Ioana Grigoras, in European Journal of Anaesthesiology. 40(2): p 78-81, February 2023

<sup>8</sup> Physician burnout undermines safe healthcare, Matthias Weigl, BMJ 2023, 378

<sup>9</sup> ASSOCIATIONS OF PHYSICIAN BURNOUT WITH CAREER ENGAGEMENT AND QUALITY OF PATIENT CARE: SYSTEMATIC REVIEW AND META-ANALYSIS, Alexander Hodkinson, et. al, BMJ 2022;378:e070442 | doi: 10.1136/bmj-2022-070442

At the same time, fatigue and burnout can lead to a higher level of workers leaving the medical profession<sup>10</sup> and reinforce the current health workforce staffing crisis. The increase in the shortage of healthcare professionals, coupled with an ageing population and increasing healthcare demands, poses a significant challenge to healthcare systems in Europe and even represents a risk for the continuity of those services.

Clinical evidence has also demonstrated the **correlation between workforce shortages and risks to patient safety**. A study on staffing for safe and effective care in an acute NHS Trust in England (Leary et al., 2016) found 40 correlations between safety factors, physiological data and staffing factors. With staff shortages rising, patient and healthcare professional safety is becoming a significant challenge. Support to implement measures at all levels of the health system is required to **ensure that healthcare professionals work in psychologically safe, well-resourced, modern and digitalised environments** throughout Europe, otherwise, patient safety will continue to be compromised.

Medication harm has not only direct and indirect consequences for patients and their families, but healthcare professionals involved in adverse medical events are also affected and require up to a 3-month absence from work due to chronic workplace stress<sup>11</sup> also known as second victim phenomenon. According to the same study, the most prevalent cause of an adverse event is medication errors, one third of all adverse events. **When a medication error occurs, the risk of death, disability, contracting a healthcare-acquired infection and the need for antibiotics increases.**

To improve medication safety, the EU has invested significant efforts to reduce harm from medication errors by deploying regulatory actions targeting upstream contributors including medication packaging. However, strategies targeting downstream determinants, such as Health Information Technology (HIT) solutions, have yet to be prioritised. For example, despite evidence showing that the introduction of medication traceability systems in hospitals is the most effective way to minimise medication errors, a full-scale roll of these systems is wanting<sup>12</sup>. If we cannot map the medication use pathway, this hinders interventions to minimise risk.

**Simultaneously, political willingness to ensure the safety of European citizens is evident.**<sup>1</sup>As early as 2002, the World Health Assembly urged Member States to pay the closest possible attention to patient safety and to establish and strengthen evidence-based systems necessary for improving patient safety and the quality of health care. This led to the launch, in 2004, of the World Alliance for Patient Safety, as a working partnership between WHO and external experts, health care leaders and professional bodies. The World Alliance introduced several important initiatives, among which the Global Ministerial Summits for Patient Safety from 2016, and the Global Patient Safety Action Plan 2021–2030<sup>13</sup> adopted in 2019 by the World Health Assembly, with a vision of “a world in which no one is harmed in health care, and every patient receives safe and respectful care, every time, everywhere”. The Global Patient Safety Action Plan 2021–2030 provided seven strategic objectives achievable through 35 strategies and proposed policies and actions to be adapted and implemented at the national level.

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<sup>10</sup> Redfern, Nancy; Bilotta, Federico; Abramovich, Igor; Grigoras, Ioana. Fatigue in anaesthesiology: Call for a change of culture and regulations. *European Journal of Anaesthesiology* 40(2):p 78–81, February 2023. | DOI: 10.1097/EJA.0000000000001767

<sup>11</sup> European Biosafety Network (2021) “Mental and Psychosocial Health in Healthcare; Preventing Medication Errors and Adverse Events and Disorders in Healthcare Workers.”

<sup>12</sup> ECAMET Alliance (2022) survey revealed the low implementation of medication traceability systems in European hospitals with hospital pharmacists reporting the most important tools required to reduce medication errors included medication error surveillance and barcode medication administration systems

<sup>13</sup> <https://www.who.int/teams/integrated-health-services/patient-safety/policy/global-patient-safety-action-plan>

In February 2023, the 5th Global Ministerial Summit for Patient Safety, following up on the Action Plan 2021–2030, adopted the Montreux Charter on Patient Safety<sup>14</sup> entitled “Less harm, better care – from resolution to implementation”, declaring that unacceptable levels of harm continue to blight healthcare systems: Europe is no exception. In the Charter, Health Ministers and top WHO officials reaffirmed that patient safety must be treated as a global public health priority by strengthening the implementation of patient safety strategies, policies and interventions. The engagement and empowerment of patients and families in care delivery was also presented as a significant action to advance patient safety. Finally, high-level policymakers and experts should set ‘appropriate priorities for medication safety, infection prevention and control, and antimicrobial resistance’.

The European Union has also shown its willingness to recognise Patient Safety as a priority. While the Commission, in its White Paper “Together for Health: A Strategic Approach for the EU 2008–2013” of 23 October 2007, identified patient safety as an area for action, the Council of the European Union adopted in 2009 a Recommendation<sup>15</sup> on patient safety directly connected with the impulses given by WHO.

This Recommendation addressed the need to support the establishment and development of national policies on patient safety by designating competent authorities or bodies responsible for patient safety on their territory, embedding patient safety as a priority issue in health policies and programmes and including a specific approach to promote safe practices to prevent the most commonly occurring adverse events such as medication-related events, healthcare-associated infections and complications during or after surgical intervention. It fostered Member States to work closely with the health technology industry to encourage better design for patient safety in order to reduce the occurrence of adverse events. It also provided that citizens and patients must be empowered and informed by, among others, involving patient organisations and representatives in the development of policies and programmes on patient safety. Finally, it insisted on the need to support the establishment or the strengthening of blame-free reporting and learning systems on adverse events.

The concern for the safety of citizens is observed through numerous European policy and legislative initiatives such as the EU Road Safety Policy Framework, the European Plan for Aviation Safety (EPAS) and more recently the EU Cybersecurity Strategy and the strategy and legislation regulating Artificial Intelligence. Existing European policy and legislative initiatives for citizen safety demonstrate the importance of leadership to reduce harm in critical areas of economic activity.

**However, such an up-to-date European patient safety strategy is absent.** Efforts to support patient safety can be found in the Regulation for a European Health Data Space (EHDS)<sup>16</sup> which prioritises the e-prescribing and e-dispensing of medicines in community, hospital, and ambulatory care pharmacies. Nevertheless, the lack of a common, overarching, strategy to fund the upscale of digital systems in healthcare settings including pharmacies will continue to inhibit progress in reducing harm from medication.

**The policy reality in Europe is that the implementation of patient safety actions is suffering from significant gaps.** The implementation of strategies to reduce harm to patients across the EU has

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<sup>14</sup> [https://pss2023.ch/wp-content/uploads/2023/03/Montreux\\_Charter\\_Patient\\_Safety\\_Summit\\_2023.pdf](https://pss2023.ch/wp-content/uploads/2023/03/Montreux_Charter_Patient_Safety_Summit_2023.pdf)

<sup>15</sup> Recommendation of the Council of the European Union of 9 June 2009 on patient safety including the prevention and control of healthcare associated infections. In its paragraph (5), it states that “This recommendation builds upon, and complements, work on patient safety carried out by the World Health Organisation (WHO) through its World Alliance for Patient Safety, the Council of Europe and the Organisation for Economic Cooperation and Development (OECD).”<sup>21</sup>

<sup>16</sup> European Commission (2022) [Proposal for a Regulation on the European Health Data Space](#)

been inconsistent<sup>17,18</sup> and attention to promoting safe quality care in health policy-making has dropped from the EU health policy agenda. Given the high-level, international calls for action and the evidence, **MEPs and the European Commission must bring patient safety back into the health policy limelight.**

**Dedicated resources for patient safety ceased in 2016 after and attention to promoting safe, quality, care has dropped from the European health policy agenda despite the inconsistent implementation of strategies to reduce harm to patients across the EU.** <sup>19 20</sup> This is even more glaring when examining the current EU public health priorities, including Europe's Beating Cancer Plan, and the newly established EU4Health programme. In the former, mention of patient safety as a strategic priority is non-existent, and in the latter, no dedicated projects or resources have been allocated for patient safety initiatives. For example, **investments to improve access to digital tools to prevent harm are lagging as are efforts to improve healthcare professionals working environment and wellbeing.**

Additional evidence of patient safety falling as a policy priority is demonstrated by the variable funding levels for patient safety programmes in Member States<sup>21</sup>. Astoundingly, in a recent OECD report (2023), one-quarter of responding countries advised that political leaders are not informed about the state of patient safety in their health system<sup>22</sup>. Furthermore, there is no agreed approach on when and how to investigate patient safety incidents. **A systematic and evidence-based approach involving all stakeholders is lacking.**

Legislation is the cornerstone of safety governance models; **the development of a European Patient Safety Strategy can close patient safety gaps**, standardise national patient safety programmes across Europe and reassure patients that lessons will truly be learned on how and why significant harm has occurred.

Thus, we call upon European policymakers at all levels to take immediate and concerted action to prioritise patient safety as a fundamental principle of the European Health Union. We urge you to:

1. **Launch a European Patient Safety Strategy** recognising the critical role of patient safety in building a responsive and resilient European Health Union.
2. **Allocate dedicated resources for patient safety:** Dedicate resources, including financial resources, for patient safety initiatives, ensuring that adequate funding is available to support the implementation of strategies that reduce patient harm.
3. **Standardise patient safety programs:** Work towards standardising patient safety programs and care delivery practices across all EU Member States to reduce disparities in patient safety outcomes.

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<sup>17</sup> European Commission (2015) "Patient Safety and Quality of Care in the EU Opinion adopted by the Expert Panel on Effective Ways of Investing in Health".

<sup>18</sup> EUPSF (2023) "[How to Achieve Real Progress In Patient Safety At National Level: Side-Event to the Global Ministerial Patient Safety Summit 2023](#)"

<sup>19</sup> European Commission (2015) "Patient Safety and Quality of Care in the EU Opinion adopted by the Expert Panel on Effective Ways of Investing in Health"

<sup>20</sup> EUPSF (2023) "[How to Achieve Real Progress In Patient Safety At National Level: Side-Event to the Global Ministerial Patient Safety Summit 2023](#)"

<sup>21</sup> EUPSF (2023) "[How to Achieve Real Progress In Patient Safety At National Level: Side-Event to the Global Ministerial Patient Safety Summit 2023](#)"

<sup>22</sup> OECD (2023) Health Working Papers No. 150 "Advancing Patient Safety Governance in the COVID-19 Response"

4. **Foster cultures of safety:** Invest in initiatives that promote a culture of safety within healthcare organisations, fostering psychologically safe environments for healthcare professionals and patients alike.
5. **Support the healthcare workforce:** Address workforce shortages and improve working conditions for healthcare professionals, recognising that their well-being is closely tied to patient safety.
6. **Promote the digital transition:** Prioritise investments in modern healthcare technologies and digital tools that can help prevent medication errors and improve the overall safety of healthcare delivery.
7. **Establish a comprehensive patient safety investigation framework:** Develop a standardised framework for investigating patient safety incidents, ensuring it encompasses clear guidelines on when and how to conduct investigations. This framework should prioritise transparency, impartiality, and the involvement of patients and their families to promote learning and accountability in cases of significant harm.

We believe that by taking these proactive measures, Europe can significantly reduce patient harm, enhance the quality of care, and ultimately build a healthcare system that prioritises the safety and well-being of all citizens. Patient safety should not be a luxury; it should be a fundamental right for every individual who seeks medical care in Europe, directly deriving from article 35 of the EU Charter of Fundamental Rights<sup>23</sup>.

#### Undersigned organisations

1. European Health Management Association (EHMA)
2. European Alliance for Access to Safe Medicines (EAASM)
3. European Association of Hospital Pharmacists (EAHP)
4. European Children's Hospitals Organisations (ECHO)
5. European Junior Doctors (EJD)
6. European Patient Safety Foundation (EUPSF)
7. European Society of Anaesthesiology and Intensive Care (ESAIC)
8. European Society of Paediatric and Neonatal Intensive Care (ESPNIC)
9. European Specialist Nurses Organisation (ESNO)
10. European Union of Private Hospitals (UEHP)
11. International Alliance of Patients' Organizations (IAPO)
12. International Society of Pharmacovigilance (ISOP)
13. Reference Site Collaborative Network (RSCN)

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<sup>23</sup> European Union, Charter of Fundamental Rights, article 35 (Healthcare): "Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities."



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