Contribution ID: ed7eb7b9-ef94-4ad0-8745-fca8ad29fcbd
Date: 04/09/2020 10:42:19

# Public consultation on European Medicines Agencies Network Strategy to 2025

Fields marked with * are mandatory.

## Introduction

The purpose of this public consultation is to seek views from EMA's and HMA's stakeholders, partners and the general public on the proposed joint **European Medicines Agencies Network Strategy to 2025** and whether it meets stakeholders' needs. By highlighting where stakeholders see the need as greatest, there is an opportunity to help shape the strategy for the coming years, 2021-2025.

The views being sought on the proposed strategy refer both to the extent and nature of the broader strategic theme areas and goals. We also seek your views on whether the specific underlying objectives proposed are the most appropriate to achieve these goals.

The strategy will be aligned with the broader **Pharmaceutical Strategy for Europe** being developed by the European Commission and its actions will seek to provide synergies with actions developed under the Pharmaceutical Strategy where their subject matter overlaps. Wherever matters of policy or potential legislative change are referred to, these should be understood as supporting the development and implementation of the broader Pharmaceutical Strategy, where the ultimate responsibility for such matters will lie.

The questionnaire has been launched on 6 July 2020, to enable stakeholder feedback to be collected on the draft network strategy and will remain open throughout the consultation period until **4 September 2020**. In case of any queries, please contact: EMRN2025strategy@ema.europa.eu.

## Completing the questionnaire

This questionnaire should be completed once you have read **the draft joint strategy document**. The survey is divided into a general section on the whole document and then focuses on each strategic theme area. You are invited to complete the sections which are most relevant to your areas of interest.

We thank you for taking the time to provide your input; your responses will help to shape and prioritise the future objectives of the European Medicines Agencies Network.

## Data Protection

By participating in this survey, your submission will be assessed by EMA and HMA. EMA collects and stores your personal data for the purpose of this survey. Requests for contributions to be published in an anonymised form, can be sent to the data controller (S-DataController@ema.europa.eu).

* Name

Jan De Belie

* Email

j.de-belie@pgeu.eu

## Stakeholder Information

* **Question 1: What stakeholder, partner or group do you represent:**

- ○ Individual member of the public
- ○ Patient or Consumer Organisation
- ◉ Healthcare professional organisation
- ○ Learned society
- ○ Farming and animal owner organisation
- ○ Academic researcher
- ○ Healthcare professional

- ○ Veterinarian
- ○ European research infrastructure
- ○ Research funder
- ○ Other scientific organisation
- ○ EU Regulatory partner / EU Institution
- ○ Health technology assessment body
- ○ Payer
- ○ Pharmaceutical industry
- ○ Non-EU regulator / Non-EU regulatory body
- ○ Other

* ***Name of organisation (if applicable):***

If not applicable, please insert "n/a"

Pharmaceutical Group of the European Union (PGEU)

# Overall strategy

* **Question 2: Please indicate which area is relevant to your area of interest?**

Please select one or both options, as applicable

- ☑ Human
- ☐ Veterinary

**Question 3: Having read the proposed strategy, how would you rate it in general terms?**

*Answer the following question on a scale of 1-5, where 5 indicates highly satisfied and 1 highly dissatisfied*

| | 1. Highly Dissatisfied | 2. Dissatisfied | 3. Neutral | 4. Satisfied | 5. Highly satisfied |
|---|---|---|---|---|---|
| * What are your overall impressions of the EMAN Strategy to 2025? | ○ | ○ | ○ | ◉ | ○ |

* **Question 4: Are there any significant elements missing in this strategy?**

*Please note that the strategy aims to focus on major areas of interest for the next five years and it is not intended to cover all activities undertaken by the Network.*

- ○ Yes
- ◉ No

**Question 5: The following is to allow more detailed feedback on prioritisation of the joint EMA/HMA goals for each strategic theme, which will also help shape the future application of resources. Your further input is therefore highly appreciated. Please choose for each row the option which most closely reflects your opinion. For areas**

**outside your interest or experience, please leave blank.**

*Should you wish to comment on any of the goals and their underlying objectives, there is an option to do so.*

**Strategic Theme area 1: Availability and accessibility of medicines**

| | Very important | Important | Moderately important | Less important | Not important |
|---|---|---|---|---|---|
| 1) Strengthen the availability of medicines to protect the health of European citizens, via: efficient and targeted regulatory measures, made possible through an in-depth understanding the root causes of unavailability of patented and off-patent products; identification of possible challenges in implementing legislation, removal of national barriers, increased coordination of the EMRN, sharing and implementation of best practices including stakeholders and increased transparency are the essential steps towards this goal. | ◉ | ○ | ○ | ○ | ○ |

| | | | | | |
|---|---|---|---|---|---|
| 2) Optimise the path from development, evaluation through to access for innovative and beneficial medicines through collaboration between medicines regulators and other decision makers in the areas of: evidence planning, including post-licensing evidence; engagement in review of evidence and methodologies, respecting remits of the various players; collaboration on horizon scanning. As a result of this work, medicines that address unmet medical needs should have broader and earlier access coverage. | ○ | ◉ | ○ | ○ | ○ |

**Strategic Theme area 2: Data analytics, digital tools and digital transformation**

| | Very important | Important | Moderately important | Less important | Not important |
|---|---|---|---|---|---|
| 1) Enable access to and analysis of routine healthcare data and promote standardisation of targeted data | ◉ | ○ | ○ | ○ | ○ |
| 2) Build sustainable capability and capacity within the Network including statistics, epidemiology, real world data and advanced analytics | ○ | ◉ | ○ | ○ | ○ |
| 3) Promote dynamic regulation and policy learning in current regulatory framework | ○ | ◉ | ○ | ○ | ○ |

| | | | | | |
|---|---|---|---|---|---|
| 4) Ensure that data security and ethical considerations are embedded in the governance of data within the Network | ◉ | ○ | ○ | ○ | ○ |
| 5) Map the use and needs of data analytics for veterinary medicines and support a streamlined approach across borders within the EEA | ○ | ○ | ◉ | ○ | ○ |

**Strategic Theme area 3: Innovation**

| | Very important | Important | Moderately important | Less important | Not important |
|---|---|---|---|---|---|
| 1) Catalyse the integration of science and technology in medicines development and ensure that the network has sufficient competences to support innovators in various phases of medicines development. | ○ | ◉ | ○ | ○ | ○ |
| 2) Foster collaborative evidence generation - improving the scientific quality of evaluations and ensuring generation of evidence useful to all actors in the lifecycle of medicines, including HTAs, and pricing and reimbursement authorities. | ◉ | ○ | ○ | ○ | ○ |
| 3) Enable and leverage research and innovation in regulatory science | ○ | ◉ | ○ | ○ | ○ |

| | | | | | |
|---|---|---|---|---|---|
| 4) Enhance collaboration with medical device experts, notified bodies and academic groups | ○ | ◉ | ○ | ○ | ○ |

**Strategic Theme area 4: Antimicrobial resistance and other emerging health threats**

| | Very important | Important | Moderately important | Less important | Not important |
|---|---|---|---|---|---|
| 1) Provide high quality information on antimicrobial consumption and surveillance data on antimicrobial resistance in animals and humans in support of policy development. | ○ | ◉ | ○ | ○ | ○ |
| 2) Contribute to responsible use of antibacterial agents and effective regulatory antimicrobial stewardship in human and veterinary sectors by putting in place strategies to improve their use by patients, healthcare professionals and national authorities | ◉ | ○ | ○ | ○ | ○ |
| 3) Ensure regulatory tools are available that guarantee therapeutic options (with a focus on veterinary medicines) while minimising impact of antimicrobial resistance on public health and the environment | ◉ | ○ | ○ | ○ | ○ |

| | | | | | |
|---|---|---|---|---|---|
| 4) Define pull incentives for new and old antibacterial agents, including investigating support for new business models and not-for-profit development | ○ | ◉ | ○ | ○ | ○ |
| 5) Foster dialogue with developers of new antibacterial agents and alternatives to traditional antimicrobials, to streamline their development and provide adequate guidance in both human and veterinary medicine | ○ | ◉ | ○ | ○ | ○ |
| 6) Improve regulatory preparedness for emerging health threats | ◉ | ○ | ○ | ○ | ○ |

**Strategic Theme area 5: Supply chain challenges**

| | Very important | Important | Moderately important | Less important | Not important |
|---|---|---|---|---|---|
| 1) Enhance traceability, oversight and security in the human/veterinary medicine supply chain from manufacturing to importation and final use of active pharmaceutical ingredients (APIs) | ○ | ◉ | ○ | ○ | ○ |
| 2) Enhance inspector capacity building at EU and international level to address the problem of APIs, new technologies and continuous manufacturing | ○ | ◉ | ○ | ○ | ○ |

| | | | | | |
|---|---|---|---|---|---|
| 3) Reinforce the responsibility for product quality by harmonising and reinforcing guidance to facilitate a coherent approach to the standards by regulators and industries | ○ | ◉ | ○ | ○ | ○ |
| 4) Encourage supply chain resilience and review long-term risks resulting from dependency on limited number of manufacturers and sites, to ensure continuity of supply and availability of medicinal products. | ◉ | ○ | ○ | ○ | ○ |
| 5) Analyse the possible implications of new manufacturing technologies in order to regulate the new supply chains needed to manufacture and distribute new types of medicinal products for human and veterinary use. | ○ | ◉ | ○ | ○ | ○ |

**Strategic Theme area 6: Sustainability of the Network and operational excellence**

| | Very important | Important | Moderately important | Less important | Not important |
|---|---|---|---|---|---|
| 1) Reinforce scientific and regulatory capacity and capability of the network | ○ | ◉ | ○ | ○ | ○ |
| 2) Strive for operational excellence, building on the work done in the current strategy | ○ | ◉ | ○ | ○ | ○ |

| | | | | | |
|---|---|---|---|---|---|
| 3) Achieve a sustainable financial and governance model for the network | ○ | ◉ | ○ | ○ | ○ |
| 4) Develop a digital strategy to drive digital business transformation | ○ | ◉ | ○ | ○ | ○ |
| 5) Enable quick, consistent and adequate response to public and animal health challenges | ◉ | ○ | ○ | ○ | ○ |

# Strategic focus areas

## * Please indicate which Strategic Theme area(s) you would like provide input

Please select as many choices as applicable.

- ☑ 1. Availability and accessibility of medicines
- ☑ 2. Data analytics, digital tools and digital transformation
- ☑ 3. Innovation
- ☑ 4. Antimicrobial resistance and other emerging health threats
- ☑ 5. Supply chain challenges
- ☑ 6. Sustainability of the Network and operational excellence

## Strategic Theme area 1: Availability and accessibility of medicines

### Question 6: Do the objectives adequately address the challenges ahead?

- ◉ Yes
- ○ No

### Comments on objectives of the strategic theme area:

We welcome the strong focus of the Network Strategy on improving the availability and accessibility of medicines for patients. We support in particular its objective to provide adequate regulatory responses to the identified root causes of medicines shortages.

We also welcome the focus on sharing and implementing ongoing best practices across Europe and the identification of possible implications and challenges in implementing new legislations. In particular, we recommend EMA and HMA to explore ongoing best practices in the reporting of signals of shortages by different actors in the supply chain. Through harmonization and coordination of such initiatives at national level at European level we believe that EMA and HMA could effectively monitor real-time supply disruptions at EU level which measure the actual unavailability of medicines for patients. We also believe the European Medicines Verification system set out by the EU falsified medicines legislation is not an appropriate tool to

monitor shortages. The system has not been designed as a track and trace system therefore the level of authentication doesn't necessarily reflect stock level data and it is not a timely and reliable indicator of the national demand, especially for products is short in supply. Moreover not 100% of packs are authenticated. Lastly, multi-market packs are uploaded in all potential destination markets and counted multiple times without being available in these markets. Alternatively, we suggest to make use of pharmacy-based reporting systems already in place in many countries guaranteeing harmonization of criteria and comparability of data, which should take into account differences in definition of a medicine shortage across borders.

Whilst PGEU welcomes further adequate regulatory and administrative simplification to help ensuring security of medicines supply, we identify some potential risks around the mentioned use of electronic product information (ePI) for this purpose. We welcome the use of ePI as a tool to increase citizens' access to objective and neutral information on pharmaceuticals at home, improving confidence and patient empowerment. In addition, due to its semi-structured and accessible format and design, ePI has indeed opportunities to improve readability and engagement of citizens to important information on pharmaceuticals. The ePI offers also additional opportunities for better linkage to and visualisation of risk-minimisation information. It will however be crucial to ensure that patients continue to have access to objective and neutral product information on pharmaceuticals in their own language. PGEU strongly supports the principle that ePI complements the use of paper package leaflets, and that it does not intend to remove or substitute the currently available paper format. As pharmacists we see that the paper package leaflets are today widely used by a very diverse group of citizens, including parts of the population with limited access to digital tools such as certain elderly and people with limited financial resources. There should therefore be safeguards in place to ensure that there will be no abuse of higher flexibility for ePI in cases of shortages resulting in a wider replacement of paper package leaflets. Given that 80% of marketing authorizations are national ones, it could also be explored to have a pan-European database of patient information leaflets / summaries of product characteristics translated into national languages. The paper patient leaflet ('PL') or primary packaging could consequently include a statement directing to the electronic product information available in other EU languages and refer to the most up-to-date version of the PL available.

Regarding the objective on achieving more transparency and good and timely communication on shortages with patients and healthcare professionals we strongly encourage national authorities to implement the principles defined in the EMA/HMA good practice guidance for communication to the public on medicines' availability issues where this is still needed. Too often, we see that community pharmacists as well as other healthcare professionals and patients receive either no, incomplete and/or delayed information on shortages. However this information is crucial to effectively prevent and manage shortages in practice and reduce the impact on patient care as much as possible.

Lastly, we welcome the focus of the strategic theme area on the coordination between regulatory policies with other policies which might affect the availability of medicines across Europe. Only by increased and meaningful coordination and collaboration across different policy areas, institutions and countries we will be able to effectively address the underlying issues which have lead to medicine shortages becoming one of the most concerning public health treads across Europe.

## Question 7: Are there any other challenges that should be addressed by the EMA/HMA network in this area?

- (●) Yes
- ( ) No

### If yes, please specify

*Please remember to specify if a particular comment relates specifically to the human or veterinary part.*

We would welcome a more clear and ambitious formulation of the objectives related to the monitoring of shortages at European level. In order to create a stronger and more structured cooperation on medicine shortages between Member States at EU level, we support an expanded role of the EMA in close cooperation with HMA in the coordination of Member States activities on the prevention and management of shortages, building on the lessons learnt during the COVID-19 crisis and notwithstanding national competence which remains the most relevant to solve problems on the field, according to local needs and specificities. EMA's expanded role should be achieved by increasing resources and by clarifying and updating its legal activities by amending Regulation (EC) No 726/2004. One of the main EMA activities should be the central information collection and monitoring of (anticipated) medicine shortages at EU level in close collaboration with HMA, complementing existing national systems, through further development of the EU SPOC and i-SPOC system, taking into account signals of shortages generated throughout the supply chain including in community pharmacies. EMA can also have a role in further harmonizing at EU level the different existing definitions of medicine shortages to allow for central monitoring.

In addition, we think the strategy needs to have a particular focus on managing the impact of Brexit on medicines supply across Europe. This relates both to the impact on the United Kingdom and countries which are highly depend on the UK market such as Ireland, Malta and Cyprus.

### Question 8: Are you undertaking concrete actions in this field that could support or complement EMA/HMA network activities?

- (●) Yes
- ( ) No

### If yes, please elaborate which ones and provide details on how these could be considered.

Each year PGEU conducts a survey among their membership to map the impact of medicine shortages across Europe from the community pharmacists' perspective. This survey, together with surveys from other healthcare professional and patient organisations, provides important insights for authorities and regulators on the impact and challenges identified in practice, which can consequently inform regulators' actions and policies. See: https://www.pgeu.eu/wp-content/uploads/2019/03/2019-PGEU-Position-Paper-on-Medicine-Shortages-1.pdf

In addition, several community pharmacy organisations across Europe have developed their own systems where pharmacists can report signals of shortages. This information is crucial to inform timely prevention and management actions on shortages since pharmacists often experience or foresee supply difficulties before the industry or wholesalers are aware that there is, or will be, a problem. In some of these countries pharmacist automatically generate such signals when they cannot order a certain product from their wholesaler for a defined amount of time. The signals can then be periodically clustered and assessed by the national competent authority to see if signals anticipate potential shortages or reflect actual shortages.

Four PGEU member organisations are involved in a twinning project, which has received funding from the European Commission, to enable the sharing of this data generated by pharmacies across borders. Firstly the knowledge of each country  system´s technical specifications will be exchanged which should get them closer to developing a common system in which there will be no lack of interoperability between Member States, and could also potentially work as a base for other future common systems which means we would be contributing to linking Europe´s fragmented resources through secure cross-border digital infrastructures. The twinning solution will be CISMED medicine shortage detection system; a system developed and implemented by the Consejo General de Colegios de Farmacéuticos de España (General Pharmaceutical Council of Spain - CGCOF) along with the Regional Pharmacists Chambers. Once Twinning activities are over, the adopter countries will have the necessary information to create a medicine shortage detection system by themselves and this would also mean they would be in a great position to build a common system between the involved countries or even scaling it up to a European level in which case they would be sharing a common repository, common communication protocols and a common definition of what a medicine shortage means. The organisations currently involved in this project are the Consejo General de Colegios Oficiales de farmacêuticos (GCCOF-España), Associação Nacional da Farmácias (ANF-Portugal), Ordre National des Pharmaciens (CNOP-France) and Federazione Nazionale Unitaria Titilari di Farmacia (Federfarma- Italia).

In Greece, the Panhellenic Pharmaceutical Association (PFS) has proposed the establishment of shortage detection system for medicines, in collaboration with governmental institutions such as National Drug Organization. To date, a list of medicines in shortage is created and the National Drug Organization forbids the exports of the listed medicines for a limited period of time, until the drug supply chain returns to normal. The efforts focus on the optimization of this process, especially regarding the data collection. PFS has proposed to the corresponding authorities a fully automated method, where the data will be collected in real time through the pharmacists, who should indicate the lack of the drug while accessing the prescription through the national electronic prescription system. National Drug Organization will be able to have access to this database and decide regarding which medicine exports should be forbidden and for how long.

## Question 9: Are there any other ongoing or planned initiatives that should be considered for this proposed strategic theme area?

- (●) Yes
- ( ) No

**If yes, please provide details of the ongoing or planned initiatives.**

The EMA Healthcare Professionals' Working Party (HCPWP) together with the Patients and Consumers' Working Party (PCPWP) are planning to update their common 2013 position on the supply shortages of medicines, see:
https://www.eahp.eu/sites/default/files
/european_patient_organisations_position_on_shortages_medicinal_products_1.pdf

## Strategic Theme area 2: Data analytics, digital tools and digital transformation

**Question 6: Do the objectives adequately address the challenges ahead?**

- (●) Yes
- ( ) No

Comments on objectives of the strategic theme area:

PGEU acknowledges the value of innovative technologies such as Artificial Intelligence (AI) as well as the access and analysis of Big Data and consider these technologies to be a useful tool to support health professionals and EU health systems. In routine practice at national level, these tools shall always be accompanied by pharmacists' expert and professional advice to improve workflow efficiency, while promoting patient safety, therapy effectiveness and offering the highest standard of pharmacy services to patients. In the era of digitalization and multiple information sources, community pharmacy remains a trusted source of reliable and independent health information for patients. The potential use of real-world evidence including evidence generation in community pharmacies to evaluate effectiveness and therapeutic added value of innovative medicines in practise should therefore also be rewarded.

In order to harness the benefits of digital for enabling meaningful innovation and enhancing patient care, a key requirement is to develop trust by all stakeholders involved through guaranteeing a high level of data protection. Patient data must be processed under a high level of data protection standards within trustworthy infrastructures that enable the access to secure data services. It also has to be ensured that data access and analysis are in line with European privacy and data protection legislation.

We support the active development and uptake of the EU Health Data Space to leverage the potential of Big Data and AI for healthcare across Europe and as a result support healthcare professionals, including community pharmacists, to provide more personalized services and treatment to patients and robust, evidence-based information on issues related to therapies while promoting safe and rational medicines use.

PGEU supports in particular the integration 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.

The production of Big Data in healthcare could be further facilitated, via linking electronic health records with e-Prescribing systems, allowing health professionals involved in patient care to access the necessary patient' s information, subject to the patient's consent. This can also promote more collaboration across many different health professionals serving the same patients as well as to promote integration of primary care systems.
On the objective 'Deliver a sustainable platform to access and analyse healthcare data from across the EU' we would welcome more information on the implications for healthcare practice and the type of data falling under the scope of this objective.

## Question 7: Are there any other challenges that should be addressed by the EMA/HMA network in this area?

- (●) Yes
- ( ) No

## If yes, please specify

*Please remember to specify if a particular comment relates specifically to the human or veterinary part.*

Human part: There should be a stronger focus on strategies/actions which aim to enhance interoperability of information systems in Europe to foster exchange of data. We see this today as a main barrier towards further successful data exchange, not only in between countries but also between different healthcare settings and systems at local, regional and national level.

### Question 8: Are you undertaking concrete actions in this field that could support or complement EMA/HMA network activities?

- (●) Yes
- ( ) No

### If yes, please elaborate which ones and provide details on how these could be considered.

PGEU has summarized the commitments of European community pharmacist as well as several policy recommendations on Big Data & AI in its Position Paper on Big Data & AI in Healthcare: https://www.pgeu.eu/wp-content/uploads/2019/03/190220E-PGEU-Position-Paper-on-Big-Data-Artificial-Intelligence-in-Healthcare.pdf

In addition, PGEU has outlined its vision for community pharmacy 2030 in a paper which also addresses the vision and best practices related to the integration of real-world evidence and digital technologies in community pharmacy practice: https://www.pgeu.eu/wp-content/uploads/2019/03/Pharmacy-2030_-A-Vision-for-Community-Pharmacy-in-Europe.pdf

### Question 9: Are there any other ongoing or planned initiatives that should be considered for this proposed strategic theme area?

- (●) Yes
- ( ) No

### If yes, please provide details of the ongoing or planned initiatives.

Community pharmacists are at the forefront of shaping a sustainable healthcare system in the digital age with electronic prescriptions, electronic medication plans, electronic health records, data sharing, preventing unnecessary GPs consultations, avoiding medication errors thus hospital admissions, and duplications of treatments, or with implementing clinical risk management systems in community pharmacy (e.g. in The Netherlands).

Community pharmacists have further developed their software and IT network to the implementation of the EU Falsified Medicines Directive, by contributing to the creation of a network of national systems and databases of medicinal products to enhance the security of the legal supply chain against the threat of

falsified medicines. This IT pharmacy network has been also used in some countries to offer nationally harmonised protocoled pharmacy services to maintain the same level of high quality throughout the country and to collect routinely evidence data (e.g. pharmacy hub “Nodofarma Asistencial” in Spain).

As healthcare providers, they remain a trusted source of reliable and independent health information for patients, whose data protection in compliance with GDPR remains a top priority for community pharmacists (e.g. dossier pharmaceutique used in France and Belgium).

Community pharmacists already use some early form of AI, namely pharmacy software, which provides housing for data concerning medication history of the patient, patient use of medication, clinical rules/clinical risk management and adherence data, gathered in compliance with GDPR.

In what follows we report additional examplse of projects undertaken by PGEU members :

Portugal - Pharmacies’ National Phone line 1400: By calling the number 1400, free phone line created by National Association of Pharmacies, Portuguese citizens can order their medicines and choose if they want to pick them up at the pharmacy or to be delivered at home.

This service is available 24/7 in all country through phone and Portuguese Pharmacies’ app and website, guaranteeing pharmaceutical advice, access to medicines and patients’ safety. Dispensing data is registered in the pharmacy software and e-prescription system (when applied).

A partnership with Portuguese Post Services complements this service, integrated in pharmacy software, for medicines’ home delivery.

Malta - Pharmacy/Pharmacists of the Patient’s Choice (POYC) National Scheme : Since 2007 the Malta Chamber of Pharmacists, the Chamber of SME’s – Pharmacy owners section and the Ministry for Health entered into a Private Public Partnership whereby National Health Service medicines to registered eligible chronic patients are dispensed their medicines (free) from the pharmacy of their choice via prior registration. The data is all held and updated on a daily basis through the inputting, by pharmacists at the point ofdispense, onto a web-based dispensing system (WPDS) interface connected with the NHS dedicated department. Community pharmacists dispense specialized hospital products, biologicals etc.also on named patient basis.

Domicilairy Delivery of Medicines (DDM): In the 2015 renewal of the POYC contract, the domiciliary delivery of medicines was introduced for over-70’s patients registered in the POYC scheme. The same WPDS system is used to implement this service. The software system is being reviewed and will soon be piloted. E-prescription is in a also pilot stage and has been escalated due to the need to go as paperless as possible in these Covid- 19 days. All medicines usage data is held by he NHS server to which pharmacists have selective access. The Malta Chamber is working with the MFH to attain interoperability of software systems across the Health
service especially the public hospital and the community pharmacies with a seamless care implementation as objective.

Greece – The Panhellenic Pharmaceutical Association (PFS) has proposed to the Greek Government the creation of a national immunization registry. In such a way, the state and its institutions could be able to know the immunization status of the community, especially in the midst of COVID-19 pandemic crisis. The implementation of such initiative may be achieved through the national electronic prescription system as follows: The correspondent healthcare professional declares each immunization individually through every civilian's social security number, in accordance to GDPR legislation. Moreover, through the proposed database, useful information could be drawn, such as the population of vulnerable persons subjected to

immunization and their demographics, allowing national healthcare authorities to consider optimization of the immunization program and keep up with public health spending, optimizing some financial outcomes.

## Strategic Theme area 3: Innovation

### Question 6: Do the objectives adequately address the challenges ahead?

- (●) Yes
- ( ) No

Comments on objectives of the strategic theme area:

Whilst PGEU is not in the position to formulate an opinion or comment on the objectives defined under this strategic area related to the development and manufacturing of medicines, we welcome the general principles defined in this thematic area.

Personalised and precision medicine(s), advances in pharmacogenomics and the increasing emergence of biotechnology are of high interest to community pharmacists since they offer opportunities for personalised treatment plans which could enhance the outcomes and safety of medicinal therapies. Community pharmacists can supply such innovative treatments where appropriate close to where patients' live or work accompanied with expert guidance on their optimal use, safety and adherence. As such, they can contribute to controlling healthcare costs for these treatments.

Community pharmacy could provide the entry-point into the health service, with the community pharmacists acting as a preventive care provider (e.g. screening for chronic diseases) and reliable, rapid diagnostic testing (e.g. for the presence or otherwise of bacterial infections).

### Question 7: Are there any other challenges that should be addressed by the EMA/HMA network in this area?

- (●) Yes
- ( ) No

### If yes, please specify

*Please remember to specify if a particular comment relates specifically to the human or veterinary part.*

The strategy needs to have a particular focus on managing the impact of Brexit on the availability of innovative treatments across Europe. This relates both to the impact on the United Kingdom and countries which are highly depend on the UK market such as Ireland, Malta and Cyprus.

### Question 8: Are you undertaking concrete actions in this field that could support or complement EMA/HMA network activities?

- ○ Yes
- ◉ No

### Question 9: Are there any other ongoing or planned initiatives that should be considered for this proposed strategic theme area?

- ◉ Yes
- ○ No

**If yes, please provide details of the ongoing or planned initiatives.**

Hospital medicines dispensed in community pharmacies (Portugal)

In December 1st, 2016, began a pharmacy-based HIV dispensing pilot, which is currently ongoing. The project is taking place in Lisbon, with the collaboration of Curry Cabral Hospital. Patients who fulfill the inclusion criteria were invited by the hospital if they want to collect their antiretroviral therapy (ARVT) medicines at a community pharmacy chosen by the patient, or if they rather maintain the dispense at the hospital. More than 400 pharmacists attended a specific training course in order to be qualified by the Portuguese Pharmaceutical Society to participate in the study. This study has an evaluation by the Consortium CEMBE/CEA/CEFAR (please see document attached).

After the pilot-project with Curry Cabral Hospital, ANF promoted a new pilot-project of pharmacy-based Specialty Medicines dispensing with Centro Hospitalar Universitário de São João (Oporto), ADIFA (Full-Service Pharmaceutical Distributors Association) and The Portuguese Pharmaceutical Society: Farma2Care project.

This project maintained the principles and requirements of the first project related with specialty medicines already announced, and introduced some novelties, as example de scope of action: beginning with HIV patients, it was planned to expand to other therapeutic areas (oncology, multiple sclerosis, immunosuppression, renal failure, hemophilia) and, eventually, cover all specialty medicines.

Farma2Care, started on the 1st of December 2019 and until patient recruitment was suspended due to COVID-19 contingencies, 26 patients were engaged in the project to be followed-up in 19 community pharmacies.

Besides these projects, is also important to notice that during COVID-19 pandemic, specific dispensing policies and regulations regarding specialty medicines were published to allow patients to obtain their specialty medicines through community pharmacy of their convenience or even at home. With these updates, from 23rd March until 31st May, it was possible to establish a nationwide response called Green Light Operation, that allowed patients to ensure their treatment continuity and to avoid unnecessary travelling to the hospital.

Green Light Operation was a multidisciplinary and structured operation that involved more than 2.270 community pharmacies, 33 hospitals, pharmaceutical wholesalers, healthcare professionals and pharmaceutical stakeholders, endorsed by both Pharmaceutical and Medical Societies. With this project it was possible, in less than 3 months, to allow more than 12.500 patients to obtain their medicines in a community pharmacy, avoiding 1,4 million of kilometers previously covered by patients (please see document attached).

In conclusion, the dispensing of specialty medicines in a community pharmacy is currently a possibility, in accordance with the provisions of joint standard DGS/INFARMED No. 03/2020 of 19th March and, after the end of the State of Emergency declared on 2nd May, through the provisions of The Minister of Health No. 5315/2020 of 7th May

## Strategic Theme area 4: Antimicrobial resistance and other emerging health threats

### Question 6: Do the objectives adequately address the challenges ahead?

- (●) Yes
- ( ) No

### Comments on objectives of the strategic theme area:

PGEU welcomes the focus on the responsible use of antibacterial agents and effective regulatory antimicrobial stewardship in human and veterinary sectors by putting in place strategies to improve their use by patients, healthcare professionals and national authorities. We support in particular its objective to raise continued awareness through education, best practices sharing and training.

European community pharmacists play pivotal roles in counselling patients and promoting antimicrobial stewardship and should be further empowered. They provide preventative action, referral, disposal, treatment in the pharmacy and constantly strive for quality improvements and innovation in pharmacy practice. We therefore encourage enhanced collaboration and communication between community pharmacists, other healthcare professionals, health service providers, regulators, industry, patients and the public. These actions should mean to involve pharmacists in AMR action plans at national level and equally make greater use of pharmacists to raise awareness for vaccination and where appropriate, greater use of pharmacists to administer vaccinations. From the pharmacists' perspective we see a great use and need for providing indications on prescriptions for antimicrobial medicines and make great use of shared electronic medication/patient records. The strategy could also look into systems to encourage the exact quantity dispensing of antimicrobials where these are not in place yet.

We also support the references made to defining a roadmap for Point Of Care (POC) diagnostics and the development of improved diagnostic test analyses requiring less time, in human and veterinary medicines. Community pharmacists can, as it is already successfully happening in several European countries such as France, Sweden and the United Kingdom, perform rapid diagnostic testing for antimicrobials (e.g. strep C-reactive protein) in pharmacies as a first port of call for patients with sore throats or prior to dispensing a prescribed antibiotic.

Another important objective highlighted is the preservation of existing therapeutic options. Strategies should include both a focus on guaranteeing security of supply for antimicrobials, which are one of the most common therapeutic classes of medicines short in supply across Europe, and a focus on the further promotion of responsible use of existing therapies as described above. We therefore welcome the reference to incentives for continuous manufacturing of old antibiotics and new business models which could stimulate the development of new antibiotics.

### Question 7: Are there any other challenges that should be addressed by the EMA/HMA network in this area?

- ( ) Yes
- (●) No

### Question 8: Are you undertaking concrete actions in this field that could support or complement EMA/HMA network activities?

- (●) Yes
- ( ) No

**If yes, please elaborate which ones and provide details on how these could be considered.**

PGEU has produced an overview of best practices of community pharmacists across Europe on fighting AMR in the 2017 PGEU Best Practice Paper on AMR: https://www.pgeu.eu/wp-content/uploads/2019/03/170629E-PGEU-Best-Practice-Paper-on-AMR.pdf

We plan to release an updated version of these best practices in November 2020, which could support EMA and HMA in its objective to raise awareness about best practices on AMR.

Each year, PGEU and its member organisations are also actively participating in the European Antibiotic Awareness Day (EAAD) and World Antibiotic Awareness Week (WAAW). EMA and HMA activities could further align with these initiatives as a mean to promote responsible use of antimicrobials at national and European level.

Below you can find some additional best practices from our members:

Portugal:
•Vaccination service delivered by community pharmacists: This service is available since 2007. From year to year, Portuguese pharmacies are increasingly recognised as important vaccination points against flu. Since 2017 data from flu vaccination is automatically integrated on e-Vaccination Bulletin. “Loures tem + Saúde”, a pilot project implemented in the city of Loures, allowed 43 pharmacies to delivery a flu vaccination under the same conditions as the National Health Service in 2019; about 10.000 patients were vaccinated through this project.

•Rapid diagnostic tests for antimicrobials in the pharmacy (e.g. streptococcal swab tests for throat infections): Pharmacy staff identified patients with a sore throat who had signs and symptoms such as fever and/or the absence of cough, and a trained pharmacist examined the tonsils for exudate and palpated for tender cervical lymphadenopathy.  For those not requiring antibiotics, the pharmacist will suggest relevant non-prescription products and give advice on how to relieve symptoms. If the swab test is positive, the pharmacist advises the patient to go see a physician for further evaluation a possible antibiotic prescription. Rapid strep tests can help save patients with sore throats or uninary tract infection (UTI) or cystitis a trip to the physician and reduce unnecessary antibiotic prescriptions once most of sore throat are caused by virus.

•Correct adherence to antibiotic therapies: The service MED180° is integrated in pharmacy information system and is supported in a range of communication channels, adjusted to all pharmacies and all users, including posology labels in the pack, dossier summary, e-mails, SMS and the Portuguese Pharmacies app.

•Disposal: The Valormed system, a collaboration between the pharmaceutical industry, wholesalers and community pharmacies in Portugal, collects all expired medicines and used packages from pharmacies. Pharmacies assume the responsibility for the reception of waste packaging of medicines on their own premises as well as the information to citizens. This service is free and available in 98% of the national territory.

Greece- The Panhellenic Pharmaceutical Association (PFS) is constantly working together with the Ministry of Health on updating the legislation regarding the administration of antibiotics. The result of this cooperation was, recently, the adaptation of electronic prescription as the sole way of dispersing systemic antibiotics to patients who possess a personal social security number, as well as the introduction of obligatory prescribing protocols for every drug containing antibiotics. Moreover, PFS is in contact with Medical and Dental Associations of Greece in order to ensure fast adaptation to the new regulations. In addition, PFS is currently working on a mass media campaign, workshops open to the public and educational visits to the schools. We try to keep our members fully updated with the latest scientific data through our lifelong learning program, organizing face to face conferences, seminars and a series of lectures through the digital platform of our Pharmacists’ Institute For Lifelong Learning (https://www.ideeaf.gr/)

### Question 9: Are there any other ongoing or planned initiatives that should be considered for this proposed strategic theme area?

- (●) Yes
- ( ) No

### If yes, please provide details of the ongoing or planned initiatives.

Community pharmacists are in many European countries closely involved in the development of antibiotic guidelines and national action plans, such as for instance in the Netherlands: https://swab.nl/en/optimize-antibiotic-policy-in-the-netherlands

## Strategic Theme area 5: Supply chain challenges

### Question 6: Do the objectives adequately address the challenges ahead?

- (●) Yes
- ( ) No

Comments on objectives of the strategic theme area:

Whilst PGEU is not in the position to formulate an opinion or comment on the objectives defined under this strategic area related to the development and manufacturing of medicines, we welcome the general principles defined in this thematic area.

We welcome the reference to strategies supporting the return of production to Europe of medicines, active pharmaceutical ingredients (APIs) and other excipients which are identified to be particularly critical and vulnerable in terms of supply. At the same time, we also believe that there is a need for developing additional strategies to achieve a stronger diversification of supply within the medicines supply chain. This could include setting requirements for manufacturers to rely on more than one API/excipient provider.

When supply challenges occur, the scope of community pharmacy practice should be extended so pharmacists can use their skills and knowledge to better manage patient care and ensure continuity of treatment as much as possible. This includes preparing compounded formulations when no alternatives are available anymore and substituting with the most appropriate alternative as part of a shared decision-making process with prescribers and patients or in accordance with national protocols where appropriate. Shared electronic communication tools between pharmacists and prescribers (e.g. shared electronic health records) can enable this process effectively and safely.

We also want to emphasize the need for building on the lessons learnt with sartans medicines as defined in the recent EMA guidance. In particular, to implement best practices in communication to the public (including healthcare professionals) and to employ more communication tools (e.g. social media) to improve the content, clarity, presentation, timing and dissemination of communication. Here we would like to emphasize the vital importance of communicating to healthcare professionals  well in advance of communicating to the general public so that the negative impact on supply and potential panic outbreak with patients can be reduced and managed in the best possible way.  In addition, as suggested in the recommendations, improvements could include giving more specific details (for example batch numbers of medicines affected if applicable) to pharmacists and prescribers and boosting cooperation among communication teams and other stakeholders. This information would be very useful for healthcare professionals to reduce the impact on patients as much as possible and be able to address their concerns.

## Question 7: Are there any other challenges that should be addressed by the EMA/HMA network in this area?

- ○ Yes
- ◉ No

## Question 8: Are you undertaking concrete actions in this field that could support or complement EMA/HMA network activities?

- ◉ Yes
- ○ No

## If yes, please elaborate which ones and provide details on how these could be considered.

Please refer to answers provided under thematic area 1 question 8.

### Question 9: Are there any other ongoing or planned initiatives that should be considered for this proposed strategic theme area?

- ○ Yes
- ◉ No

---

## Strategic Theme area 6: Sustainability of the Network and operational excellence

### Question 6: Do the objectives adequately address the challenges ahead?

- ◉ Yes
- ○ No

Comments on objectives of the strategic theme area:

We agree with the objectives defined.

### Question 7: Are you undertaking concrete actions in this field that could support or complement EMA/HMA network activities?

- ○ Yes
- ◉ No

### Question 8: Are you undertaking concrete actions in this field?

- ○ Yes
- ◉ No

### Question 9: Are there any other ongoing or planned initiatives that should be considered for this proposed strategic theme area?

- ○ Yes
- ◉ No

---

### Any other comments

*Please feel free to provide any other additional comments not provided in the previous questions*

Thank you very much for completing the survey. We value your opinion and encourage you to inform others who you know would be interested.

### Useful links

EU Medicines Agencies Network Strategy (https://www.ema.europa.eu/en/about-us/how-we-work/european-medicines-regulatory-network/eu-medicines-agencies-network-strategy)

European Medicines Agencies Network Strategy to 2025 (https://www.ema.europa.eu/en/documents/other/european-medicines-agencies-network-strategy-2025-protecting-public-health-time-rapid-change_en.pdf)

Pharmaceutical Strategy for Europe (https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1242-Pharmaceutical-Strategy-Timely-patient-access-to-affordable-medicines/public-consultation)

### Background Documents

european-medicines-agencies-network-strategy-2025-protecting-public-health-time-rapid-change_en.pdf

### Contact

EMRN2025strategy@ema.europa.eu