PGEU feedback on the Evaluation roadmap and Inception Impact Assessment on 'a European Health Data Space'

The Pharmaceutical Group of the European Union (PGEU), the organisation representing community pharmacists in 32 European countries, welcomes the European Commission's Roadmap and inception impact assessment on the European Health Data Space.

We support the Commission's general objective of facilitating the access of health data across the Union for primary and secondary uses whilst ensuring citizens have control over their own health data.

PGEU also agrees it is vital to strengthen health systems and the healthcare workforce, including by digital transformation and by increased integrated and coordinated work among the Member States, as well as by sustained implementation of best practice and data sharing, while respecting the legitimate purpose of the use of health data in line with General Data Protection Regulation (GDPR) rules and by taking the necessary measures to avoid any misuse thereof.

Since the beginning of community pharmacy computerisation in the 1990s, the profession has demonstrated its willingness to adopt innovative technologies to offer the highest standard of pharmacy services. In the area of eHealth, no other healthcare profession has invested more than community pharmacy in terms of its own funds. It has developed the necessary infrastructure and culture to implement innovative eHealth technologies with the ultimate goal to deliver significant benefits to the public.

A number of advantages can be achieved from using **eHealth solutions within the pharmacy network**. They include greater accessibility to care, further integration of the primary healthcare system, improved health outcomes, reduced costs to health system payers, improved health literacy, support for self-care, enhanced patient safety and increased quality of care. The deployment of these tools is supported by the use of best practices within pharmacists' regulatory and ethical frameworks, as well as by pharmacists keeping their ICT knowledge and skills up to date as required.

The development and expansion of digital health is expected to bring significant benefits to patient care and health systems performance[1] yet digital solutions as well as standards and certification processes of digital health products and services are fragmented at both national and European levels. Despite recent progress, many **ePrescription systems** in Europe are not deployed with full national coverage.

In 2016, PGEU adopted a statement on eHealth[2] where it provided a few recommendations which are still applicable in order to maximise the potential of digitalisation of healthcare at EU level. Firstly, PGEU believes eHealth should be integrated into health systems complementing and supporting existing practice, with pharmacy potentially as a link between several services, organisations and infrastructures.

---

[1] EXPH (EXpert Panel on effective ways of investing in Health), Assessing the impact of digital transformation of health services, 20 November 2018
[2] See PGEU Statement on eHealth

In several EU countries, community pharmacies are already engaged in the exchange of cross-border ePrescriptions via the eHealth Digital Service Infrastructure (eHDSI).[3] We welcome the ongoing roll-out of these services across the EU as an opportunity for safer and more effective cross-border healthcare provision in the EU.

Furthermore, as recommended by the 2019 European Parliament report on the implementation of the Cross-Border Healthcare Directive[4], **electronic health records** should be linked with ePrescribing systems, thus allowing healthcare professionals involved in patient care to access necessary patient information from the electronic health record, and ultimately, enabling them to deliver personalised and well-informed care to their patients. There also should be an interoperable facility across healthcare professionals and settings to integrate and update the electronic health record with relevant information when necessary, in order to increase the capacity to identify and address potential medication and patient safety-related issues.

PGEU also recommends promoting **interoperability of information systems** in Europe to foster exchange of data across community pharmacies and health professionals. Furthermore, we recommend using **Artificial Intelligence (AI) and new digital technologies** to boost inter-professional collaboration as well as to promote integration of primary care systems. In order to fully harness the benefits of AI in healthcare, we also consider that a key requirement is to develop trust by all stakeholders involved through guaranteeing a high level of data protection.[5]

PGEU strongly believes that communication and collaboration between patients, healthcare professionals and ICT developers is crucial to obtain the full potential of eHealth technologies and health data sharing as well as to build confidence and trust. When developing guidelines for eHealth, as well standards for digital health products and services, policy makers are called upon to meaningfully involve their end users.

In addition, community pharmacists acknowledge the benefits that **Big Data and AI** can bring for European health systems and consider these technologies as a useful tool to support healthcare professionals. In routine practice at national level, these tools shall be always accompanied by pharmacists' expert and professional advice, in order to improve workflow efficiency, while promoting therapy effectiveness and offering the highest standard of pharmacy services to its patients.

In this respect, community pharmacists are committed to use their unique position at the heart of European communities and leverage the potential of Big Data and AI to provide **more personalised advice to patients** and robust, **evidence-based information** on issues related to their therapies while promoting **safe and rational medicines use.** Community pharmacists have the infrastructure, culture and expertise to make use of the potential of Big Data and AI in healthcare and to provide trusted sources of reliable and independent health information to patients by making the innovative digital solutions integral to community pharmacy practice[6].

---

[3] https://ec.europa.eu/health/ehealth/electronic_crossborder_healthservices_en
[4] European Parliament REPORT on the implementation of the Cross-Border Healthcare Directive (europa.eu) (A8-0046/2019)
[5] See PGEU Response to the EC Roadmap on Artificial Intelligence (AI) – ethical and legal requirements
[6] See PGEU Position Paper on Big Data and Artificial Intelligence dated from February 2019 here.

Furthermore, community pharmacists **collect and generate real world evidence** that can contribute to evidence-based health policy and best practices in patient care. For example, data collected during practice audits, service evaluation, cost-effectiveness analyses, post-marketing authorisation safety studies, non-interventional trials and post-marketing authorisation efficacy studies can demonstrate the value that pharmacy services provide in terms of better outcomes and reduced costs for health services.

Integrating **real-world data on pharmacovigilance, adherence and effectiveness of medicines** into practice, to improve safeguarding and advice on the safe use of medicines for each individual patient, is also widely welcomed by community pharmacists.

Finally, the community pharmacy profession should be recognised, supported and adequately reimbursed for their continuous investment in eHealth, ICT infrastructure, digital skills of the workforce and contribution to improved health outcomes and reduced healthcare costs. They should also be rewarded for the use of real-world evidence including evidence generation in community pharmacies to evaluate the effectiveness and therapeutic added value of innovative medicines in practise.