



The Lebanese Order of Pharmacists
26th Annual Congress

Teaming Up for Excellence in Patient Care
معاً للتميز في رعاية المريض

Management of Drug Shortages on the Local, National and EU Level

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Disclosure

I, Joan Peppard, declare to meeting attendees that there are no financial relationships with any for-profit companies that are directly or indirectly related to the subject of this presentation.



Drug shortages = Medicines shortages

Medicines shortages will be used throughout the presentation since all EAHP actions are linked to 'medicines shortages'

EMA = European Medicine Agency – Responsible for managing products approved for all Europe

HMA = Heads of each National Medicine Agency – lead on behalf of EMA on products that will be centrally approved, responsible for older products that were approved at country level



European Association of Hospital Pharmacists

- An association of national organisations in 35 countries representing hospital pharmacists at European and international levels.
- *EAHP represents and develops the hospital pharmacy profession within Europe in order to ensure the continuous improvement of care and outcomes for patients in the hospital setting*



Background to EAHP

- Founded in 1972
- Represent c.21,000 hospitals in 34 countries
- Hold an annual Congress
- Publish a Journal, EJHP, x6 a year
- Educational opportunities
- Advocate on key issues
- The General Assembly - 2 delegates from each country - each year hear the report from the Board and determine the priorities for the next year



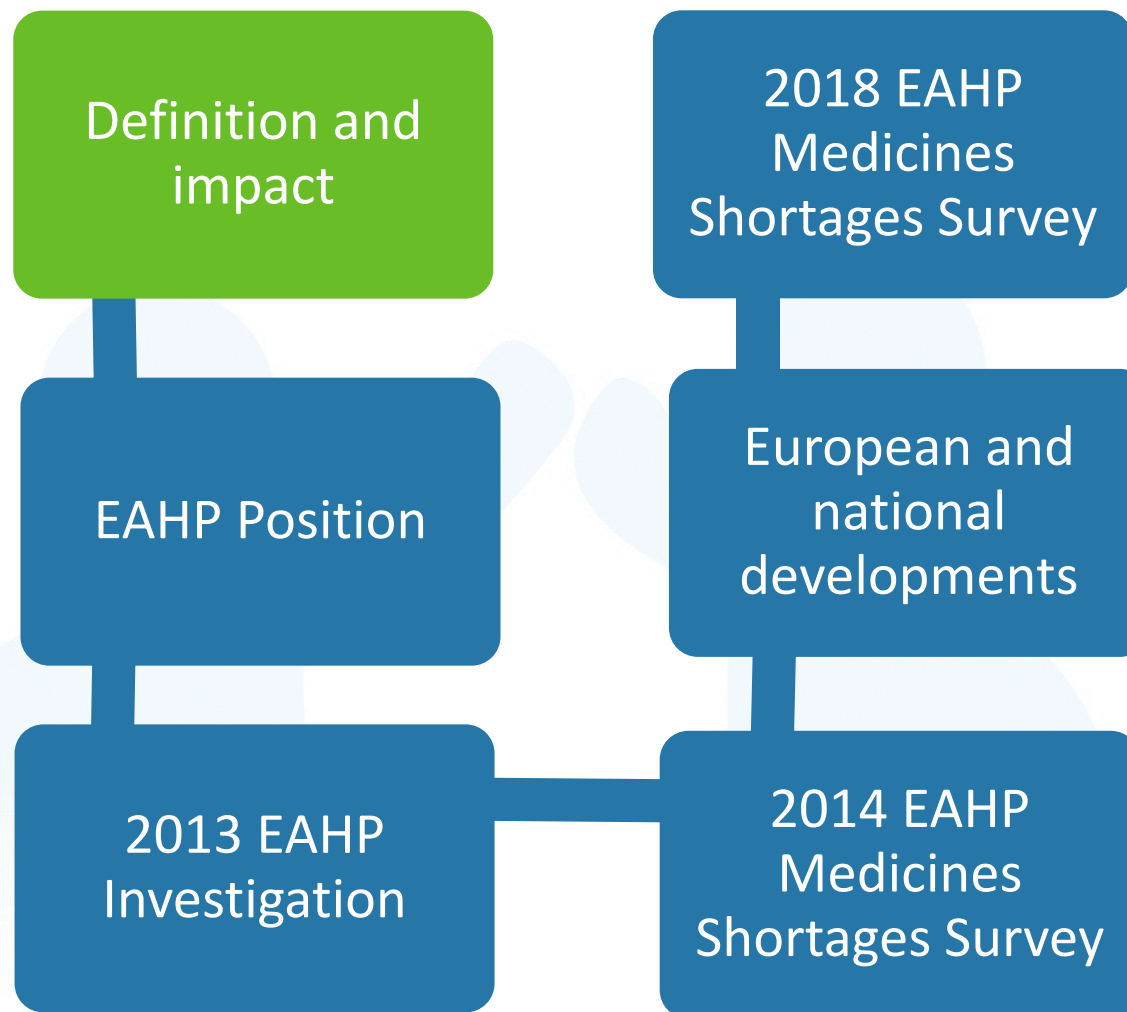


Learning objectives

Participants will

- be made aware of the severity of the medicines shortage problem in Europe;
- be informed of the importance of communication between the different actors in the supply chain; and,
- learn about national and European measures focussed on the management of medicines shortages.







A common problem that is differently defined

Medicine shortages could be defined as:

- “a supply issue that affects how the pharmacy prepares or dispenses a drug product or influences patient care when prescribers must use an alternative agent”
(Fox et al, 2009, AJHP)
- “a period of time when the total supply of all versions of a drug available at the user level will not meet the current demand for the drug at the user level.”
(Thompson, 2011, AJHP)
- “the supply of a medicinal product is inadequate to meet the needs of patients.”
(HPRA Ireland, 2018)



A common problem that is differently defined

Medicine shortages could be defined as:

- Medically necessary: “any drug product used to treat or prevent a serious disease or medical condition for which there is no other adequately available drug product that is judged by medical staff to be an appropriate substitute.” (FDA Catalogue)

Inconvenience to the patient and cost to the patient, institution, and manufacturer are insufficient reasons for classifying a product as a medical necessity

- “Medicine shortages that affect or are likely to affect more than one (EU) Member State, where the European Medicines Agency has assessed the shortage and provided recommendations.” (European Medicines Agency (EMA))



A common problem that is differently defined

- A common European definition is lacking.
- EMA and the Heads of Medicines Agency (HMA) are seeking to develop a common definition in their joint task force on availability of authorised medicines for human and veterinary use

Despite the lack of a common European definition the problem is growing and impacting hospital pharmacists and patients.



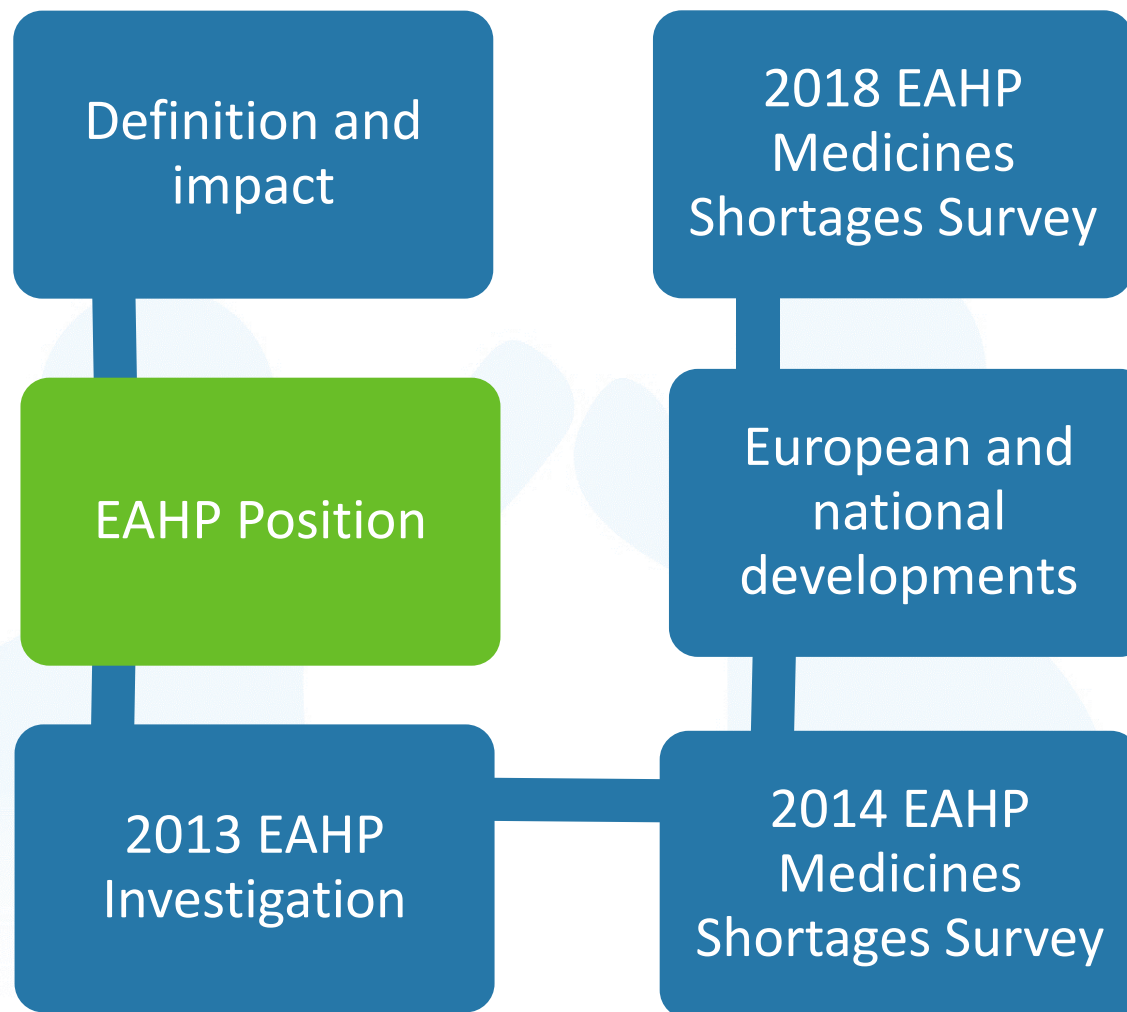
What do medicines shortages mean for hospital pharmacists?

- Increased medicine expenditure
- Antimicrobial resistance
- Delays/cancellations in treatments (e.g. surgery)
- Impact on conducting clinical trials
- Altering protocols/formularies
- Opportunity cost – time away from other more positive actions
- Medication errors
- Increased patient re-admission to hospital



What do medicines shortages mean for patients?

- Inconvenience
- Increased costs
- Increase in the potential morbidity/mortality of treatments
- Decrease in patient safety?
- Delays/cancellations in treatments (e.g. surgery)
- Alternatives – allergic patient, complex patient





Problems faced by hospital pharmacists on national + local level

- Increased reports shared with EAHP that highlighted the growing problem in EAHP's member countries
- Trend: more medicine shortages in hospital pharmacies
- Need for reliable, transparent and up-to-date information on:
 - Cause of shortage;
 - Duration of shortage;
 - Solutions for patients.
- EAHP General Assembly adopts position on medicines shortages in 2012



EAHP's Statement on Medicines Shortages

- Outlines the problem
- Offers solutions how prescribers, hospital pharmacists, wholesalers and manufacturers could help address the problem
- Calls for further investigation since further information on the causes is lacking
- No surprise that we find common ground with the issues identified in the paper by Dr. Katia Iskandar Chair OPL Drug shortages subcommittee.



EAHP's Statement on Medicines Shortages

How can prescribers contribute to the management of medicines shortages?

- By being aware of the problem;
- By discussing with hospital pharmacists potential changes to prescribing policies if necessary; and,
- By taking due notice of hospital pharmacy communications on the issue.



EAHP's Statement on Medicines Shortages

How can wholesalers contribute to the management of medicines shortages?

- By communicating effectively to hospital pharmacies about likely and current shortages, and in a timely manner;
- By making appropriate use of quotas as a tool to ensure fair distribution when demand exceeds supply; and,
- By prioritising replenishment of supplies over routine delivery when a shortage is relieved.



EAHP's Statement on Medicines Shortages

How can manufacturers contribute to the management of medicines shortages?

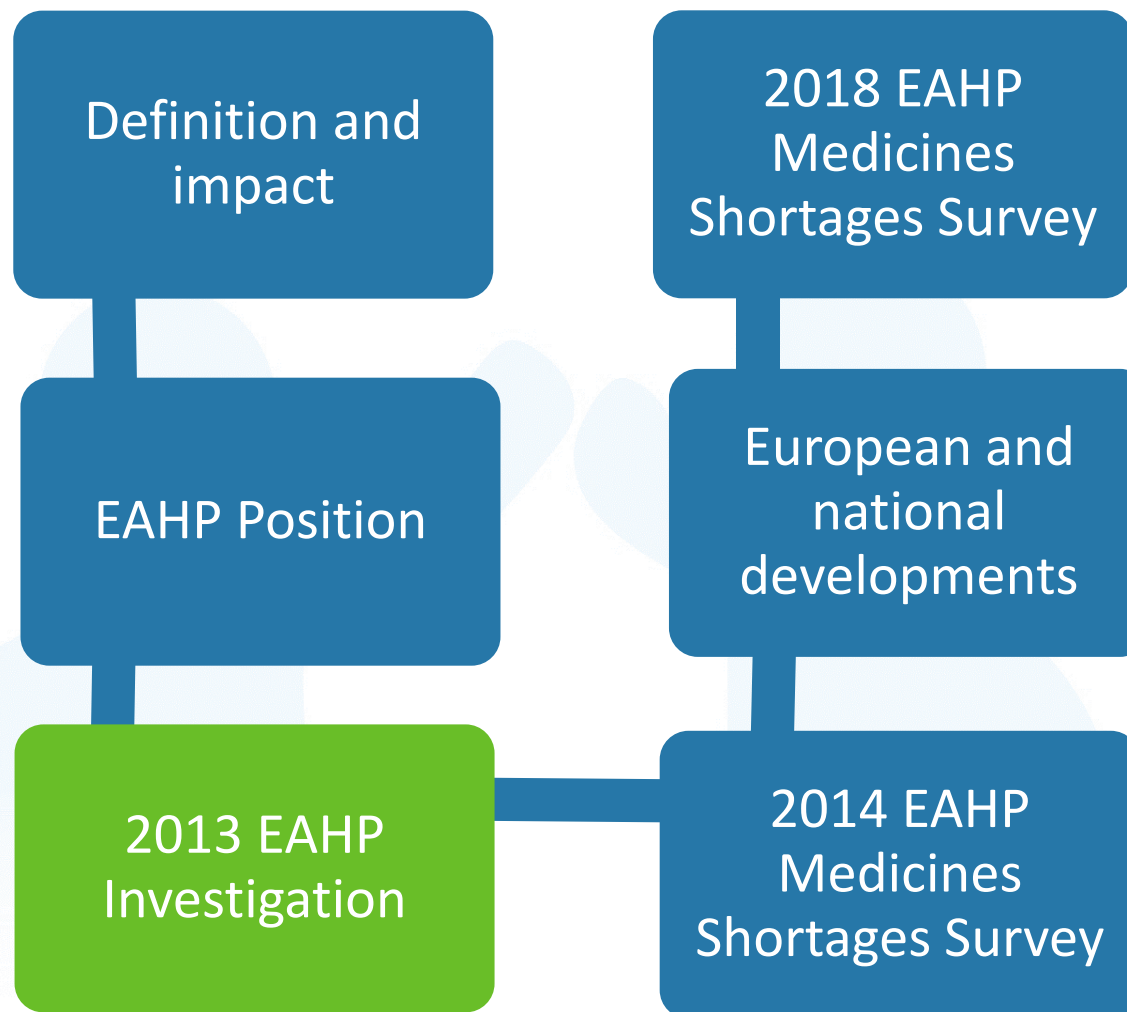
- By providing adequate notice and alert of manufacturing problems (outlining also how imminent the shortage is, the expected duration of the shortage, whether alternatives are available, and the size of the manufacturer's share of the market for the product);
- By offering active assistance to hospital pharmacies in the management of shortage problems, such as maintaining dedicated helplines;
- By ensuring maintenance of adequate "buffer stocks" of medicines, especially for critical medicines such as those used by emergency departments in hospitals;
- By conducting customer audits and surveys to assess the performance of supply arrangements and to identify any potential improvements; and,
- By working with urgency to bring to an end the shortage difficulties currently being experienced across Europe, including root cause analysis of why the problems are occurring and how they might be resolved most quickly.



EAHP's Statement on Medicines Shortages

What should hospital pharmacists do to manage medicines shortages?

- Be vigilant and alert to the issue of medicines shortage;
- Share relevant information of forthcoming shortages with colleagues, including hospital management and prescribers;
- Use, and keep up to date, pharmacy skills to identify other solutions when a shortage occurs, which might eventually include small scale production of medicine without a marketing authorisation; and,
- Consider contingency arrangements for future shortages





Gathering the evidence – EAHP 2013 Investigation

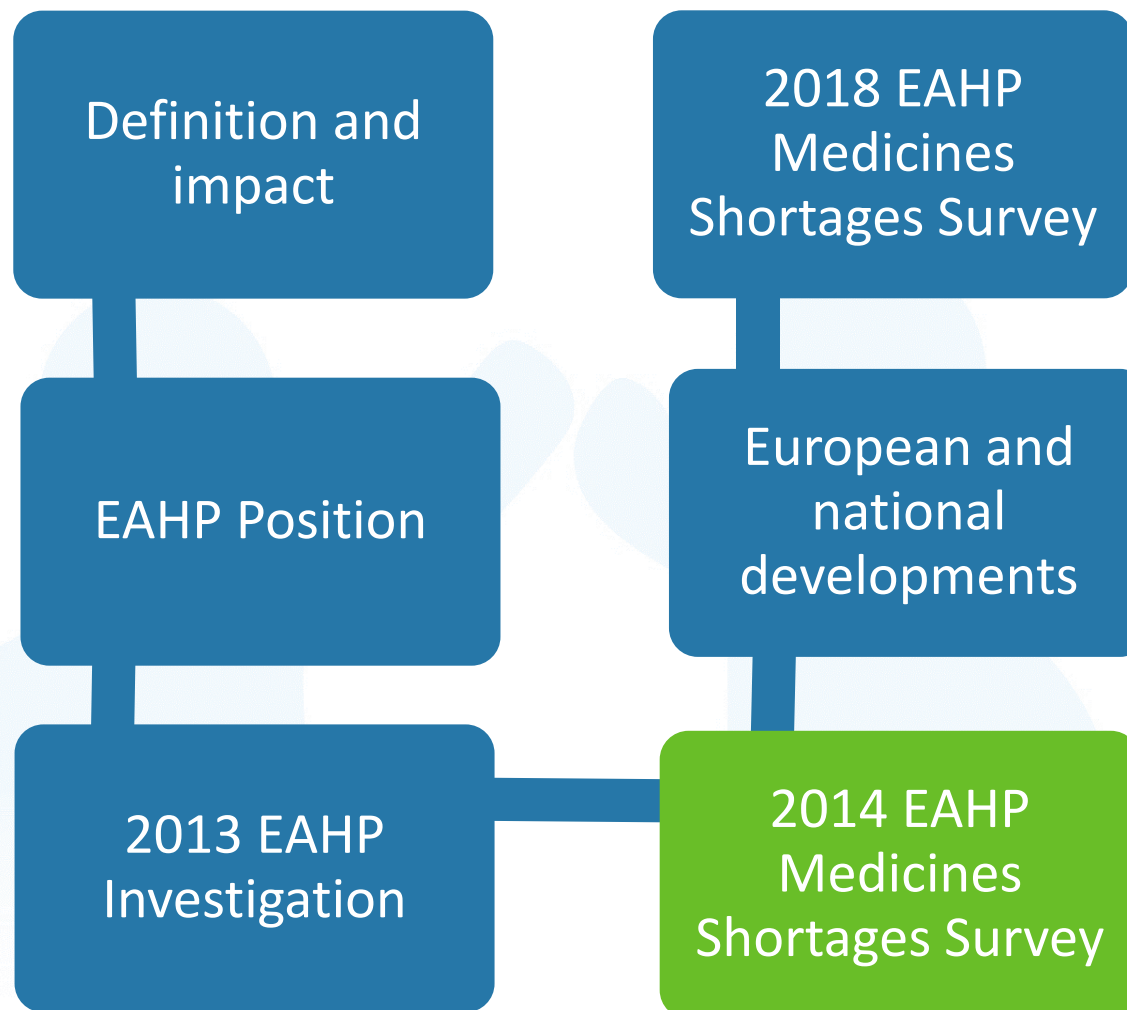
- 99% of HPs experiencing problems with medicines shortages
- 67% said it's a daily or weekly problem
- 73% said the problem is getting worse

25 countries involved

Exercise triggered by increasing shortage reports by EAHP members



Medicines shortages in European hospitals



2014 EAHP Medicines Shortages Survey

Reasons to conduct such a survey which was the largest at that time:

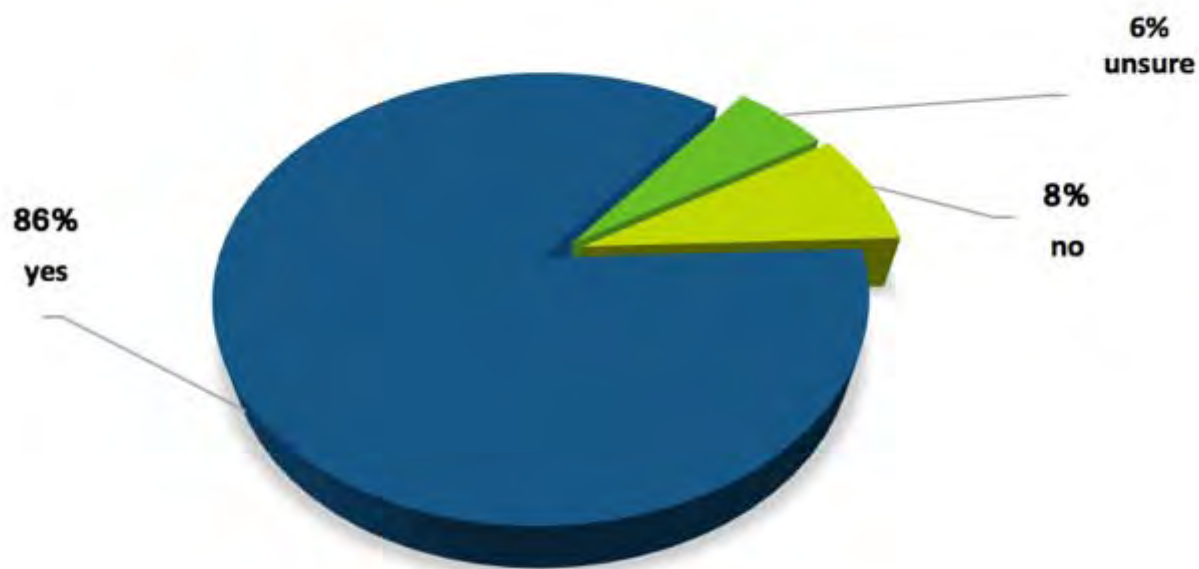
- Medicines shortages are serious, threaten patient care in hospital & require urgent action.
- Medicines are not simple items of commerce, they are an essential component of patient care.
- Previous EAHP research in 2013 but still an ‘information gap’ that needs to be addressed.





2014 EAHP Medicines Shortages Survey – the results

Are medicines shortages a current problem in the hospital you work in, in terms of delivering the best care to patients and/or operating the hospital pharmacy?



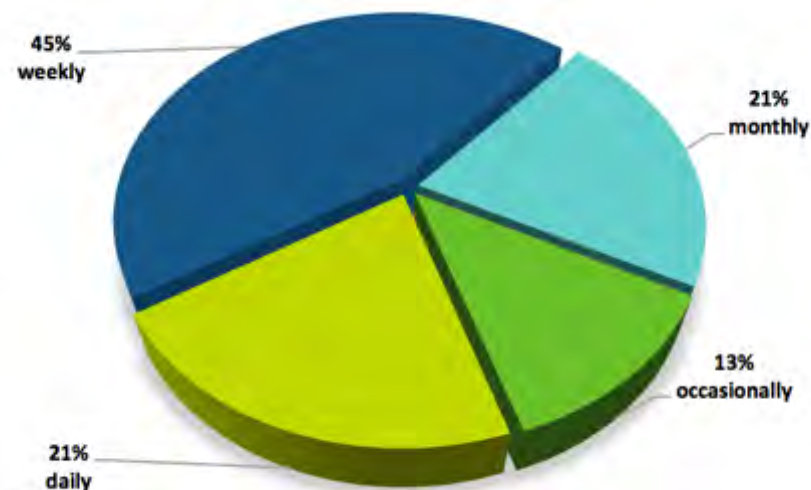
- “This is a growing problem & takes up a lot of working time which could be spent on other tasks.” - Hospital Pharmacist (Ireland)
- “There is always, at any given time, shortage of one medicine or the other. Often essential medicines where there is no or poor alternatives. This problem has grown over the last decade.” - Hospital Pharmacist (Norway)



2014 EAHP Medicines Shortages Survey – the results

How often does your hospital pharmacy experience shortages?

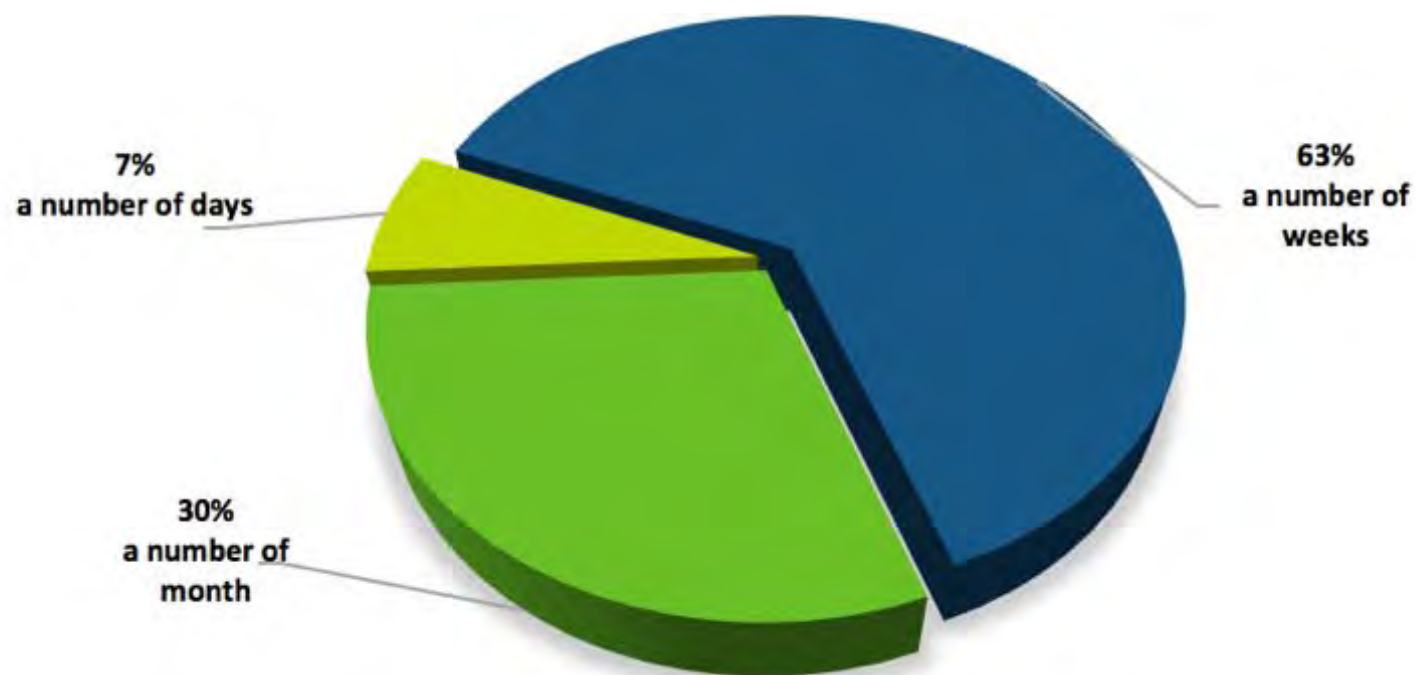
- Increase of shortages in comparison to 2013 EAHP investigation
- 66% of respondents said that medicines shortages affect their hospital pharmacy on a daily or weekly basis in 2014
- 63 % respondents indicated that shortages are a daily or weekly occurrence in 2013





2014 EAHP Medicines Shortages Survey – the results

In your experience, how long would you estimate the average or typical medicines shortage normally lasts for?

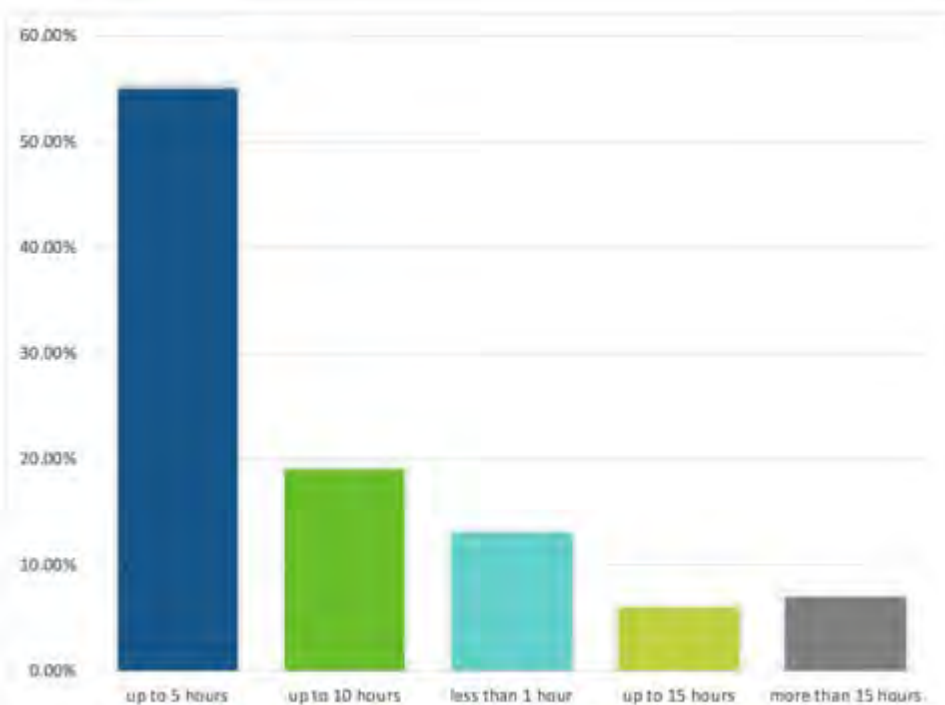


- “High % of respondents in Ireland, Italy, Slovakia and Spain report that a typical medicine shortage takes a number of months to resolve.



2014 EAHP Medicines Shortages Survey – the results

Pharmacy staff time diverted to address shortage problems in an average working week.



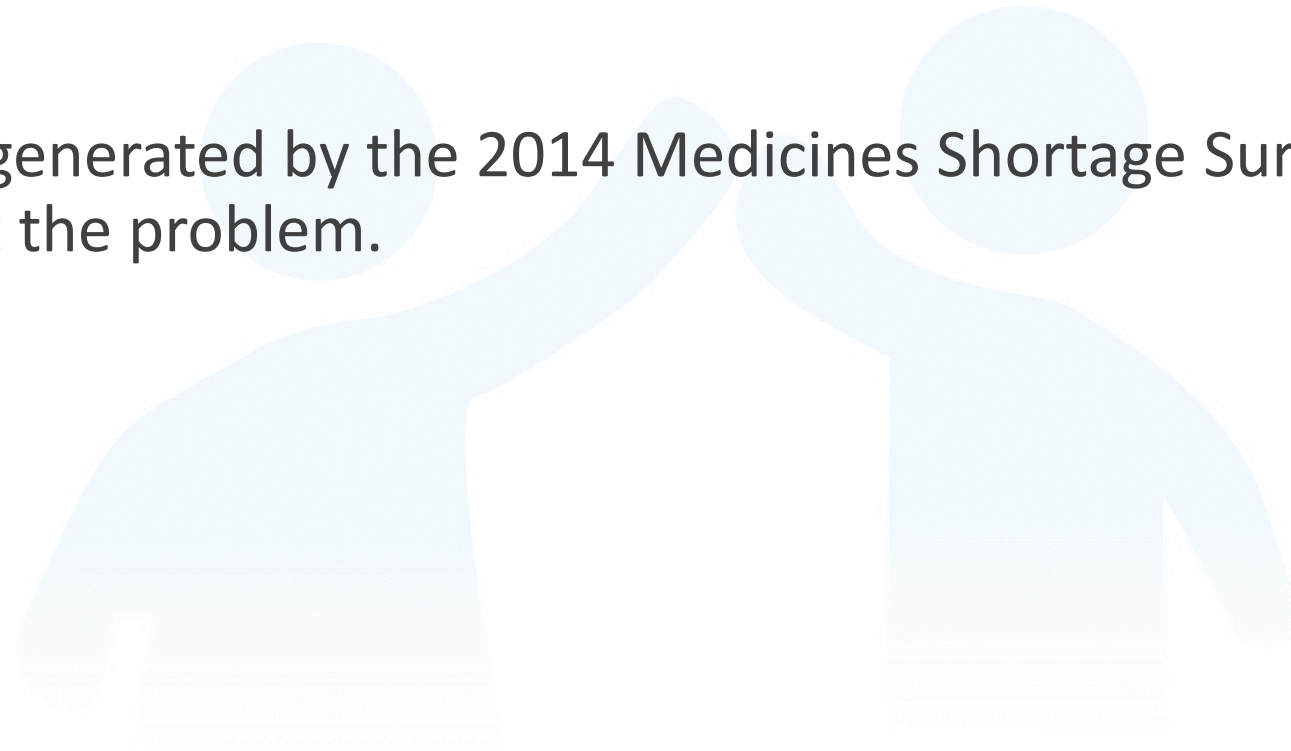
- “Accumulation of pharmacist, technician and pharmacy assistant would be 19.25 hours [in an average working week]” - Hospital Pharmacist (Belgium)
- “As a pharmacy department in general 1.5 (full time equivalent) pharmacist work solely on chasing out-of-stock items.” - Hospital Pharmacist (Malta)
- “ 15 working hours is only the administration of shortages. Unknown number of hours are spent on the wards with information and new routines.” - Hospital Pharmacist (Norway)

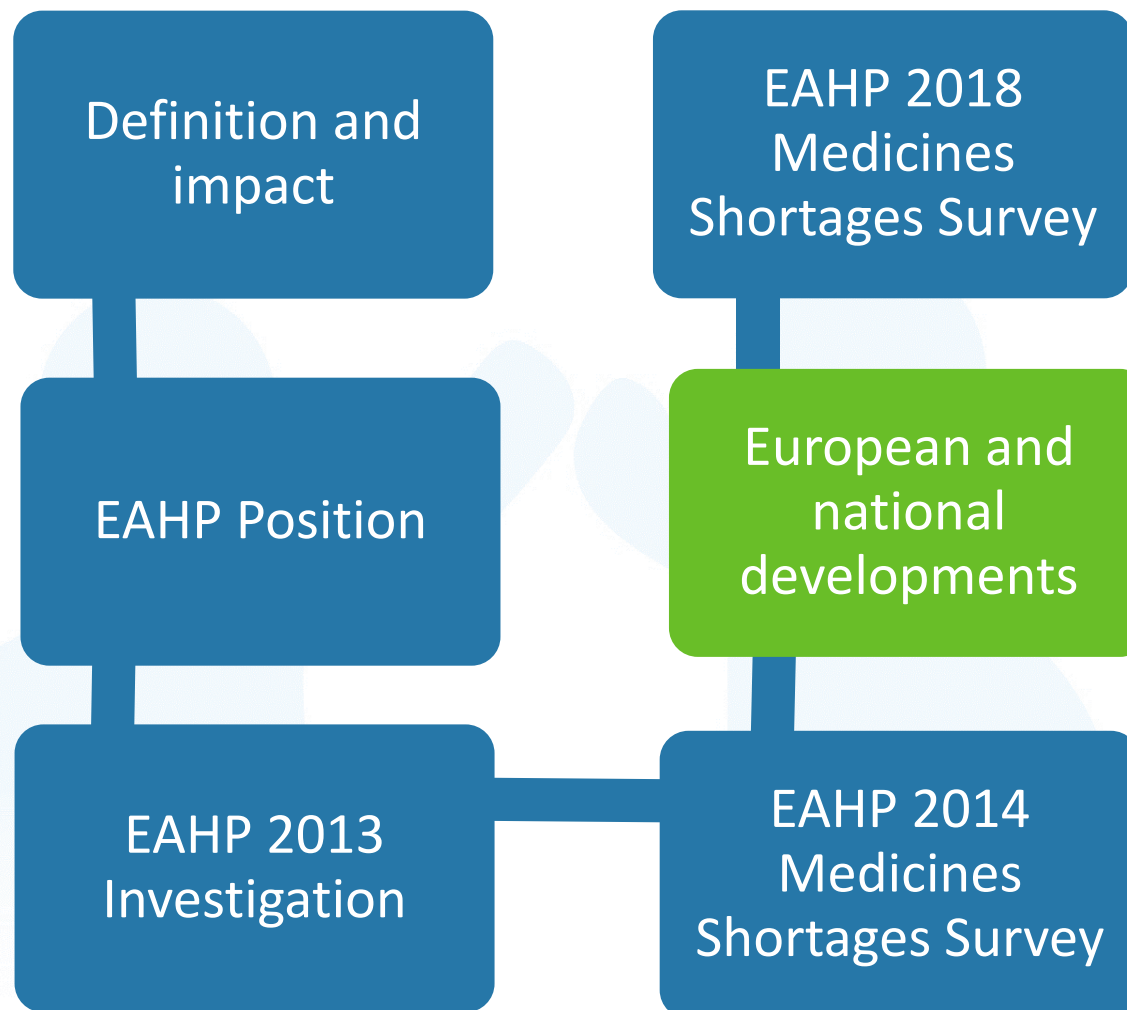


2014 EAHP Medicines Shortages Survey – the results

75.4% of all respondents either agreed or strongly agreed that shortages have a negative impact on patient care.

EAHP used data generated by the 2014 Medicines Shortage Survey to raise awareness about the problem.







Supply chain actor activities on European level

Collaboration between European supply chain actors led to the adoption of a consensus paper on medicines shortages information

- Provision of information
- Transparency and availability of data,
- Examples of existing good practices
- Recommendations for an ideal medicines shortages information systems.
- Mitigation of the impact of shortages on patients





COST Action CA15105 - European Medicines Shortages Research Network

Cost Action 15105 is a project funded by the European Cooperation in Science and Technology (COST) that address supply chain problems to patients.

5 Multi-stakeholder Working Groups on:

- Landscape Analysis and outreach
- Debugging API and medicines manufacturing disruptions
- Debugging provision and procurement disruptions
- Clinico-pharmacological needs
- Measuring the impact of shortages on outcomes



COST Action CA15105 - European Medicines Shortages Research Network

Output

- Research papers (e.g. ‘Systemic Measures and Legislative and Organizational Frameworks Aimed at Preventing or Mitigating Drug Shortages in 28 European and Western Asian Countries’)
 - Survey on Risk Assessment
 - Qualitative study on the patients’ perspective about medicine shortages during the hospital stay
- Further deliverables to be finalised in 2019
- COST Action CA15105 will end in spring 2020



EMA/HMA task force on



- Task force set up to develop and coordinate actions that are necessary to facilitate a better prevention, identification, management and communication of shortages to ultimately ensure continuity of supply of human and veterinary medicines.
- Work programme 2018 to 2020 foresees actions
 - Linked to marketing authorisations;
 - Addressing supply disruptions; and
 - Improving communication.





National developments – the Irish example

Medicinal Product Shortages - A framework for a multi-stakeholder approach to handling shortages of human medicinal products

- Developed in collaboration with stakeholders to address issue of medicines shortages in Ireland.



Source: HPRA, Medicinal Product Shortages Framework



National developments – the Irish example

- The HPRA framework
 - Defines the topic
- “the supply of a medicinal product is inadequate to meet the needs of patients.”
 - outlines roles and obligations of the different stakeholders
 - details how shortages should be reported
 - provides categories for therapeutic alternatives and patient impact that assist with determining the impact level

Communication is the underlying principle of the framework!

As a next step preventive strategies will be developed by HPRA and the stakeholder group.



My HPRA: Login Register Search our website

- ABOUT US MEDICINES VETERINARY MEDICAL DEVICES BLOOD, TISSUES, ORGANS COSMETICS CONTROLLED SUBSTANCES

Taking Medicines Safely

We've launched a national information campaign to highlight the importance of taking medicines safely and effectively.

For the full benefit, take 3 minutes.



And follow the directions that come with your medicine.

Find a medicine

- Medicines Veterinary Medicines Generics

Enter a Trade Name, Active Substance or Licence Number...

View all Medicines Advanced Search

I want to:

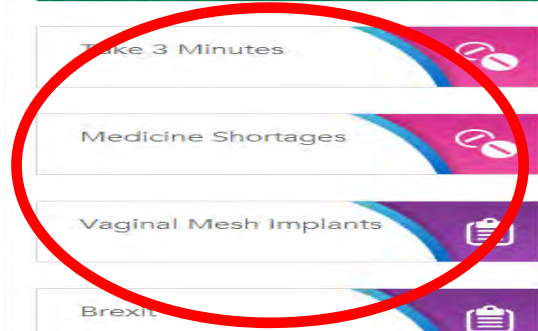
- Report an issue Get fees info See guides & Visit the Innovation

Latest updates

Table with columns for category, title, and date. Includes updates like 'Medicinal Product Shortages - update - 7 November 2018' and '2019 Patient Education Programme now open for applications'.

The HPRA for:

- Patients & Public Healthcare Professionals Industry Take 3 Minutes Medicine Shortages Vaginal Mesh Implants Brexit





National developments – the Irish example

Marketing Authorisation Holders

Please complete the [Notification of medicinal product shortage from marketing authorisation holder](#) form and return to shortages@hpra.ie and to the HSE Corporate Pharmaceutical Unit.

Wholesale Distributors and Manufacturers:

Please complete the [Report of Medicinal Products Shortages from Wholesale Distributors and Manufacturers](#) form and return this form to shortages@hpra.ie.

Patients and Healthcare Professionals:

Please complete the [Report of a Medicinal Product Shortage from Patients and Healthcare Professionals](#) form and return to shortages@hpra.ie. When completing this form, please include as much information as possible.



- Improving quality of submissions
- Paediatric medicines
- Parallel distribution
- Patient registries
- Pharmacovigilance
- Post-authorisation procedural Q&A
- Referral procedures
- Variations

EMA shortages catalogue















You can find information on ongoing and resolved **shortages that EMA has assessed at:**

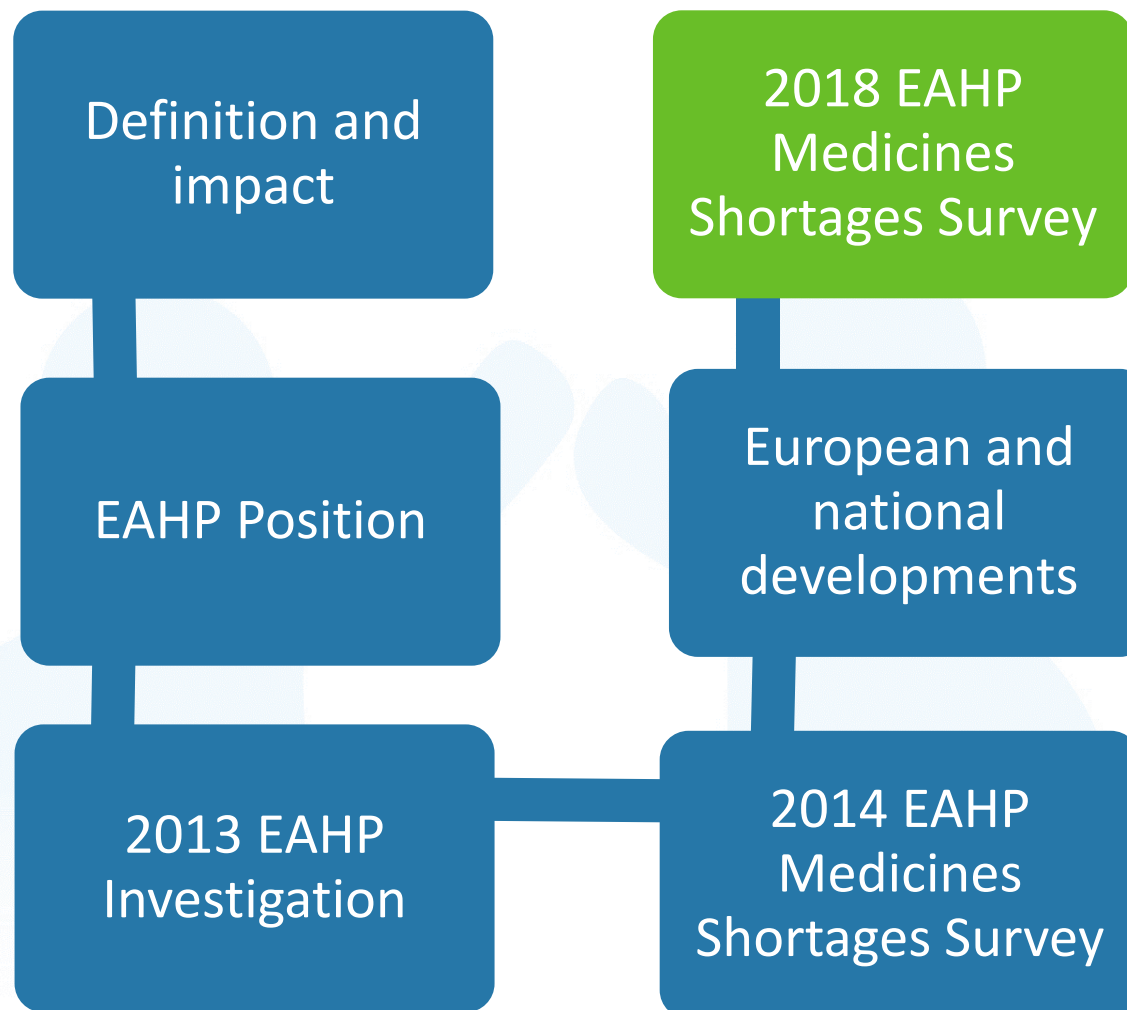
- [Ongoing shortages](#)
- [Resolved shortages](#)

You can **download this information in Excel table format at:**

- [Downloads: shortages.](#)

National registers

EU Member State	Medicine shortage register
 Austria	https://medicineshortage.basg.gv.at (DE)
 Belgium	https://www.famhp.be/en (EN)
 Bulgaria	http://www.bda.bg/bg/ (BG)
 Croatia	http://www.halmed.hr/en (EN)
 Cyprus	No online register available
 Czech Republic	http://www.sukl.cz (CZ)
 Denmark	https://laegemiddelstyrelsen.dk (DK)
 Estonia	http://www.ravimiamet.ee (ET)
 Finland	http://www.fimea.fi (FI)
 France	https://ansm.sante.fr (FR)
 Germany	https://www.bfarm.de (DE) www.pei.de (DE)
 Greece	http://www.eof.gr (GR)
 Hungary	https://www.ogyei.gov.hu (HU)
 Ireland	https://www.hpra.ie/ (EN)





Reasons to conduct a new survey exercise in 2018

Medicines Shortages remain high on the EU agenda

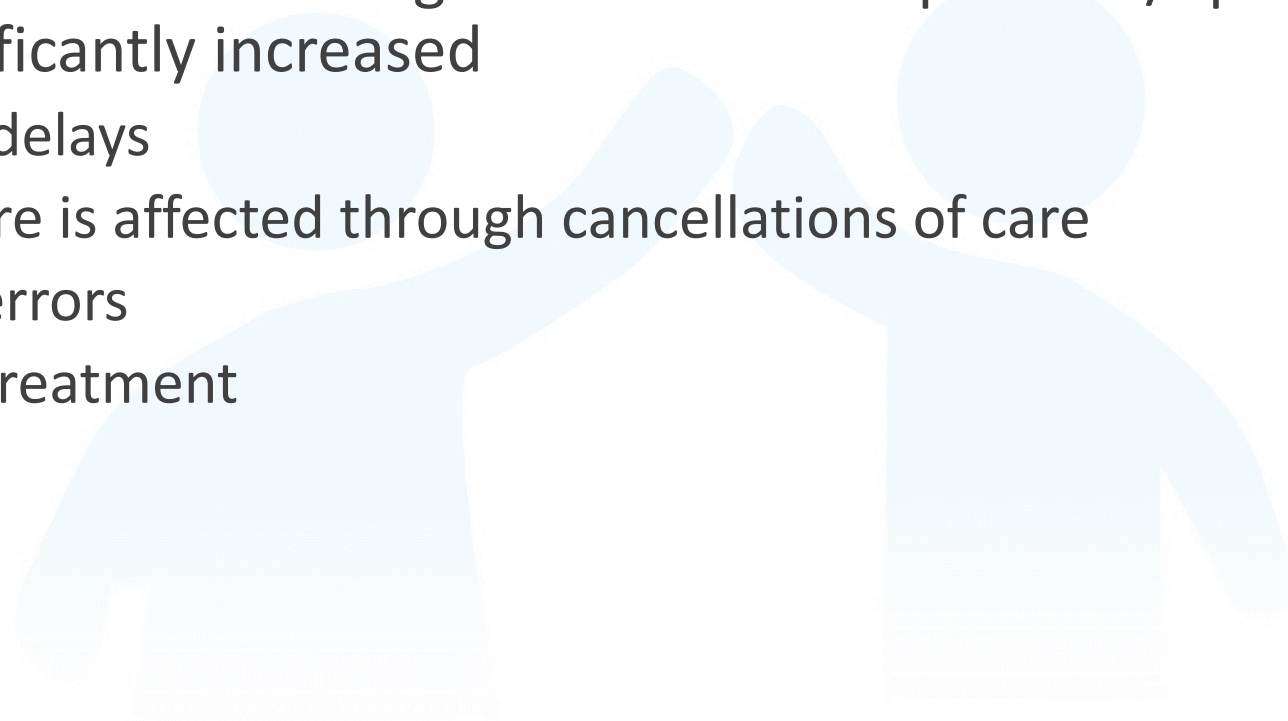
- COST Action CA 15105 on medicines shortages
- Joint supply chain actors statement
- Task force on availability of medicines set up by EMA + HMA; workshop on 8th November
- Supply chain actors renewal of call for action

BUT no new data on the shortage situation is emerging in Europe



2018 EAHP Medicines Shortages Survey – the results

- 1666 responses from 38 countries
- Shortages remain a major issue in Europe (91.8% in 2018 | 86.2% in 2014)
- Problems in terms of delivering the best care to patients/operating the hospital pharmacy significantly increased
 - Patient care delays
 - Quality of care is affected through cancellations of care
 - Medication errors
 - Suboptimal treatment





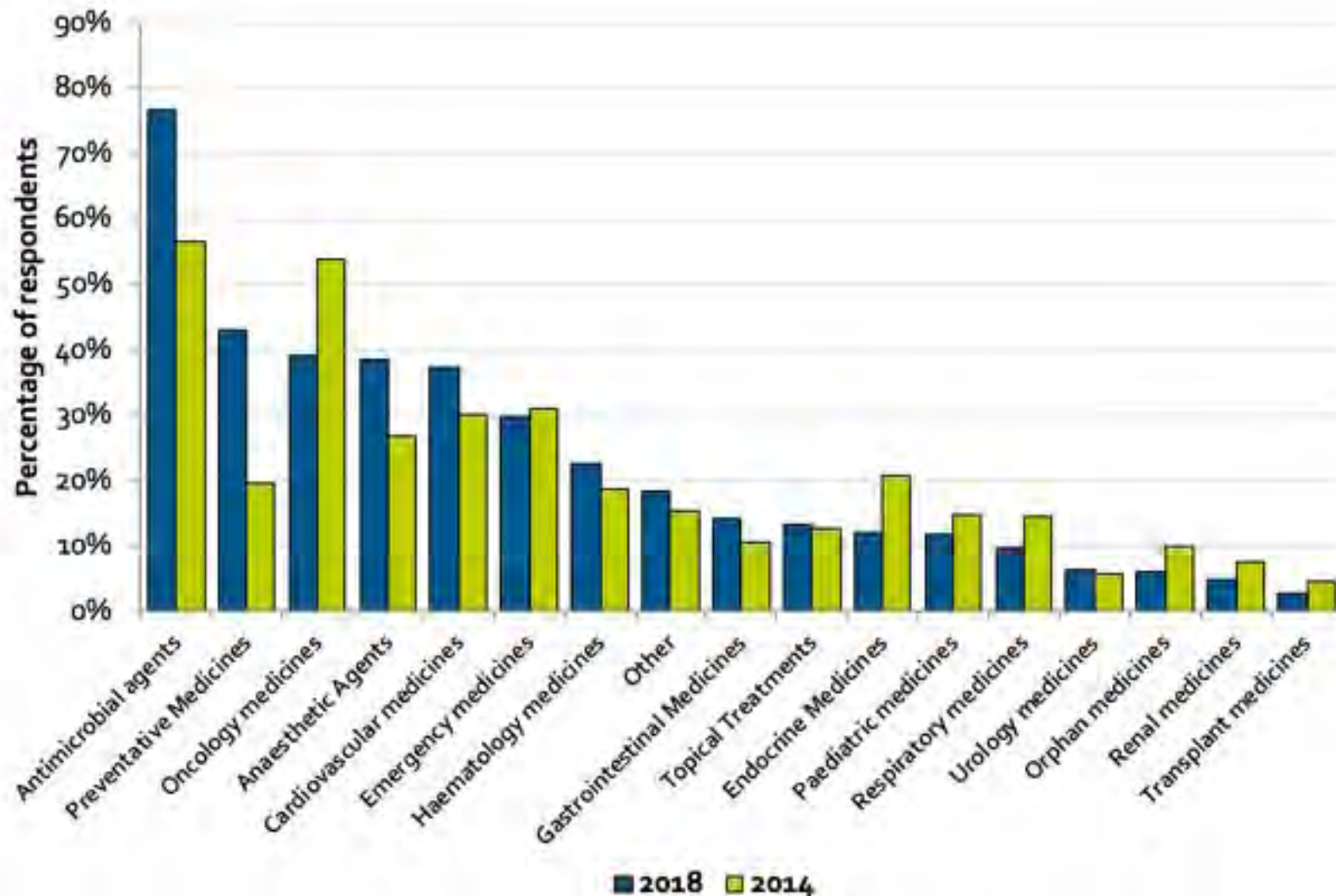
2018 EAHP Medicines Shortages Survey – the results

- 1666 responses in 2018 in comparison to 607 in 2014
- Biggest increase in responses
 - UK + 284
 - France + 189

Country	Responses (2018)	Responses (2014)	Country	Responses (2018)	Responses (2014)
Albania	1	0	Latvia	4	2
Austria	29	21	Lithuania	1	8
Belgium	90	94	Luxembourg	3	0
Bosnia & Herzegovina	19	9	Malta	6	11
Bulgaria	3	6	Montenegro	4	0
Croatia	26	25	Netherlands	20	11
Cyprus	2	1	Norway	21	11
Czech Republic	26	4	Poland	32	13
Denmark	10	25	Portugal	85	42
Estonia	17	15	Romania	24	2
Finland	33	1	Russia	1	0
France	192	3	Serbia	20	8
FYROM	14	4	Slovakia	23	16
Germany	78	10	Slovenia	18	5
Greece	84	14	Spain	190	105
Hungary	33	12	Sweden	5	0
Iceland	9	4	Switzerland	67	7
Ireland	51	47	Turkey	61	5
Italy	73	41	UK	291	7



2018 EAHP Medicines Shortages Survey – the results

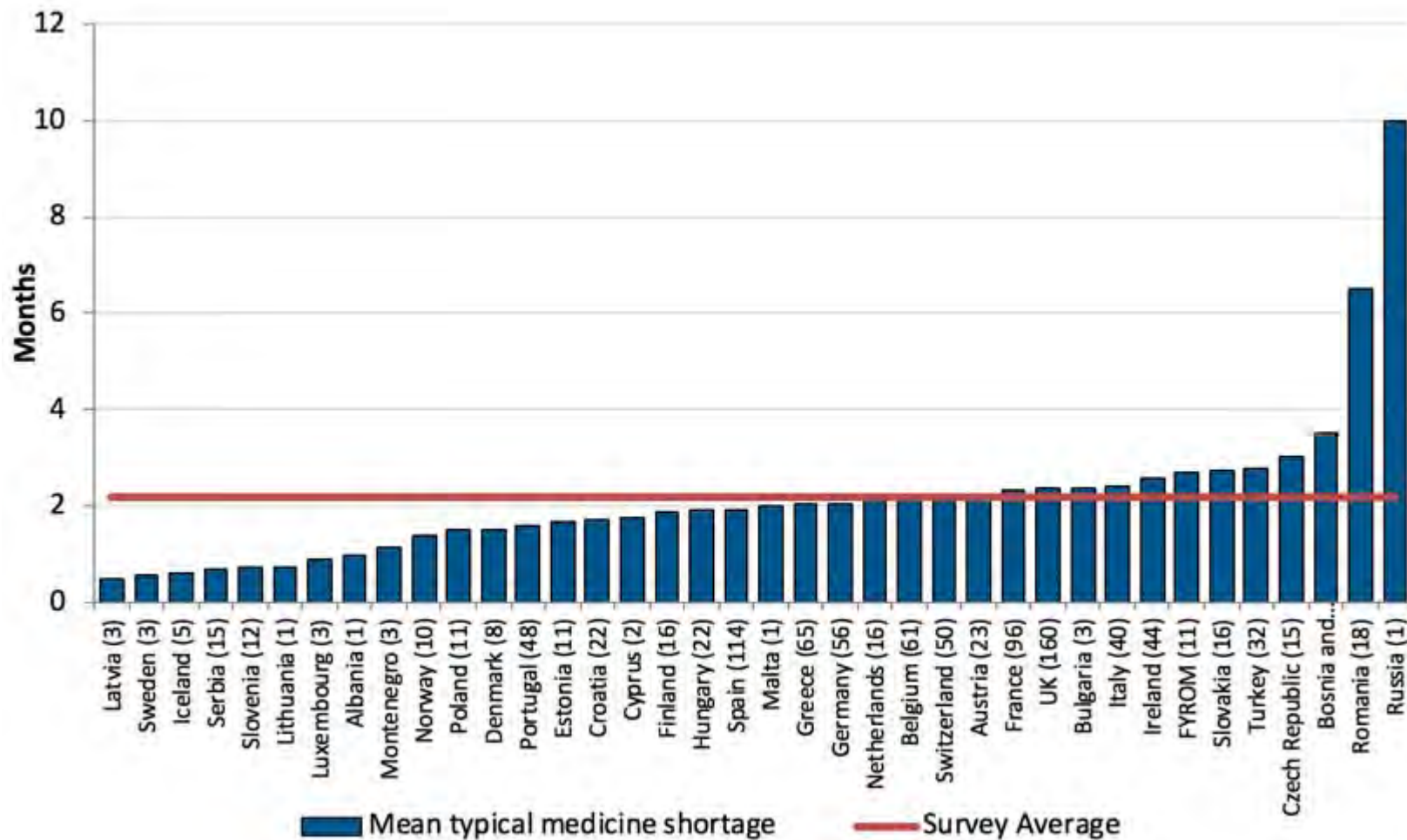


Areas of medicines for which shortages are most commonly experienced:

- Originator (65%)
- Generic (77%)
- Unlicensed medicines (14%)
- Biosimilar medicines (8%)



2018 EAHP Medicines Shortages Survey – the results

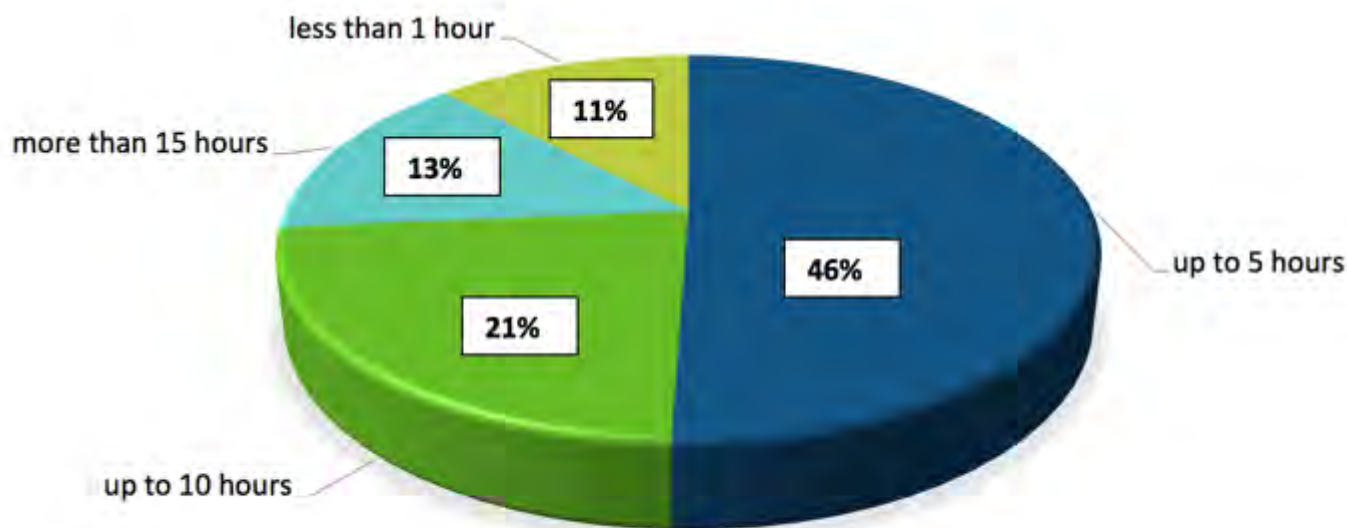


Duration of the average shortage

■ 2 months +

2018 EAHP Medicines Shortages Survey – the results

Amount of time spent dealing with medicines shortages



- “A pharmacist of the team spent about 8 hours per week to solve the problems of drug shortage.” – Hospital Pharmacists (France)
- “The shortage of medicines in our hospital carries the following consequences: an increase in extra work both at the care and administrative level; discomfort and nervousness on the part of all personnel, both health and non-health [...].” – Hospital Pharmacist (Spain)



2018 EAHP Medicines Shortages Survey – the results

Impact on patient care

- Provision of treatment through a therapeutic equivalent or near equivalent medicine, without major disruption to treatment: - almost 98% 'most of the time' (69% of 969 respondents), 'sometimes' (19%), 'all of the time' (9%), 'rarely' (2%), 'never' (0.3%)
- Staff time – significant increase reporting that more than 5 hours per week are spent to deal with shortages



59% care delayed



31% cancellations of care



25% medication errors



25% suboptimal treatment



20% increased length of hospital stay



5% readmissions due to treatment failure



1% death



2018 EAHP Medicines Shortages Survey – the results

Communication is key!

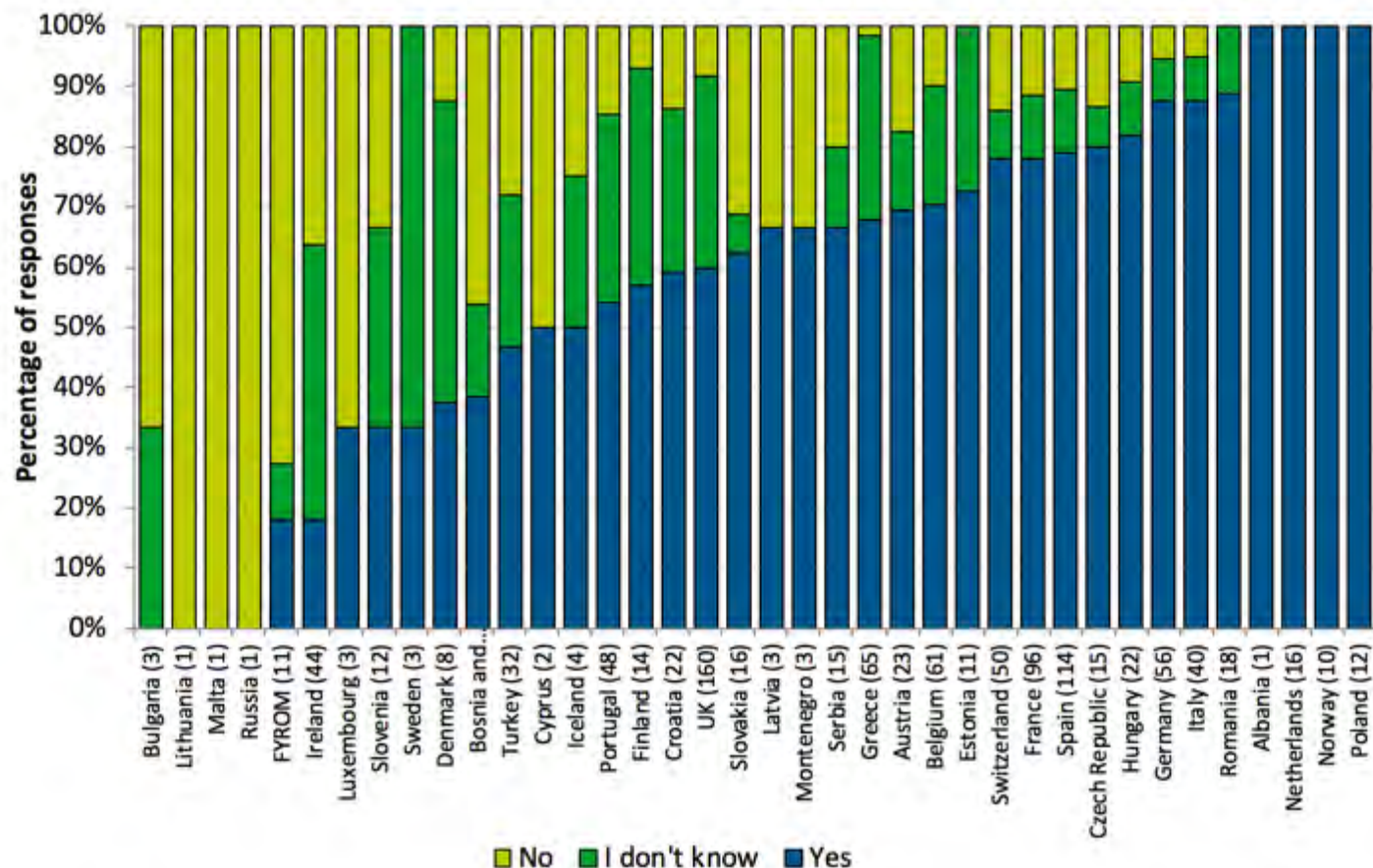
Responses calling for increased communication/collaboration:

- “A better information network should be initiated so that information about shortages and availability of medicines is shared among European countries.” – Hospital Pharmacist (Bulgaria)
- “Better national connection, information exchange and drug distribution between hospitals.” – Hospital Pharmacists (Croatia)
- “Collaboration between countries is very useful.” – Hospital Pharmacist (Iceland)
- “I beg for more effectiveness, more often in our countries, we have to deal with shortages far before authorities are aware of it.” – Hospital Pharmacist (France)
- “Information in an early state by manufacturer (to hospital, ministry of health) is the most effective preventing measure.” – Hospital Pharmacist (Poland)



2018 EAHP Medicines Shortages Survey – the results

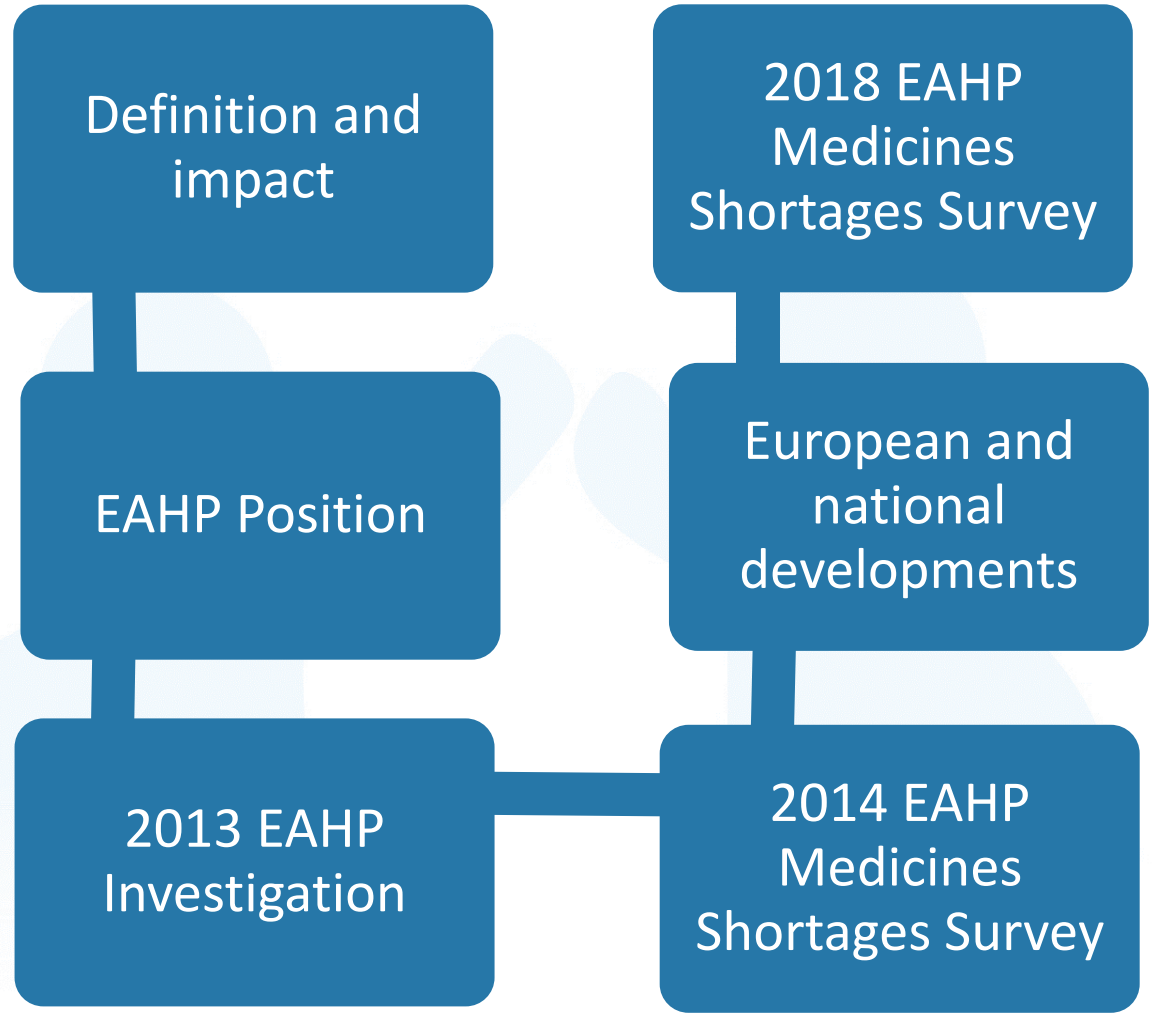
Communication – good practices already exist on national level



- In Poland, 22% of respondents (N=9) judged their system to be effective.
- In the Netherlands (94% positive response to the question if the system is effective/functional, N=16) the shortage information is frequently updated, which is important for helping pharmacists to manage shortages.



Where next?





Looking to 2019 – will the shortages get worse?

- Falsified Medicines Directive February 2019
 - Will there be stockpiling?
 - Will the requirements mean commercial decisions not to supply a small market?
- Brexit – 30 March 2019
 - Will there be an agreement
 - Will we have new border controls affecting all points of the ‘just in time’ supply chain?
 - Stockpiling in UK?
- Additional EMA and FDA inspections on manufacturing sites?
- ASHP revised their guide to managing shortages *Am J Health-Syst Pharm.* 2018; 75: e593-601



Professional Relationships

- Management of shortages is a challenge to the pharmacy team
- The confidence in the pharmacy service can be affected by multiple failures to have the required medicines available
- Good communication systems with up to date and accurate information is essential to maintain confidence
- A national approach in a small country , as outlined in the OPL group chaired by Dr. Katia Iskandar , will reduce duplication of effort and is improving the situation in Ireland



Learning objectives:

Participants will

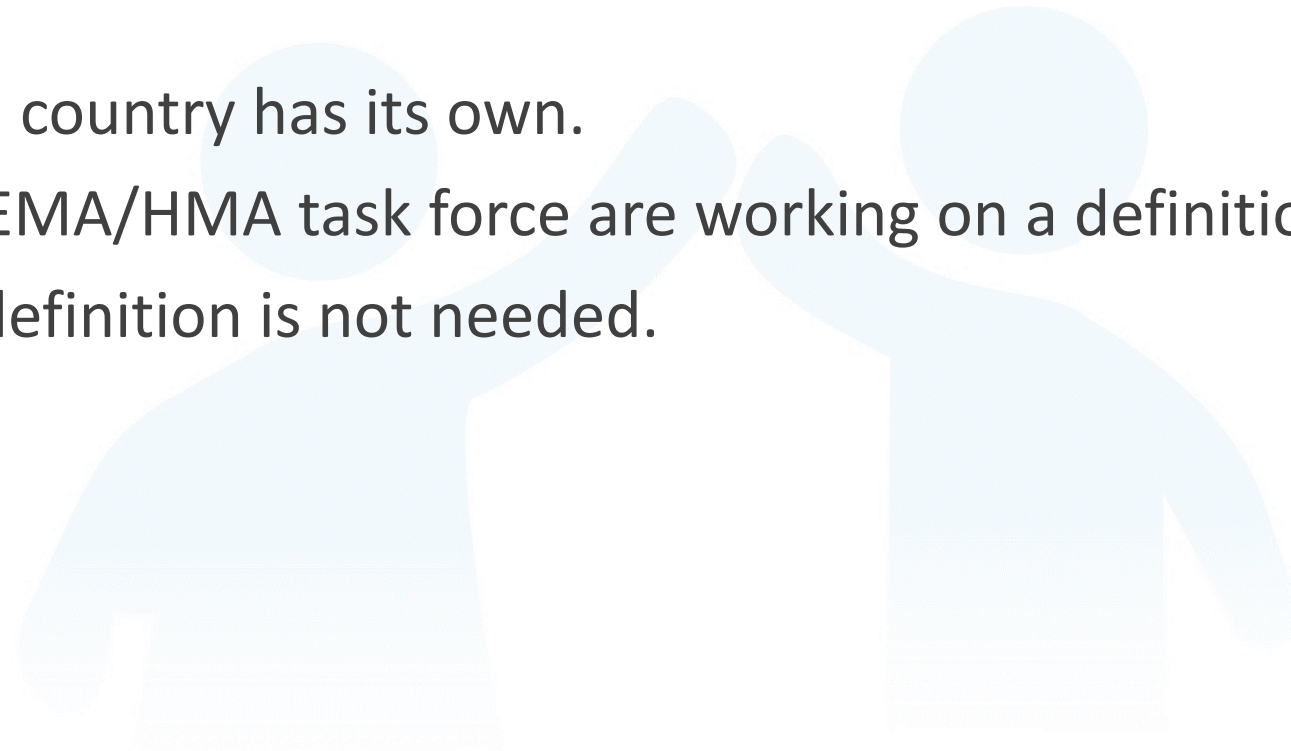
- be made aware of the severity of the medicines shortage problem in Europe;
- be provided with information highlighting the importance of communication between the different actors of the supply chain; and,
- learn about national and European measures that aim at facilitating the management of medicines shortages.



Question 1

Is there a common European definition of ‘medicines shortages’?

- A) Yes.
- B) No, but each country has its own.
- C) No, but the EMA/HMA task force are working on a definition.
- D) No, since a definition is not needed.

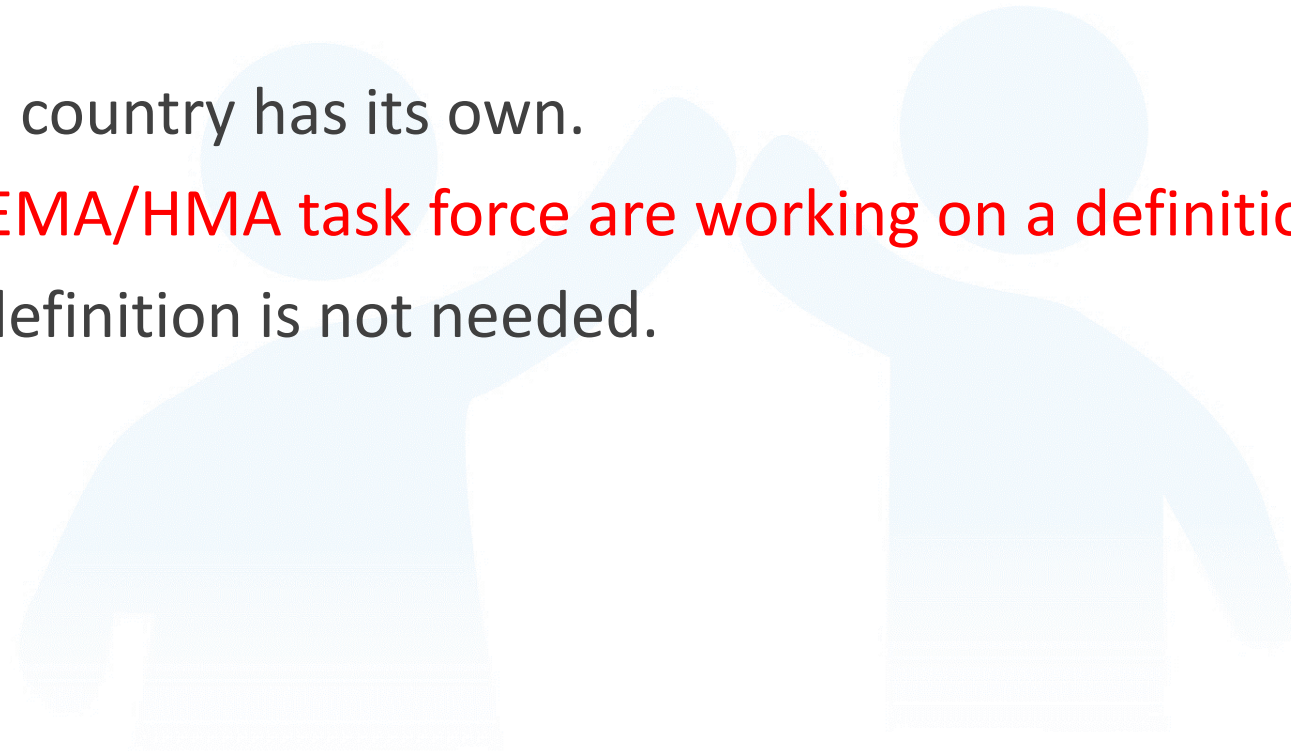




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Question 2

- Is the medicines shortage problem decreasing in Europe?

- A) No, 100% of the 2018 survey respondents highlighted that shortages are a current problem.
- B) Yes, because the EMA/HMA have set up a task force.
- C) Yes, because legislation has been adopted to ensure that shortages cannot occur.
- D) Yes because there is a shortages catalogue on the EMA website



Question 2

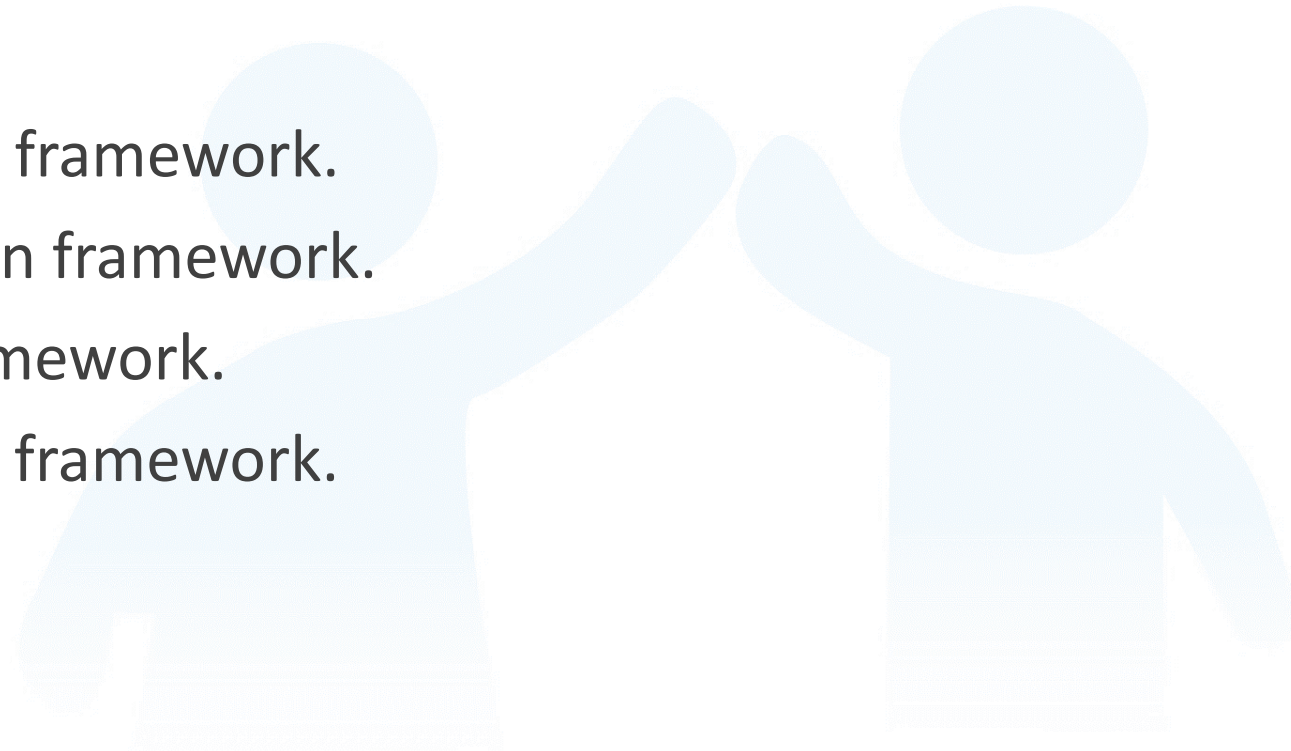
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Question 3

Which national medicinal product shortages framework that highlights the importance of communication between the different stakeholders was presented?

- A) The Swedish framework.
- B) The European framework.
- C) The Irish framework.
- D) The German framework.

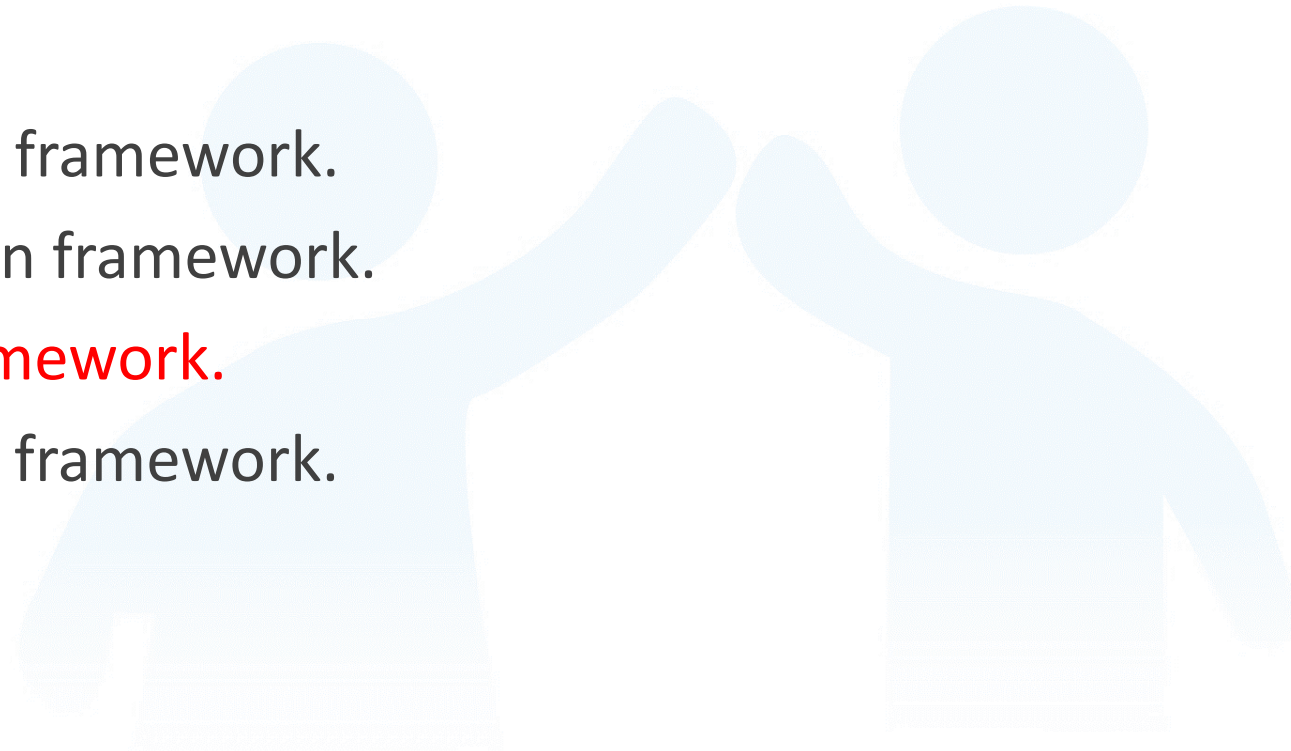




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- **C) The Irish framework.**
- D) The German framework.





Key Takeaways

- Information is key for the management of medicines shortages by pharmacists.
- All supply chain actors should work together.
- More action is needed on national, European and international levels to tackle this growing problem.
- The report 'Drug shortage in Lebanon' reflects the current worldwide issue.

THANK YOU

