









PGEU ANNUAL REPORT 2023

Chronic medicine shortages affect patients' health and pharmacy practice



TABLE OF CONTENTS

	About PGEU - Mission and Vision	2
	Foreword by Koen Straetmans, PGEU President 2023	3
	2023 at a glance	5
	The year of shortages	23
	A look forward	29
	PGEU Secretariat	31
	PGEU Executive Committee 2023	32
	PGEU Members 2023	33

About PGEU

Mission and Vision

The Pharmaceutical Group of the European Union (PGEU) is the organization representing European community pharmacists. PGEU members are the national associations and professional bodies of community pharmacists in 33 European countries, including EU Member States, EFTA countries, the UK and EU candidate countries.

PGEU represents about 500.000 pharmacists and 200.000 pharmacies in the European Region.

PGEU's vision is to see community pharmacists recognised as key health professionals delivering a dynamic contribution to the health of people while strengthening European health systems. Community pharmacists work at the heart of communities, providing high-quality, professional advice on the safe, effective, and rational use of medicines. Community pharmacists are often the first point of contact between patients and the healthcare system. They are also usually the last healthcare professional patients contact before taking their medicines. These factors position pharmacists in a key position to make an invaluable contribution to public health.

I'd say "Pharmacists are often the first point of contact between the patient and the healthcare system, and usually the last healthcare professional patients contact before taking their medicines."

FarmaciaVirtuale.it



FOREWORD BY PGEU PRESIDENT 2023

It is with great pleasure that I present you the PGEU Annual Report 2023.

In reflecting on the achievements of the past year, we are reminded of our unwavering commitment to advance the role of community pharmacists in safeguarding public health, enhancing patient care and ensuring access to medicines for all citizens across Europe. PGEU could as always count on the enduring support and collaboration of its members, whose dedication continues to shape the future of pharmacy practice.

Last year we had the privilege to meet the EU Health Commissioner, Stella Kyriakides. Her public acknowledgment of the vital role played by community pharmacists in ensuring patients' access to medicines serves as a testament to the invaluable contributions of our profession. Such recognition reaffirms PGEU engagement in advocating for policies that empower pharmacists to effectively serve as frontline trusted healthcare professionals working at the service of their communities.



As you delve into the contents of this Annual Report, you will see that the main challenges for community pharmacists are medicines shortages – a pressing issue that demands urgent attention and concerted action. Despite the tireless efforts of pharmacists, shortages persist, undermining patient care and eroding trust in the healthcare system. The growing burden of shortages not only poses logistical challenges but also highlights the need for effective measures to strengthen supply chains and enhance shortages prevention and management mechanisms. In this light PGEU contributed to the debate on the reform of the EU pharmaceutical legislation which promises to improve shortages prevention, monitoring, communication and management.

It has been a truly rewarding experience to serve my profession as PGEU President and I am grateful to all PGEU members and staff for their continued support throughout my presidency.

**- KOEN
STRAETMANS**



[PGEU Medicine Shortages
Report 2023](#)



[PGEU Position Paper on the
European Commission proposal
for the revision of the general
pharmaceutical legislation](#)



[PGEU Position Paper on the Role
of Community Pharmacists in
Vaccination](#)



[PGEU Position Paper on
Antimicrobial Resistance \(AMR\)](#)



[Joint Statement on the
European Health Data Space](#)

2023

at a glance

January



Medicine shortages, PGEU in the press

On 23 January, PGEU published the results of its annual medicine shortages survey. The survey outlined the negative impact that shortages have on patients and on pharmacists daily practice and also highlighted the main recommendations from community pharmacists.

The results of the survey attracted great media attention and it was quoted by several media across Europe.



Coalition for Vaccination Conference

On 17 January, PGEU, together with CPME and EFN, organised the Coalition for Vaccination Conference in Brussels. Four panels of leading experts discussed vaccination policies, increasing vaccine confidence and uptake, and cooperation and communication as key elements to achieve high vaccination rates at European level. PGEU President Koen Straetmans, Alain Delgutte from the Ordre des Pharmaciens Français, Gabriel Branco and Catarina Silva from the European Pharmacy Students' Association contributed to the different panels highlighting the role of pharmacists in the healthcare sector, particularly in supporting vaccination promotion, awareness, communication and delivery.



February



Annual EMVS Forum

On 10 February, the European Medicines Verification Organization organised the first European Medicines Verification System Annual Forum. The conference was organised in the European Parliament, and it was hosted by the rapporteur of the Falsified Medicines Legislation, MEP Marisa Matias. The conferences looked at the achievements accomplished throughout the 4 years of “go-live”, the lessons learned and the future challenges for the system. PGEU outlined the impact of the implementation of the legislation in pharmacy daily practice. National competent authorities presented experiences in securing the supply chain and their collaboration with the national medicines verification system. Global trends on counterfeiting in the pharmaceutical sector were also discussed.



IMMUNION project meeting

On 14 February, PGEU took part in the final meeting of the IMMUNION project. IMMUNION (“Improving IMMunisation cooperation in the European UNION”) was a 2-year project (2021-2023) co-funded by the European Union Health Programme, in the ultimate goal of increasing vaccine confidence and uptake.

Led by EuroHealthNet, the project brought together members of the Coalition for Vaccination (established by the EU in 2019), as well as partners across the EU. It built on learnings from the past and added value to vaccination efforts at national, regional and global level.

PGEU has been honoured to be a partner of this project which contributed to strengthen collaboration between healthcare professionals and other stakeholders, addressing issues of access to accurate, evidence-based information about vaccination. The project also developed tools and resources to increase vaccine coverage, in particular amongst underserved populations.



March

EMA Multistakeholder Workshop on medicines shortages

On 1-2 March, PGEU participated in the EMA Multistakeholder Workshop on medicines shortages. The aim of the workshop was to inform stakeholders about the HMA/EMA Task Force activities on medicines shortages and availability and interfaces with other initiatives, to update stakeholders on progress with the Task Force deliverables and identify areas of agreement as well as areas for further discussion and to share stakeholders' perspectives and (ongoing/planned) initiatives to address availability issues and discuss how these can contribute to the future deliverables of the Task Force.

PGEU contributed to the session on prevention of shortages, showcasing the European community pharmacists' contribution to prevent medicines unavailability. PGEU shared the results of the Medicine Shortages Survey 2022, together with best practices from members on systems in place to prevent medicine shortages. During the discussion, PGEU voiced the European Community pharmacists opinions and possible solutions to help tackle medicine shortages, further clarifying that the European Medicines Verification System is not a suitable platform to prevent medicine shortages, as the system and the legislation that precedes it have not been designed and intended to that purpose, as an end-to-end and not a full track-and-trace system, therefore unable to provide a reliable picture of medicines availability across Europe.

Roundtable on self-care

On 9 March, PGEU participated in a roundtable on self-care organised by the self-care company Haleon and hosted in the European Parliament by MEP Stelios Kympouropoulos (EPP, Greece). The discussion focused on 10 recommendations to remove the barriers and promote the widespread adoption of self-care included in a White Paper drafted by Haleon. PGEU outlined the important contribution of community pharmacists promoting and facilitating self-care.

PGEU at DIA Europe

PGEU participated at the DIA (Drug Information Association) Europe conference. PGEU voiced the community pharmacists' perspectives in relation to the revision of the general pharmaceutical legislation, access to medicines, patient information, advocacy & policy, electronic product information leaflet (ePIL), Health Technology Assessment (HTA), and COVID-19 showcasing best practices from PGEU members.



April

Global medicines shortages - an EU perspective

On 19 April, PGEU participated as a speaker in the webinar “Global medicines shortages - an EU perspective”, organized by the Finnish branch of the Pharmacists without Borders association. PGEU presented the results of the PGEU Medicine Shortages survey 2022 and shared the best practices from its members on early reporting and signalling of shortages. It was an opportunity to showcase PGEU policy recommendations and findings from the annual shortages survey and raise awareness for the necessary policy changes to effectively tackle medicine shortages.

23rd BaltPharm Forum

PGEU President Koen Straetmans, attended the 23rd BaltPharm Forum that took place in Latvia, on 21-23 April. The Pharmacists’ Society of Latvia (LFB) organized the 23rd BaltPharm Forum, bringing together Estonian, Latvian and Lithuanian pharmacists, to discuss “The problems and perspectives of pharmaceutical care practice in Baltics”.

During this conference, PGEU President delivered a presentation showcasing Community Pharmacy services across Europe, with a view on its implementation and future perspective.

Drug shortages - Profits before patients

On 25 April, PGEU participated in the event “Drug Shortages - Profits Before Patients”, organized by the European Consumer Organisation (BEUC) in the European Parliament. Representatives from the European Commission, the pharmaceutical industry and civil society organisations expressed their views on the much-awaited publication of the Revision of the General Pharmaceutical Legislation.



General Pharmaceutical Legislation

Revision – Stakeholder Roundtable

On 10 May, PGEU was invited to take part in a roundtable discussion hosted by the European Commission (DG SANTE) about the reform of the EU pharmaceutical legislation. Attention was given by a number of stakeholders to key topics such as the definition of unmet medical needs, electronic product information and transferable vouchers. PGEU intervened to highlight in particular the community pharmacists' views regarding shortages, stressing the importance of earlier notification and monitoring as well as shortage prevention plans for marketing authorization holder, and calling for short-term measures while waiting for the new legislation to be introduced. PGEU also highlighted concerns in relation to the exclusivity of the use of the electronic product information, with other stakeholders present at the meeting echoing PGEU's concerns that this should be complementary only.

EAFP Conference

On 18 May, PGEU participated to the European Association of Faculties of Pharmacy (EAFP) Annual Conference 2023, on "Sustainability of Pharmacy, Pharmacy Practice and Pharmacy Education". PGEU was part of the Dean's forum and stakeholder discussion, alongside the European Association of Hospital Pharmacists (EAHP), to discuss sustainability of the pharmacy practice together with the Deans of the European Faculties of Pharmacy. PGEU shared its views on pharmacy workforce shortages, the digital and green transition that is accompanying the development of the pharmacy profession and raised awareness to the topic of sustainability on the community pharmacy setting.



EAFP EUROPEAN ASSOCIATION OF
FACULTIES OF PHARMACY



FarmaciaVirtuale.it

GIRP 64th Annual Meeting and Conference



PGEU Secretary General addressed the GIRP 64th Annual Meeting and Conference, in Bucharest. During the roundtable "Translating the EU Pharmaceutical Legislation into Better Access and Affordability", Dr. Passarani outlined PGEU's views on the reform of the EU pharmaceutical legislation and emphasised the need for urgent actions to address the problem of medicines shortages. Furthermore, she supported the measures proposed in the new European Commission proposal including earlier notification of supply disruption, better monitoring and assessment, as well as the requirement for marketing authorisation holders to have in place shortages prevention plans for all medicines.

PGEU at 59th AESGP Annual Meeting



On 24 May, PGEU participated to the 59th AESGP Annual Meeting in Paris, speaking on the contribution of community pharmacists to medicines switches. During the discussion, the PGEU Professional Affairs Advisor showcased the key role that pharmacists in Europe play in counselling patients on the use of Non-Prescription Medicines and providing care for patients. In particular, it was focused on the advancements in the different countries on switching from prescription-only medicines to non-prescription medicines, highlighting success stories and exploring possibilities to revitalize switch at EU level. PGEU emphasized the importance of having a pharmacy-only medicines list (a list of non-prescription medicines that can only be dispensed in a pharmacy by a community pharmacist). Mr. Batista further highlighted the specialized role of pharmacists as medicine experts, and the expanded roles that these healthcare professionals have taken in the community, developing pharmacy services and contributing to the resilience of healthcare systems through counselling and advising patients and consumers on the use of non-prescription medicines.

Affordable Medicines Europe General Assembly

PGEU Secretary General spoke at the General Assembly of Affordable Medicines Europe - the EU organization representing parallel traders - that took place in Madrid on 25 May. She outlined PGEU views on the reform of the EU pharmaceutical legislation - with a special focus on medicines shortages and electronic product information - and about the implementation of the EU falsified medicines legislation.



June

Meeting with HERA

On 2 June, PGEU met with the EU Agency for Health Emergency Preparedness and Response (HERA) Deputy Director General, Laurent Muschel and his team to discuss about medicines shortages, antimicrobial resistance - including rapid strep tests in pharmacies to minimize the use of antibiotics and about early notification of shortages of critical medicines by community pharmacists - and vaccination.

Meeting with the European Commission on the EU Coalition for Vaccination

On 7 June, PGEU met with the European Commission (DG SANTE) together with the other two co-chairs of the EU Coalition for vaccination, namely the European Federation of Nurses (EFN) and the Standing Committee of European Doctors (CPME). The representatives of healthcare professionals discussed the European Commission support to the Coalition for Vaccination, the planned use by the Coalition of the tools developed by the IMMUNION project PGEU was involved in and the future of the Coalition for Vaccination.

Ukrainian Chamber of Pharmacists Congress

On 8 June, PGEU spoke at the Congress "Pharmacies of the World 2023" organised by the Ukrainian Chamber of Pharmacists. PGEU was invited to speak about the EU regulatory framework on pharmaceuticals and also about establishment rules for pharmacies in Europe and professional qualifications.





PGEU Annual Conference 2023 in Genval (Belgium)

PGEU members met in Genval on 13 June to discuss digital solutions such as value of patients' data to improve quality of care, and health data to promote public health. They also exchanged views with the European Medicines Agency, with key EU stakeholders - including the European Federation of Pharmaceutical Industries and Associations (EFPIA), the rare disease patients organization EURORDIS, the Standing Committee of European Doctors (CPME), the European Public Health Alliance - and with national institutions - including Sciensano and the French Health Data Hub.

75th Anniversary of the Austrian Chamber of pharmacists

On 16 June, PGEU Secretary General participated in a conference organised in Vienna by the Austrian Chamber of pharmacists on the occasion of the 75th Anniversary of the organization. She participated in a debate regarding pharmaceutical care and pharmacy services.

Joint Statement on the European Health Data Space

On 19 June, PGEU signed a joint statement together with CED, CPME, EFN and HOPE to a number of policymakers from the European Parliament and Council regarding the European Health Data Space. This statement emphasized the role of professional obligations regarding confidentiality, the need for resources and financial support for healthcare professionals in the digital transition and clarifications regarding professional liability.



25th Anniversary of Affordable Medicines Europe

On 21 June, PGEU participated in a conference organised by the European Association of parallel traders, Affordable Medicines Europe, in the occasion of the 25th anniversary of the organisation. Keynote speeches from former Commissioner for the internal market, Mario Monti, and former President of the General Court José Luís da Cruz Vilaça outlined the history of the EU internal market for medicines.



EMA workshop on Real World Data and Real World Evidence

On 26-27 June, PGEU participated in the European Medicines Agency "Multi-stakeholder workshop on Real-World Data (RWD) quality and Real-World Evidence (RWE) use", that took place in Amsterdam, the Netherlands. PGEU participated in the discussion on real world evidence regulatory assessment and decision-making processes, presenting the community pharmacists contribution to RWD collection and RWE generation, together with the challenges that healthcare professionals face in this realm.



10th Anniversary of EMA HCPWP

On 27 June, PGEU attended the 10th anniversary of the EMA Healthcare Professionals' Working Party (HCPWP). An informal group of healthcare professional organisations was first created in 2006. Following the adoption of the first formal framework for interaction with healthcare professionals and their organisations by the EMA Management Board in 2011, the group was formalised into an official working party in June 2013.

July

SANT: Hearing on Medicine shortages

On 13 July, PGEU was invited to intervene in the European Parliament's Subcommittee on Public Health (SANT) hearing on Medicine shortages. The presentations from different stakeholders were followed by a debate amongst MEPs on the role of the European Commission and the Member States regarding any necessary action to restore pharmaceutical sovereignty in Europe and local pharmaceutical production, with particular attention to the priority given to essential and strategic medicines. PGEU Secretary General outlined the impact of shortages on community pharmacy and PGEU policy recommendations.

September

EIPG meeting and Seminar

On 8 September, PGEU participated in a meeting with EIPG (the European Industrial Pharmacists Group) Bureau and other sister organisations in relation to common priorities in the pharmaceutical sector. PGEU also participated in the EIPG Seminar on the "New Pharmaceutical Legislation", organized in the European Parliament. PGEU presented its main priorities for the upcoming months, highlighting the revision of the general pharmaceutical legislation, medicine shortages and antimicrobial resistance.



Event on the Electronic Product Information (ePIL)

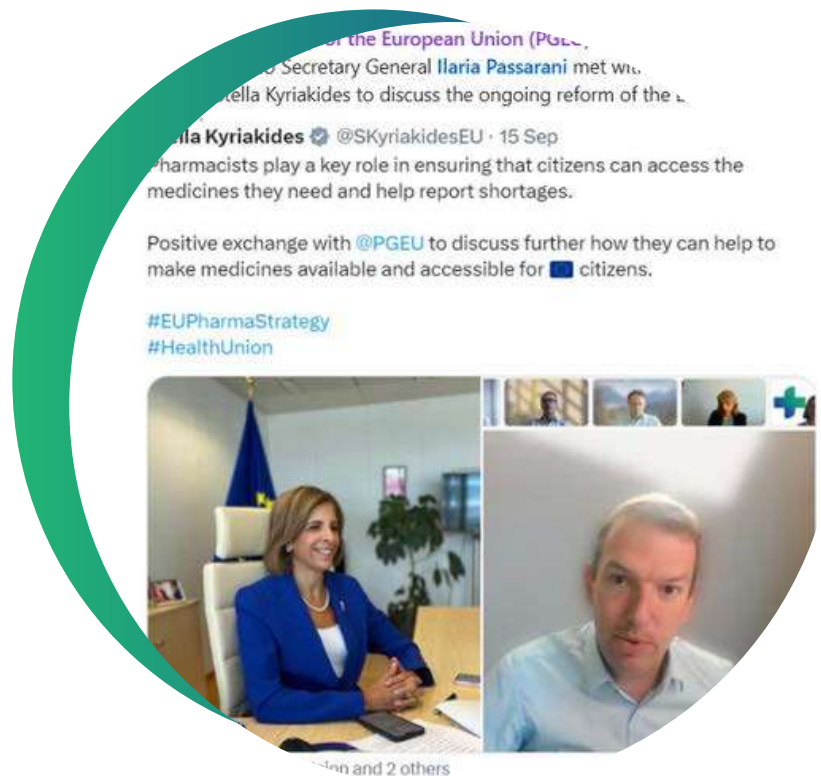
On 12 September, PGEU President participated in an event organised by the Belgian Pharmaceutical Industry pharma.be about "Electronic product information for medicines: exploring opportunities and understanding the user's perspectives", showcasing the community pharmacists' perspective in relation to the use of electronic product information (ePIL) in primary care. He addressed the complementary role that ePIL can play for patient information, explaining the community pharmacy perspective. Moreover, he voiced the concerns linked with data privacy and patient protection in the digital versions of product information.

Meeting with EU Health Commissioner Stella Kyriakides

On 15 September, PGEU met with EU health commissioner Stella Kyriakides. PGEU President and Secretary General discussed medicines shortages, antimicrobial resistance, vaccination and the reform of the EU pharmaceutical legislation with the European Commissioner. Ms. Kyriakides extended her gratitude and appreciation to all European community pharmacists for their role during Covid and for what they do every day for citizens. She also stressed the key role pharmacists play in ensuring patients' access to medicines.

FIP Congress

On 24-28 September, PGEU President Koen Straetmans participated in the International Pharmaceutical Federation 81st World Congress of Pharmacy and Pharmaceutical Sciences, in Brisbane Australia. PGEU President also met with FIP officials to discuss about topics of common interest and about further strengthening the collaboration between PGEU and FIP.



Meeting with DG GROW

On 15 September, PGEU met with the Directorate General for Internal Market, Industry and SMEs (DG GROWTH) together with the European Associations of Doctors (CPME) and Nurses (EFN) to discuss health workforce shortage and the Professional Qualifications Directive.



EMVO NCA Workshop

On 26 September, PGEU joined the National Competent Authorities (NCA) workshop organized by the European Medicines Verification Organization (EMVO). This was the first face-to-face workshop organized since the entry into force of the Falsified Medicines Directive (FMD). During the meeting, the European Commission, EMVO, NCAs, and National Medicines Verification Organizations (NMVO) and stakeholders discussed key topics about the status of the FMD implementation.



October

2023 EU Flu Day

On 11 October PGEU spoke at the 2023 EU flu day conference organised by the Steering Group on Influenza Vaccination in the European Parliament. PGEU promoted the role of pharmacists in vaccinations and best practices at national level.

Annual Meeting of the Coalition for Vaccination

On 24 October, PGEU co-chaired the Annual Meeting of the Coalition for Vaccination. The Annual Meeting of the Coalition for Vaccination brought together the Full Members and the Associated organisations to discuss the recent developments on the European Commission work on vaccination, sharing the recent developments and future initiatives on vaccination by the members of the Coalition, and foresee future steps. There was also a communication on the activities on vaccination by the different stakeholders, a discussion on the future activities of the Coalition, and a presentation of a study done by the consultancy Ernst & Young on the coherence, complementarity and continued relevance of actions in the Council Recommendation on strengthened cooperation against vaccine-preventable diseases in view of possible similar policy initiatives in the future.



Meeting with the Austrian Delegation

On 24 October, PGEU hosted a meeting with a group of representatives from the Österreichischer Apothekerverband (Austrian Pharmacy Owners Association) in Brussels to discuss the main EU legislative initiative with direct impact on Austrian pharmacists.

European Commission Communication on medicines shortages

On 24 October, the European Commission published a Communication addressing medicine shortages in the EU. PGEU issued a press release welcoming the Commission's call for Member States to monitor and enforce companies' obligations to supply the market with adequate quantities of medicines, the creation of a Union list of critical medicines and of a voluntary solidarity mechanism. PGEU supported the effective use of regulatory flexibilities to mitigate shortages, the strengthening of EU coordination, the improvement of demand and supply forecasting as well as the proposed long-term measures to enhance supply security.



November

EMA Healthcare Professionals Working Party (HCPWP) and Patient and Consumers Working Party (PCWP) Joint meeting

On 14-15 November, PGEU took part in the EMA Healthcare Professionals Working Party (HCPWP) and Patient and Consumers Working Party (PCWP) joint meeting, in Amsterdam.

The main topics discussed were the availability and accessibility of medicines, Health Technology Assessment, preparedness, and the EU list of critical medicines.



Prioritizing COVID-19 patients – European Parliament event

On 14 November, PGEU participated to an event on “Prioritizing care for high-risk COVID-19 patients in the EU: policy recommendations” organised at the European Parliament by Active Citizenship Network. The discussion focused on the need to invest more in health and on the need of patients suffering from post and long COVID-19 as well as on the need to protect high-risk COVID-19 patients. PGEU outlined the key role of community pharmacies in COVID-19 testing and vaccination and in supporting patients including in underserved areas.

Vaccines Europe – EU elections event

On 14 November, PGEU participated to an event organised in the European Parliament by Vaccines Europe, the EU trade association representing vaccines producers. Vaccines Europe presented its manifesto for the EU election, calling for an EU immunization strategy. PGEU presented the role of community pharmacists in vaccination, including information to patients, awareness campaign and administration of vaccines in community pharmacies.



The economic and social impact of self-care

On 15 November, PGEU participated to an event organised by AESGP, the self-care industry trade association, for the presentation of a study on the economic and social impact of self-care. PGEU stressed the role of community pharmacists as essential partners in promoting and supporting self-care contributing to improved health outcomes for individuals and health systems.



Antimicrobial resistance targets: How can we reach them by 2030?

On 20 November, PGEU attended an event organized by the European Center for Disease Prevention and Control to celebrate the European Antibiotic Awareness Day. During the event community pharmacists were presented as a valuable asset to allow for greater access to vaccination and quality information for the communities.



Gravitate-Health annual International Advisory Board meeting

On 21 November, PGEU took part in the Gravitate-Health International Advisory Board and Steering Committee meeting. The Gravitate-Health project's aim is to develop the Gravitate Lens (G-lens), which focuses on approved electronic product information (ePI) using each person's health data, tailoring information to patients on medicines. PGEU shared its concerns on the use of personal data and about patients' privacy.



Joint EMA/HMA AI Workshop

On 20 and 21 November, PGEU joined the Joint Heads of European Medicines Agency and Heads of Medicines Agencies (EMA/HMA) AI workshop - Smart regulation in a rapidly evolving world. During the two sessions, experts in the field presented the latest developments with AI technology and their impact on medicines' lifecycle and regulatory activities. During the workshop, attention was given to the AI policy landscape applying to the use of technology in medicines development, and the challenges with applying the technology, including key concerns from various stakeholders. During the workshop, EMA presented their draft Reflection paper on the use of Artificial Intelligence (AI) in 5 the medicinal product lifecycle and EMA's AI Roadmap.



December

Pharmacists' contribution to pharmacovigilance

During the year 2023, PGEU continued its active participation in the PRISMA working group (Pharmacovigilance Risk Assessment Committee Risk Minimisation Alliance of the European Medicines Agency) – a PRAC pilot on stakeholder engagement for the implementation of risk minimisation measures (RMM) in healthcare. Community pharmacists play an active role in pharmacovigilance and contribute to the discussions to better understand the barriers and enablers of RMM implementation and to proactively advise on RMM options for specific medicines. Furthermore, community pharmacists are represented at PRAC level on behalf of healthcare professionals' representatives. During 2023, PGEU continued its contribution to the EMA PRAC Multistakeholder Working Group on Digital Support Tools for RMM and their Effectiveness Evaluation, discussing options, opportunities and challenges of digital support tools for RMM, their use and effectiveness.



PGEU contribution to Revision of the Package Leaflet

During 2023, PGEU represented healthcare professionals in the EMA Quality Review of Documents subgroup for the revision of the package leaflet. In this structure, representatives of patients, consumers and healthcare professionals provide feedback in the review process, that aims to improve the content and structure of the leaflets, making it more understandable for patients. PGEU is an active collaborator in the area of patient education, as community pharmacists are usually the healthcare professional that patients consult before taking their medication.

EU First EU list of Critical Medicines

On 12 December, the European Commission, the European Medicines Agency (EMA) and the Member States' Heads of Medicines Agencies (HMA), published the first Union list of critical medicines. This list contains over 200 active substances for human use considered critical for healthcare systems across the EU/EEA, for which continuity of supply is a priority and shortages should be avoided.

PGEU was involved, together with other healthcare professionals, patients and consumers organisations in reviewing the communication materials to foster clear communication, avoid confusion and advise on best communication practices.

PUBLICATIONS



PGEU Medicine Shortages Report 2023

In 2023, medicine shortages continued to affect all European countries, and grew worse compared to 2022 in most countries. Shortages of medical devices available in pharmacy continue to exist across all categories in various European countries, with significant differences across countries. Pharmacists across the EU spend nearly three times as much time addressing shortages as they did a decade ago, amounting to almost 10 hours per week on average.

PGEU Position Paper on the reform of the EU pharmaceutical legislation

PGEU published its position on the European Commission proposal for the revision of the general pharmaceutical legislation in December. In this paper, community pharmacists outline their views on the European Commission's initial legislative texts, focusing on priority areas such as medicine shortages, the electronic product information, antimicrobial resistance, pharmacovigilance and specific provisions on the scope of the legislation and those referring to falsified medicines.

In its position, PGEU voices community pharmacists' concrete proposals in these key areas calling, for example, for increased transparency and timely communication on medicine shortages to affected stakeholders. Regarding the electronic Product Information (ePI), PGEU calls for its use as a tool to complement, but not replace, the current paper versions of the package leaflets and for the inclusion of stronger provisions to safeguard patient privacy and to allow the access to the ePI preferably via the national regulatory authorities or the Agency. In addition, PGEU calls for workable solutions that would allow community pharmacists to continue to advise and safely dispense common antimicrobials to patients to treat uncomplicated infections as opposed to the blanket obligation for prescription proposed by the European Commission.

PGEU Position Paper on the role of community pharmacists in vaccination

Community Pharmacists can contribute through diverse ways to vaccination strategies, protecting public health and contributing to a robust and sustainable healthcare system. Pharmacists are ideally placed at the heart of communities to provide information, advice, referral, treatment, and preventative actions to reduce the burden of communicable and vaccine-preventable diseases. As part of their wider public health mission, community pharmacists and pharmacy organisations are also involved in public awareness campaigns on topics such as antimicrobial resistance and vaccine hesitancy.

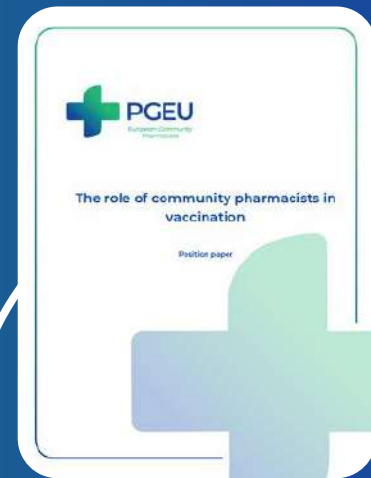
In this position paper PGEU suggests a number of policy recommendations to maximise the contribution that community pharmacists make to tackling vaccine-preventable diseases and improving vaccination coverage.

PGEU Position Paper on antimicrobial resistance

PGEU published its Position Paper on antimicrobial resistance (AMR) in June. Community pharmacists play a key role in antimicrobial stewardship, including counselling and advising on the prudent use of antibiotics and other antimicrobials, as well as their correct disposal. Pharmacies can be used as healthcare settings for effective public health campaigns on AMR. Community pharmacists have shown that the network of pharmacies spread across the territory offers highly accessible testing services to the population during the COVID-19 pandemic (in at least 12 countries). Pharmacists play a fundamental role in pharmacy-based vaccination which is a valuable tool in the fight against AMR.

Joint Statement on the European Health Data Space

PGEU signed in 2023 a joint statement together with CED, CPME, EFN and HOPE, on the European Health Data Space Regulation. This statement emphasized the role of professional obligations regarding confidentiality, the need for resources and financial support for healthcare professionals in the digital transition and clarifications regarding professional liability.

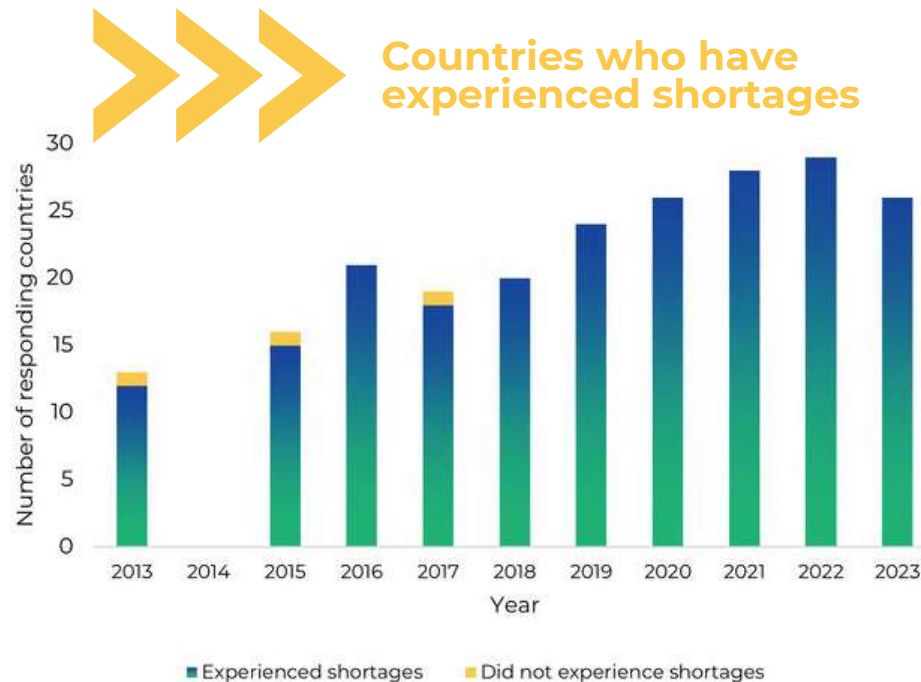


PGEU Position Paper on Antimicrobial Resistance



The year of shortages

Medicine shortages have a negative impact on patients' health and constitute a burden for the daily work of pharmacists. Every year since 2013, PGEU runs a survey through its members, capturing the community pharmacists' perspective on medicine shortages. For **the sixth year in a row, all PGEU members that contributed to the survey have experienced shortages** - what was before a difficulty in some of the countries is now considered a pan-European chronic problem.



From antibiotics to cardiovascular to respiratory, **all types of medicines continued to be in short supply in 2023**. The PGEU annual medicine shortages report indicates that the **situation grew worse compared to previous years**. In the Netherlands alone 2.292 shortages were registered last year affecting about 5 million people. Other countries like Sweden, Portugal and Spain saw a significant increase in the number of shortages. Despite pharmacists continued best efforts to find solutions, shortages still leave many patients without their prescribed treatment. This situation causes **frustration and inconvenience for patients and erodes their trust in pharmacists and in the healthcare system**. Shortages cause stress for pharmacy staff and impose an additional administrative burden on pharmacies daily work.



The year of shortages

“ In 2023 every pharmacy across the EU spent on average **almost 10 hours per week dealing with medicine shortages.** ”



This **time has tripled over the last 10 years**; precious time which could be devoted to other useful tasks such as providing patients advice on the safe and effective use of medicines. **Pharmacies struggle even more to provide patients solutions for shortages given the current healthcare workforce shortage.**

At the end of 2022 and the beginning of 2023, Europe saw a surge in respiratory infections during the winter season. This was accompanied by an increase demand for common antibiotics such as amoxicillin – especially for paediatric use. The increased demand helps to explain the supply disruptions that pharmacists reported in various countries and required immediate and concrete actions. Collaborating with the National Competent Authorities and the European Medicines Agency, **pharmacists were able to find solutions to temporarily alleviate the problem.** However, the options available to pharmacists in the different countries to find solutions for patients in case the prescribed medicine is unavailable still differ substantially. Providing pharmacists with the right tools and flexibilities that enable them to fully leverage their skills, knowledge, and experience will result in better solutions being found for patients – for example by **substituting** a medicine in short supply with an available alternative or **compounding** medicines in the correct dose for paediatric patients.

“ In April, the European Commission published the much-awaited proposal for a reform of the EU pharmaceutical legislation. PGEU welcomed the important provisions to improve the supply of medicines to meet patients’ needs, regardless of where they live in the Union, in line with the objectives set by the European Commission’s pharmaceutical strategy. ”

The year of shortages

Community pharmacists were glad to see introduced important and useful tools to address medicine shortages, including the earlier notification of anticipated supply disruptions, marketing cessations and withdrawals. **PGEU supports the European Commission proposals to strengthen Member States' coordination in monitoring and mitigating shortages**, with a stronger involvement of the European Medicines Agency (EMA) and a key role for the Executive Steering Group on Shortages and Safety of Medicinal Products, also known as Medicine Shortages Steering Group (MSSG). Similarly, **PGEU is positive about the expansion of the use of the European Shortages Monitoring Platform (ESMP) to facilitate the collection of information on shortages, supply and demand for medicinal products**, including information on marketing status and marketing cessations.

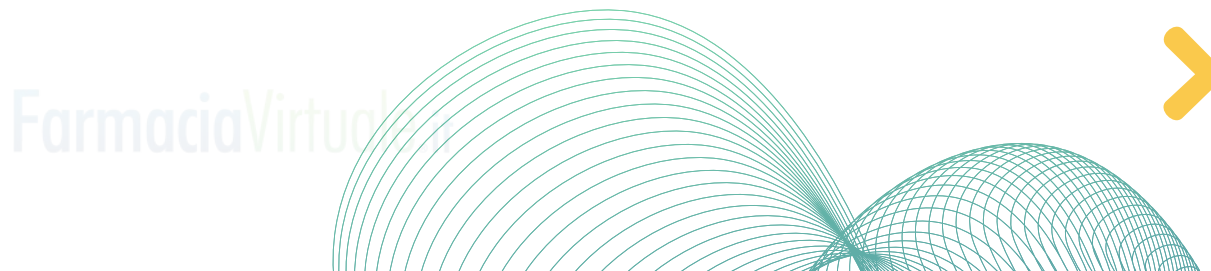
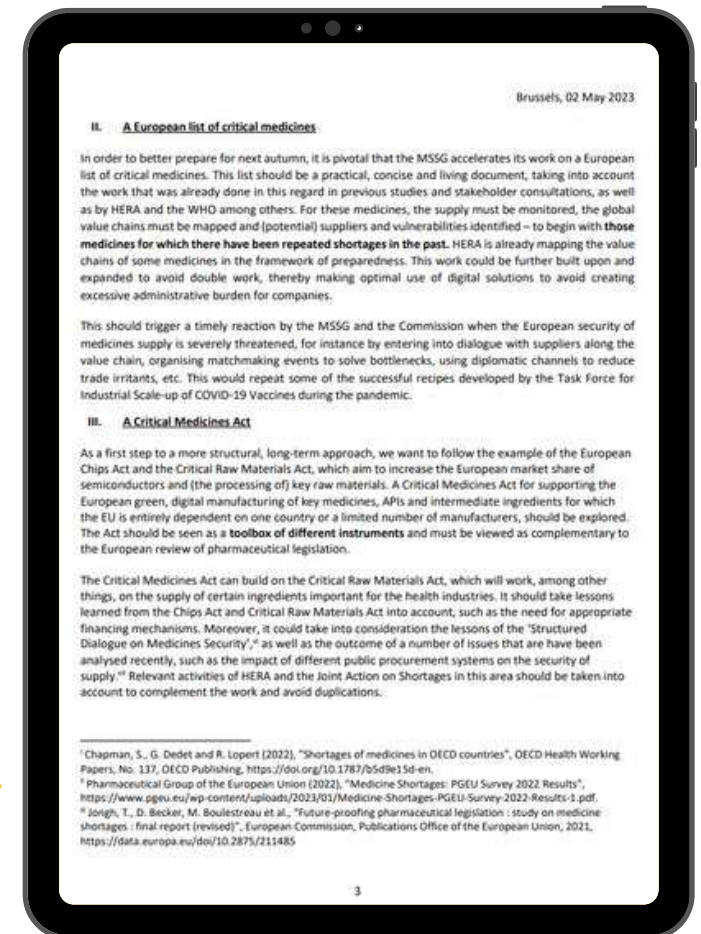
“ PGEU calls to allow for supply chain actors to report medicine shortages to competent authorities have also been reflected in the European Commission's proposal. While the reporting of anticipated shortages is strengthened, community pharmacists would like to see clearer provisions regarding transparent and timely communication to the impacted stakeholders, in a rational and phased manner. ”



The year of shortages

Among the important **measures introduced by the European Commission**, community pharmacists support the requirements for a better oversight of manufacturers' supply chains, including in the **implementation of shortages prevention and mitigation plans**. PGEU considers that these plans should be transparent and accessible to the medicines regulators and that they are efficiently implemented once a shortage is anticipated or confirmed. Lastly, PGEU strongly supports the much-needed clarifications of the **responsibilities of marketing authorization holders and wholesale distributors to ensure the appropriate and continued supply of medicines**. We are convinced that these will help Member States define the appropriate obligations for each actor nationally and result in a better functioning supply chain to the benefit of patients.

Shortly after the European Commission's proposal to reform the General Pharmaceutical Legislation was adopted, several Member States published, in May, a Non-Paper on Improving the security of medicines supply in Europe, outlining steps at short, medium and long term, to improve the critical situation that Europe was facing. The political document, spearheaded by Belgium and backed by another 22 countries, considered the complexity of the problems linked with shortages of medical products, and proposed concrete measures: to instal an **EU voluntary solidarity mechanism, to establish an EU list of critical medicines**, and to explore a **Critical Medicines Act**. The document, that quoted PGEU Shortages Survey 2022, was praised by Member States and was seen as complementary to the initiatives being carried out by the European Medicines Agency and the reform of the pharmaceutical legislation.

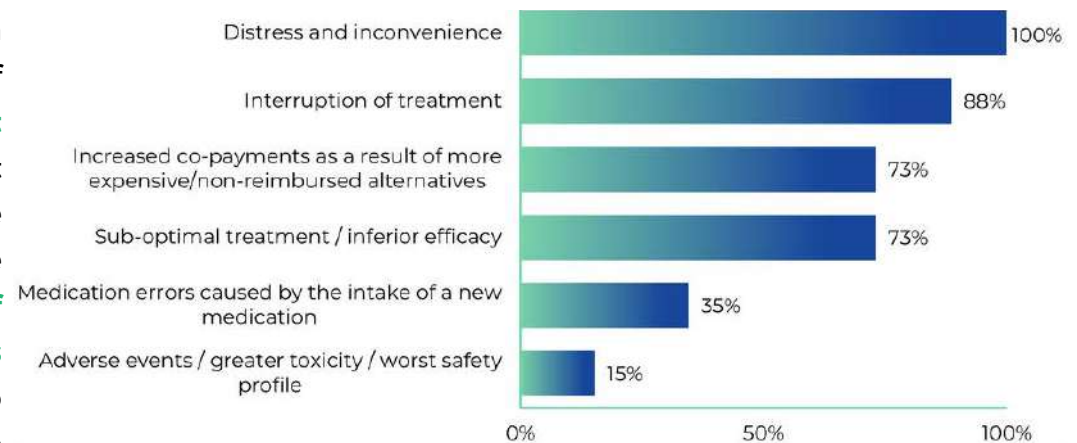


The year of shortages

On 24 October the European Commission published a Communication on addressing medicines shortages. The Commission called on Member States to monitor and enforce companies' obligations to supply the market with adequate quantities of medicines and referred to the creation of a Union list of critical medicines and of a voluntary solidarity mechanism. In line with PGEU demands, the communication also referred to the **effective use of regulatory flexibilities to mitigate shortages, the strengthening of EU coordination, the improvement of demand and supply forecasting as well as the proposed long-term measures to enhance supply security.**

From the measures proposed, PGEU alerted for the need to **carefully elaborate the common strategic approach to stockpiling** to guarantee that stockpiles will not be to such an extent as to jeopardize the general supply of medicines, nor should they generate unnecessary waste. This can be achieved by ensuring progressive requirements for rolling buffer stocks, allowing for these to be built over time rather than all at once and through proper stock management. Simultaneously with the European Commission's communication, the European Medicines Agency published the MSSG Toolkit on recommendations on tackling shortages of medicinal products. These included details of the newly created voluntary solidarity mechanism, that allows Member States to support each other in the face of a critical medicine shortage.

In December, the European Commission, the European Medicines Agency and the Member States' Heads of Medicines Agencies (HMA) published the very **first European Union list of critical medicines**. This list shows an important part of the EU's efforts under the European Health Union to ensure patients have the medicines they need, by fostering the **security of supply of critical medicines and preventing shortages from occurring**. It is also part of the EU's efforts to improve its resilience and strategic autonomy in the face of geopolitical and unexpected challenges.



Impact of medicine shortages on patients

The year of Shortages

This year, even more than the previous ones, PGEU continued to **bring this topic up on the political agenda**. PGEU participated in numerous events, **met with EU institutions, EU agencies, european stakeholders, NGOs, and other health care professional organizations** presenting and showcasing the community pharmacists' perspective on this topic. We also received a record amount of attention from media, PGEU's messages and reports were quoted, sourced and echoed in different fora at national, EU and international level.



PGEU participated in numerous events, met with EU institutions, EU agencies, european stakeholders, NGOs, and other health care professional organizations presenting and showcasing the community pharmacists' perspective on this topic. ”

Despite the attention given this year to the topic, there is still a lot to be done to address the root causes of the problem, which are both diverse and complex. **It is vital to improve reporting, monitoring, and communication on medicine shortages**. It will also be important to provide the European Medicines Agency with additional resources to develop activities on the prevention and management of shortages in coordination with Member States. The reform of the EU pharmaceutical legislation provides a unique opportunity to build a more resilient supply chain and improve shortages prevention, monitoring, and management. And while this year, we saw some measures to address this chronic problem being presented, we still need **immediate action to reverse the negative trend that pharmacists have been denouncing for over a decade**. We remain committed to cooperating with all those aiming at addressing this issue and finding solutions for patients so that they can receive their treatment, regardless the country where they live in.

A look forward

With the upcoming **European elections in June**, the year ahead holds significant **importance for the future of health in the EU** and therefore also for national healthcare system and pharmacies.

In this pivotal moment, it is imperative to ensure that health remain high on the EU political agenda.

Confronted with the ongoing conflict in Ukraine, armed conflicts in the Middle East, record-breaking temperatures, and the many other complexities of a rapidly changing world, we must remain vigilant to ensure that health continues to be a top priority for all policy makers.

At PGEU we will as always advocate for effective and evidence-based policies that promote public health, guarantee access to medicines, strengthen the sustainability of health system and improve patients care.

Central to our efforts will be the ongoing commitment to **combat antimicrobial resistance**, a public health threat that requires urgent action and collective responsibility. Through education, stewardship, and advocacy, we can mitigate the spread of resistant bacteria and preserve the efficacy of life-saving antibiotics for future generations.

Furthermore, with the ever-expanding frontiers of healthcare innovation, we must address the **ethical and regulatory challenges** posed by advancements in **Artificial Intelligence (AI)**. While AI holds tremendous potential to revolutionize healthcare delivery, its implementation must be guided by principles of transparency, accountability, and patient safety and safeguard the integrity and trustworthiness of healthcare systems.



In the coming year the **European Health Data Space Regulation** will become an EU law and it will have a significant impact on community pharmacy. The EHDS presents a groundbreaking opportunity to reshape the landscape of patient care, data sharing, and healthcare delivery across the EU. By breaking down barriers to **data sharing, pharmacists can have access to comprehensive patient health records, enabling them to make more informed decisions about medication management and provide personalized care.** However, despite the numerous benefits, the greatest challenge from a community pharmacist's perspective will lie in **ensuring data security and privacy.**

As the negotiations on the reform of the EU pharmaceutical legislation progress PGEU priority will be to make sure that the new legislation helps **mitigate the persistent problem of medicines shortages** and will **improve patients access to affordable medicines.**

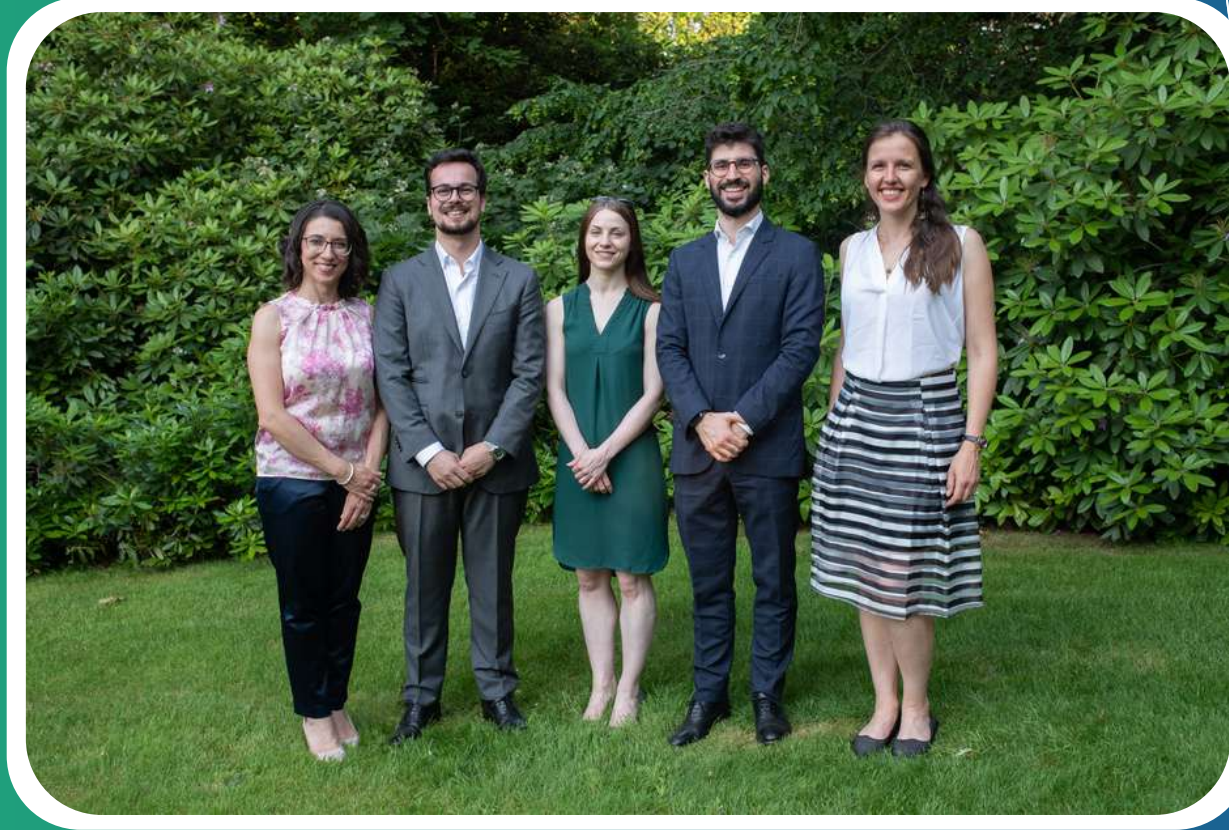
We also remain committed to working closely with the European Medicines Agency, with the European Center for Disease Prevention and Control as well as with patients and consumers association, with the other EU healthcare professionals, with the pharmaceutical industry and with the other stakeholders of the medicines supply chain.



- ILARIA PASSARANI



PGEU SECRETARIAT



● **Ilaria Passarani**
Secretary General

● **Jorge Batista**
Professional Affairs Advisor

● **Audrey van Coillie**
Senior Office Manager

● **Gwen Lehane**
Legal Advisor

● **Diogo Dominguez-Piedade**
Economic Affairs Manager

● **Leonor Araújo**
EPSA Officer
Past - Catarina Silva

PGEU EXECUTIVE COMMITTEE 2023



Belgium

A.P.B - Association Pharmaceutique Belge/Algemene Pharmaceutische Bond (Association of Pharmacists Belgium)
Orde der Apothekers – Ordre des Pharmaciens (Belgian Order of Pharmacists)

Bulgaria

Български фармацевтичен съюз (Bulgarian Pharmaceutical Union)

Finland

Suomen Apteekkariliitto / Finlands Apotekareförbund (Association of Finnish Pharmacies)

Hungary

Magyar Gyógyszerész Kamara (Hungarian Chamber of Pharmacists)

Italy

Federazione Ordini Farmacisti Italiani (FOFI) (Federation of the Order of Italian Pharmacists)
Federfarma (Italian Pharmacy Owners Federation)

Latvia

Latvijas farmaceitiskās aprūpes asociācija (Pharmaceutical Care Association of Latvia)

Luxembourg

Syndicat des Pharmaciens Luxembourgeois a.s.b.l. (Union of Luxembourg Pharmacists)

Netherlands

KNMP - Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie (Royal Dutch Pharmaceutical Association)

Romania

Colegiul Farmacistilor din Romania (The Romanian College of Pharmacists)

PGEU Members 2023

Ordinary Members

Austria

Österreichische Apothekerkammer (Austrian Chamber of Pharmacists)
Österreichische Apothekerkammer (Austrian Chamber of Pharmacists)

Belgium

A.P.B - Association Pharmaceutique Belge/Algemene Pharmaceutische Bond (Association of Pharmacists Belgium)
Orde der Apothekers - Ordre des Pharmaciens (Belgian Order of Pharmacists)

Bulgaria

Български фармацевтичен съюз (Bulgarian Pharmaceutical Union)

Croatia

Hrvatska Ljekarnička Komora (Croatian Chamber of Pharmacists)

Cyprus

Παγκύπριος Φαρμακευτικός Σύλλογος (ΠΦΣ) (Pancyprian Pharmaceutical Association)

Czech Republic

Česká lékárnická komora (Czech Chamber of Pharmacists)

Denmark

Danmarks Apotekerforening (The Association of Danish Pharmacies)

Estonia

Eesti Proviisorapteekide Liit (Estonian Pharmacies Association)

Finland

Suomen Apteekkariliitto / Finlands Apotekareförbund (Association of Finnish Pharmacies)

France

Fédération des Syndicats Pharmaceutiques de France (Federation of Pharmaceutical Unions of France)
Ordre National des Pharmaciens - Conseil Central A (The National Chamber of Pharmacists - Pharmacy Owners Section)
USPO - Union des Syndicats de pharmaciens d'officine (Trade Union of Community Pharmacists)

Germany

ABDA - Bundesvereinigung Deutscher Apothekerverbände (Federal Union of German Pharmacists Associations)

Greece

Πανελλήνιος Φαρμακευτικός Σύλλογος (Panhellenic Pharmaceutical Association)

PGEU Members 2023

Ordinary Members

Hungary

Magyar Gyógyszerész Kamara (Hungarian Chamber of Pharmacists)

Ireland

Irish Pharmacy Union

Italy

Federazione Ordini Farmacisti Italiani (FOFI) (Federation of the Order of Italian Pharmacists)
Federfarma (Italian Pharmacy Owners Federation)

Latvia

Latvijas farmaceutiskās aprūpes asociācija (Pharmaceutical Care Association of Latvia)

Luxembourg

Syndicat des Pharmaciens Luxembourgeois a.s.b.l. (Union of Luxembourg Pharmacists)

Malta

Kamra ta' l-Ispijjara ta' Malta (Malta Chamber of Pharmacists)

Netherlands

KNMP - Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie (Royal Dutch Pharmaceutical Association)

Poland

Naczelna Izba Aptekarska (Polish Pharmaceutical Chamber)

Portugal

Associação Nacional das Farmácias (National Association of Pharmacies)
Ordem dos Farmacêuticos (Pharmaceutical Society)

Romania

Colegiul Farmacistilor din Romania (The Romanian College of Pharmacists)

Slovak Republic

Slovenská Lekárnická Komora (Slovak Chamber of Pharmacists)

Slovenia

Lekarniška Zbornica Slovenije (Slovenian Chamber of Pharmacy)

Spain

Consejo General de Colegios Farmacéuticos de España (General Pharmaceutical Council of Spain)

Sweden

Sveriges Apoteksförening (Swedish Pharmacy Association)

PGEU Members 2023

Observer Members

Kosovo

Oda e Farmacistëve të Kosovës
(Chamber of Pharmacists of Kosovo)

North Macedonia

Фармацевтска комора на Македонија
(Pharmaceutical Chamber of Macedonia)

Norway

NAF – Apotekforeningen (Norwegian Pharmacy Association)

Serbia

Farmaceutska komora Srbije
(Pharmaceutical Chamber of Serbia)
-Savez farmaceutskih udruženja Srbije
(Pharmaceutical Association of Serbia)

Turkey

Türk Eczacıları Birliği (Turkish Pharmacists' Association)

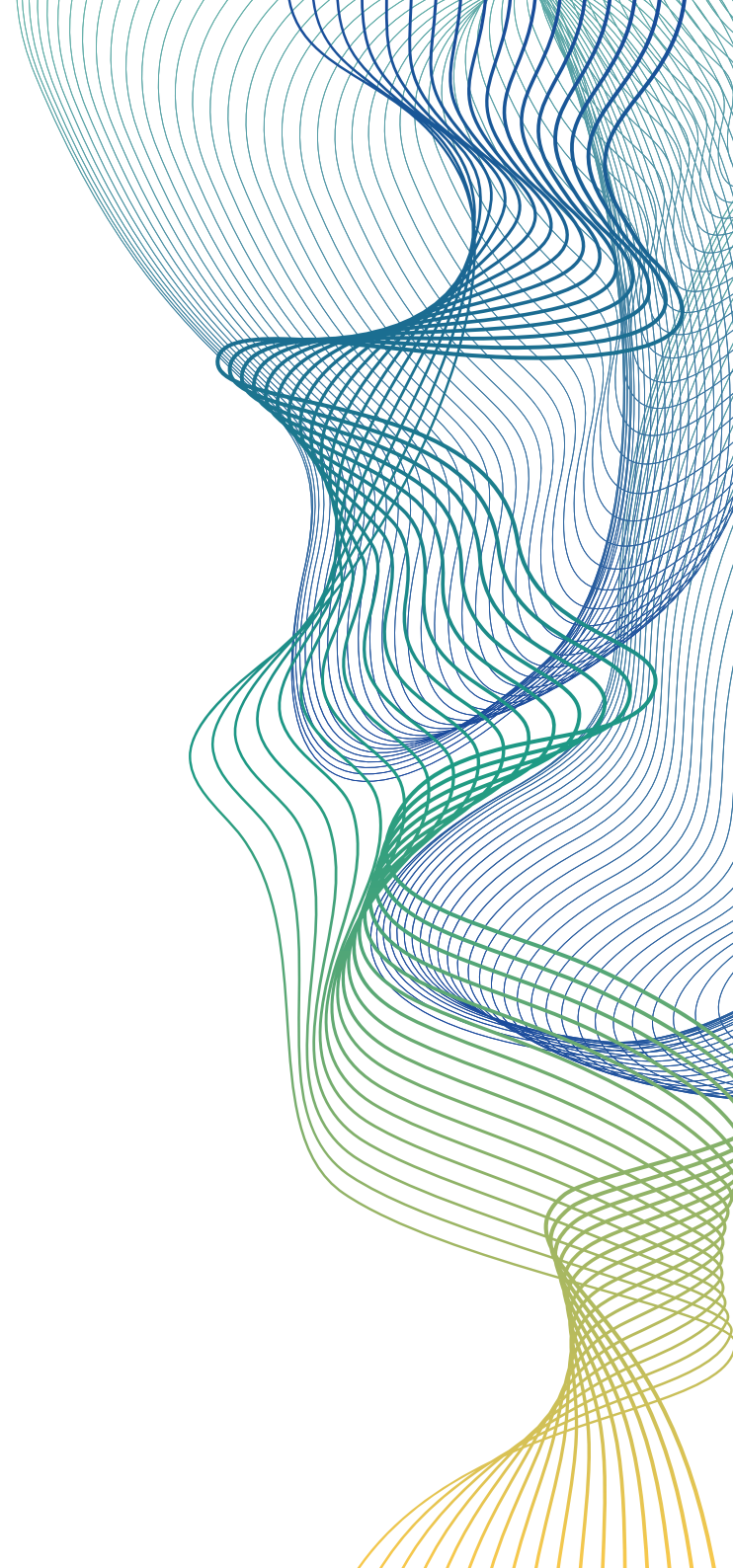
United Kingdom

National Pharmacy Association
Pharmaceutical Society of Northern Ireland





FarmaciaVirtuale.it





PGEU

*European Community
Pharmacists*

**Rue du Luxembourg 19, 1000 Brussels,
Belgium**

T: +32 (0)2 238 08 18

Email: pharmacy@pgeu.eu

www.pgeu.eu

FarmaciaVirtuale.it