



MEDICINES SHORTAGES IN EUROPEAN HOSPITALS

*The evidence and
case for action*

Results of the largest pan-European survey on medicines supply shortages in the hospital sector, its prevalence, nature and impacts for patient care.

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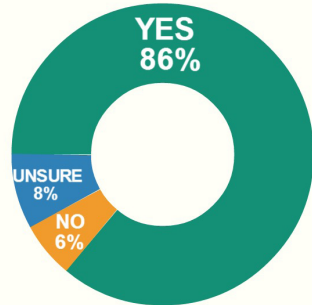
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MEDICINES SHORTAGES SURVEY RESULTS

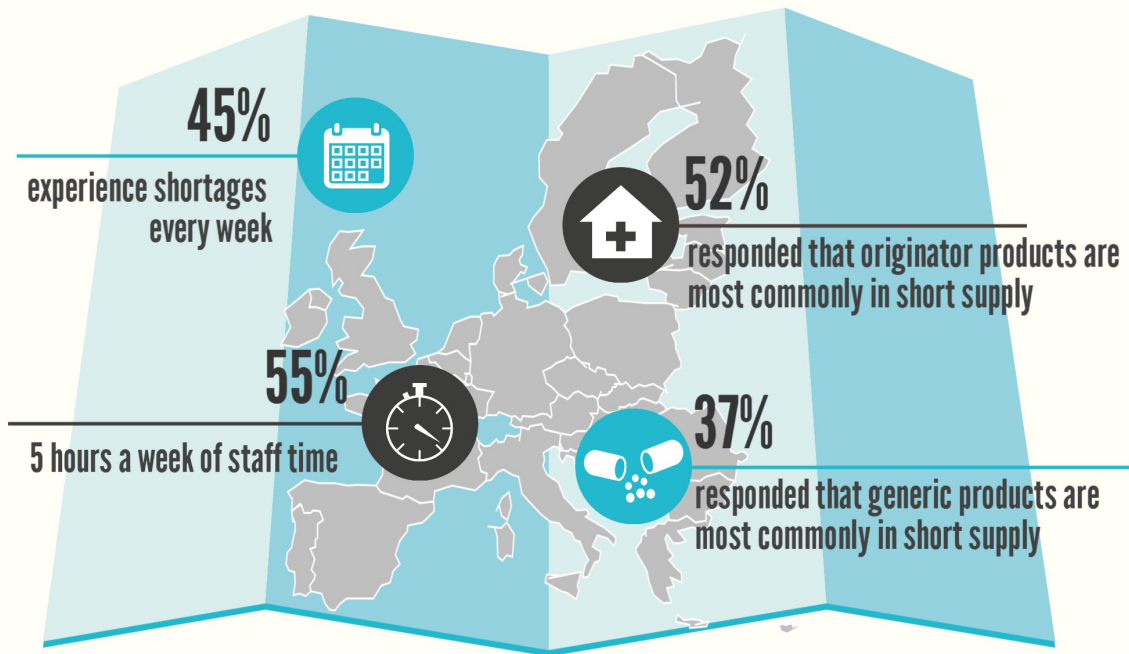
Are medicines shortages a current problem?



Over 600 hospital pharmacists from 36 countries responded



Questions relating to: impact of shortages, supply to hospitals and proposed solutions



TOP 3 THERAPEUTIC AREAS OF MEDICINE AFFECTED



Survey respondents expressed their view that greater legal clarity regarding the responsibility of suppliers (manufacturers/ wholesalers) to report supply disruptions at an early stage is required. They also signaled support for a scale up improvement of the European Medicines Agency database of medicines in shortage in order to improve information on the topic for the benefit of

What is a hospital pharmacy without medicines?

It's a hospital pharmacy that will struggle to provide the best care to patients.

This is no abstract question. As our report on the status of medicines shortages in European hospital pharmacies shows, in every European country surveyed, hospital pharmacists report the problem of medicines being in shortage, with 86% saying it creates difficulties in delivering care to patients and/or operating the hospital pharmacy.



This is the crucial point. The impact of medicines in shortage does not limit itself as simply an organisational headache for the pharmacy (though it is certainly that!) – the detrimental impact to patients is very real. Doses are missed, treatments are switched to less efficacious alternatives, and medical errors are caused as a result. Add the extra stress in a safety critical environment, the loss of man hours and the gross distraction shortages cause to the provision of other pharmacy services and you have a pan-European public health threat requiring action at the EU level. EAHP calls for:

- **Improved collection of information about medicines shortages in Europe**

A reliable catalogue of medicines in shortage across Europe, listing reason, likely duration, and other advice to pharmacies, prescribers and patients is needed. Evidence from the United States suggests such improvements in information collection and dissemination by the Food and Drug Administration has both assisted healthcare professionals in more effectively managing problems caused by shortages, as well as giving policy makers a clearer understanding of the true nature of the public policy urgency.

In view of its existing, if limited, catalogue on European medicines shortages, and its established role in EU medicines regulation, we see the European Medicines Agency (EMA) as an ideal agency for this task.

Such development should be accompanied by an annual report by the EMA to the European institutions and governments on the status of medicines shortages in Europe, and actions required towards achieving improvement. This is similar to legislation introduced in the USA in 2012.

- **Clarification and enforcement of legal responsibilities for reporting disruptions to supply**

As evidenced in this report, hospital pharmacists' preferred remedial measure to ameliorate the medicines shortage problem is improvement to the requirements upon manufacturers to report likely supply disruptions. Legislation introduced in the USA in 2012 to tighten such requirements has helped in contingency planning and improved policy understanding of the problem.

- **An inquiry at the European level into the primary factors causing medicines shortages**

Given the clear picture in this report –that medicines shortages are a pan-European problem - the task of resolving the difficulties cannot be left to national governments alone. The European Commission should conduct a high level investigation to understand the precise factors that create cross border medicines shortages and examine its own role in bringing nations together to tackle the issue. The Commission should:

- acknowledge the existence of the shortage problem;
- appreciate its responsibilities to help countries meet the challenge; and,
- urgently address the evidence base for response as well as a fair distribution based on the needs of the patients.

The scale of medicines shortages in Europe provides a call to action to all of us who express interest in preserving and enhancing high quality healthcare.

We now ask others to join us in securing the solutions necessary.

Dr. Roberto Frontini

Medicines shortages* are an ongoing problem for the provision of healthcare not only in Europe’s hospital sector, but also in the community sector^[1]. Shortage problems are not only contained in their prevalence to within the borders of Europe either, but are evidenced to be a worldwide problem^[2].

Countries such as the USA^[3] and the Netherlands^[4] have made notable steps in both documenting and responding at a regulatory level to the problem. However, at a pan-European level, there remains both a gap in the known and circulated evidence of medicines shortages, and a corresponding failure to take active international regulatory measures.

EAHP’s 2014 medicines shortage survey is therefore a response to this information gap and is designed to provide policy and decision makers with the clearer picture required to adequately assess the nature and available solutions to the problem.

The survey results are presented in several sections:

- prevalence of shortages
- medicines affected
- supply of medicines
- duration of shortages
- impact of shortages
- actions taken to minimise impact
- solutions
- literature

**For the purpose of this report an adapted definition from the Food and Drug Administration (FDA) was used in which a medicine shortage may be defined as “a situation in which the total supply of all clinically interchangeable versions of a regulated drug is inadequate to meet the current or projected demand at the user level.”*

The survey was primarily available online, though some paper based contributions were also accepted. A total of 607 responses were received from 36 European countries including EAHP member countries and non EAHP member countries Monaco, Cyprus and Liechtenstein. Responses from non-European countries were also received including Lebanon, Israel and Saudi Arabia. These responses are not included in the analysis provided in the following pages. The survey opened on 19th March 2014 and closed on 7th May 2014.

Country	Responses	% of total	Country	Responses	% of total
Austria	21	3.5	Latvia	2	0.3
Belgium	94	15.4	Liechtenstein	1	0.2
Bosnia and Herzegovina	9	1.5	Lithuania	8	1.3
Bulgaria	6	1.0	Malta	11	1.8
Croatia	25	4.1	Monaco	3	0.5
Cyprus	1	0.2	The Netherlands	14	2.3
Czech Republic	4	0.7	Norway	11	1.8
Denmark	25	4.1	Poland	13	2.1
Estonia	15	2.5	Portugal	42	6.9
Finland	1	0.2	Romania	2	0.3
F.Y.R.O.M.	4	0.7	Serbia	8	1.3
France	3	0.5	Slovakia	16	2.6
Germany	10	1.6	Slovenia	7	1.2
Greece	14	2.3	Spain	105	17.3
Hungary	12	1.8	Switzerland	7	1.2
Iceland	4	0.7	Turkey	5	0.8
Ireland	47	7.7	UK	7	1.2
Italy	41	6.7	Non European	6	0.2

Table 1 – Number of responses and percentage (%). All countries included if at least 1 complete response was received. Number indicates responses received via any method including online (+/paper/conference app). Former Yugoslav Republic of Macedonia is referred to as F.Y.R.O.M. in this report.

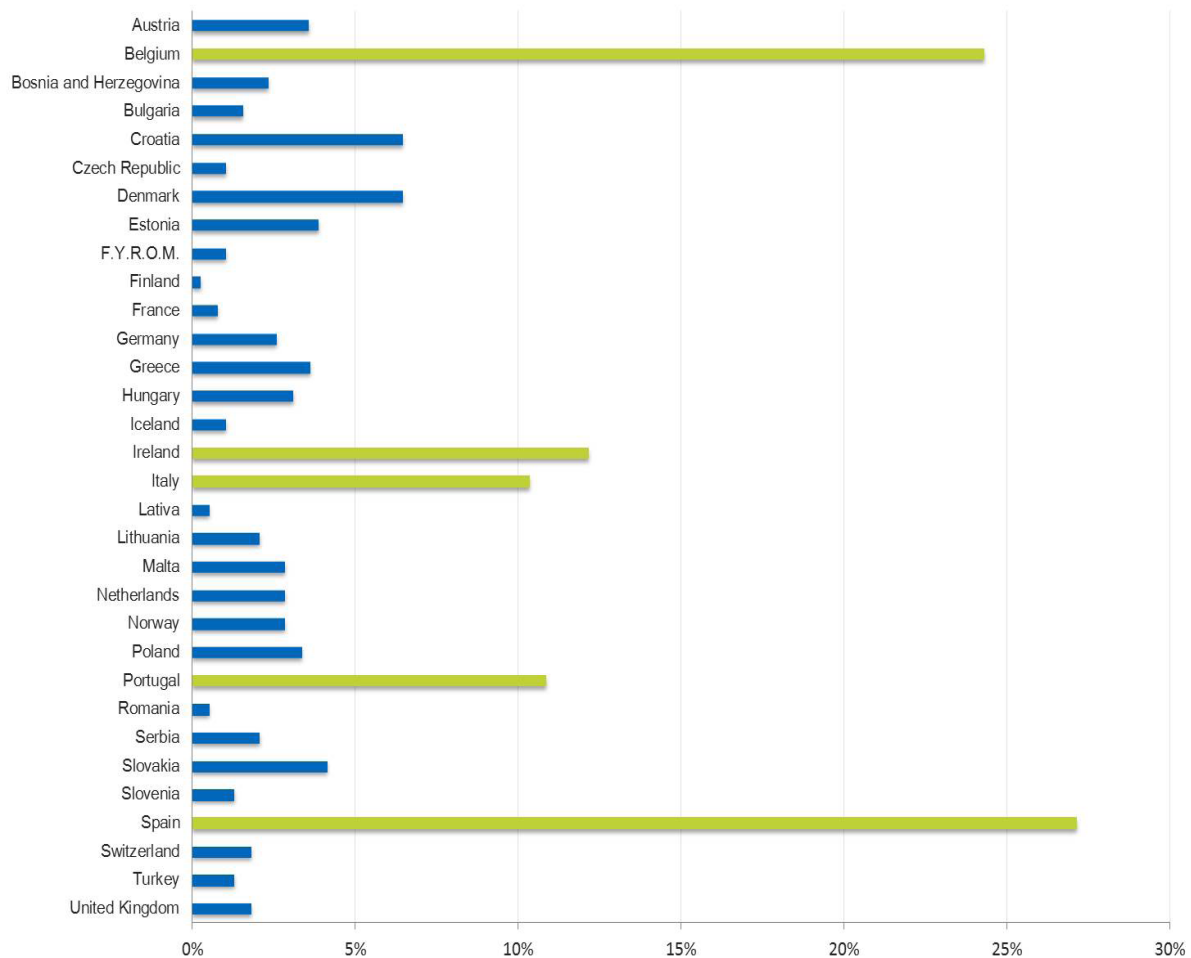


Chart 1 – Number (%) of complete responses by EAHP member countries. Monaco, Lichtenstein and Cyprus are excluded. The highest numbers of responses were from Spain, Belgium, Ireland, Italy and Portugal respectively. N=587

The 2014 EAHP survey should be seen within the context of a previous, shorter and smaller survey conducted in 2013. Results can be found on the EAHP website www.eahp.eu.

EAHP thanks its members for the time given to distributing and responding to the 2014 survey.



The prevalence of shortages

The prevalence of shortages affecting EAHP members, and how often these occur is difficult to ascertain in Europe with different systems (or no systems) for hospital pharmacists to report shortages.

In this section a number of questions were asked in an attempt to quantify and further investigate the scale of the problem of shortages within Europe.

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

537 respondents answered this question with the majority (86.2%, n=463) stating that **medicines shortages are a current problem in terms of delivering the best care to patients and/or operating the hospital pharmacy**.

The remaining 8.2% (n=44) of respondents stated that medicines shortages are not a current problem, with 5.6% (n=30) unsure.

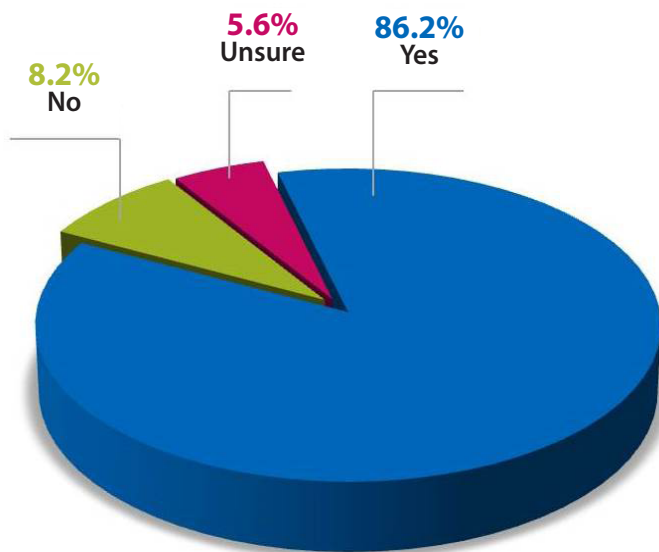


Chart 2– proportion of hospital pharmacists (%) stating that medicines shortages are a current problem in their country. N=537

The majority of hospital pharmacists who answered this question (86.2%, n= 463) stated that medicines shortages are a current problem in terms of delivering the best care to patients and/or operating the hospital pharmacy.

This is a high proportion and corresponds to the results of the previous survey conducted by EAHP^[5, 6] in 2013 where 99% of those who responded (n=339) said that they had experienced shortages in the last 12 months.

In this survey (2014) the countries listed below had the highest level of responses stating shortages are a problem:

- 98.8% (n=83) from Belgium
- 97.8% (n=44) from Ireland
- 87.2% (n=34) from Portugal
- 83.0% (n=73) from Spain and
- 77.1% (n=27) from Italy

These results occur despite known attempts at a national level in these countries to address the problem. This gives the impression that more effective solutions lie at the European level.

Notably high levels of agreement also came from Austria, Slovakia, the Netherlands, Denmark and from outside the European Union (EU), Norway.

No country surveyed responded with less than 60% agreement that medicines shortages are a current problem. The lowest proportion of agreement was from Croatia (60.9% n=14).

COMMENTS

"This is a growing problem & takes up a lot of working time which could be spent on other tasks."

Hospital Pharmacist, Ireland (Dublin)

"Always shortage of one or more medicines, at any time."

Hospital Pharmacist, Norway (Oslo)

"We always found an alternative – but took significant time to do this."

Hospital Pharmacist, Belgium (Antwerp)

"In the last year shortages become more current."

Hospital Pharmacist, Belgium (West Flanders)

"Up to now we always solved a problem, but it takes much more energy and time."

Hospital Pharmacist, Slovakia (Bratislava)

"Not in terms of operating the hospital pharmacy, but maybe in terms of delivering the best care (in some cases a substitute drug is given)."

Hospital Pharmacist, Bosnia and Herzegovina

"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 (Oslo)

"There are shortages of medicines but nothing alarming."

Hospital Pharmacist, Croatia (Zagreb)

"I would really like to know the reasons for the shortages."

Hospital Pharmacist, Denmark

Approximately how often does your hospital pharmacy experience shortages?

Most hospital pharmacists responded that they are affected by shortages on a weekly basis.

Hospital pharmacists are affected by shortages on a daily basis, with 21.1% (n=111) replying that they experience a shortage of a medicine every day.

The situation for the majority of those who replied was that they experience shortages at least weekly, 45.2% (n=238) selecting this response.

21.2% (n=112) replied that they are affected by shortages on a monthly basis with 12.4% (n=65) stating that they are affected occasionally.

This resulted in a combined 87.6% (n=454) of the respondents replying by saying that they are affected by medicines shortages at least monthly.

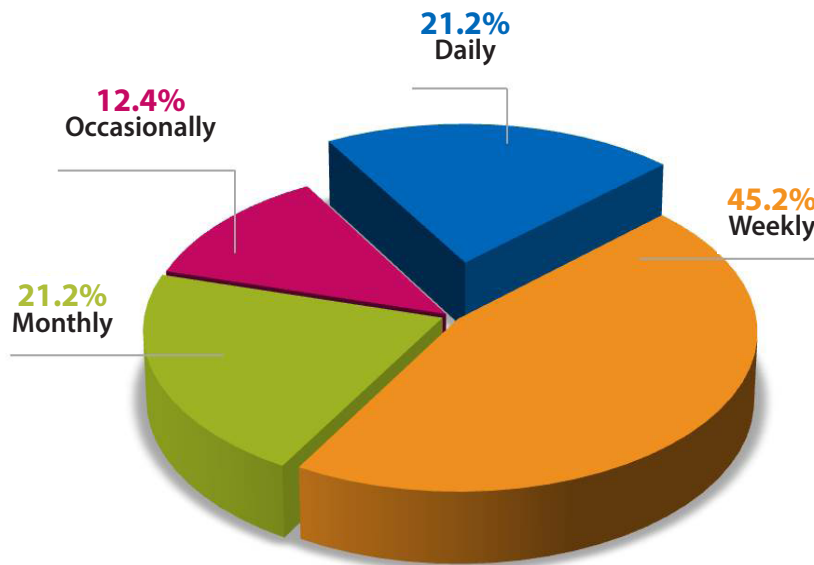


Chart 3– Shortages frequency (N=526)

The results of this question can be compared to results from EAHP's 2013 survey in which 63.1% (n=214) stated that they experienced shortage problems as a weekly, sometimes daily occurrence^[5]. 27.1% (n=92) stated that they experienced shortages at least once a month, with 9.7% (n=33) stating that they only experienced shortages a few times a year^[5].

	Response Percent	Response Count
Problems with medicines shortage in our hospital are a weekly, sometimes daily, occurrence	63.1%	214
Our hospital experiences medicines shortage problem at least once a month	27.1%	92
Not very often, maybe a few times a year	9.7%	33
Comment		13
answered question		339
skipped question		7

Chart 4 - Occurrence of shortages in the 2013 survey as a comparison

This supports the results from the previous survey and indicates that for the second time in which EHP has conducted such a survey a high proportion of hospital pharmacists are affected by shortages at least monthly.

The unpredictability of shortages and lack of information provided to healthcare professionals make it increasingly difficult to plan effective coping strategies to provide medication to patients^[7]. As in the previous study, the frequency is affecting the daily work of a pharmacist and this may be an increasing trend. It is vital that the collection and analysis of information about medicines shortages is improved so that the shortages problem can be investigated and resolved as soon as possible.

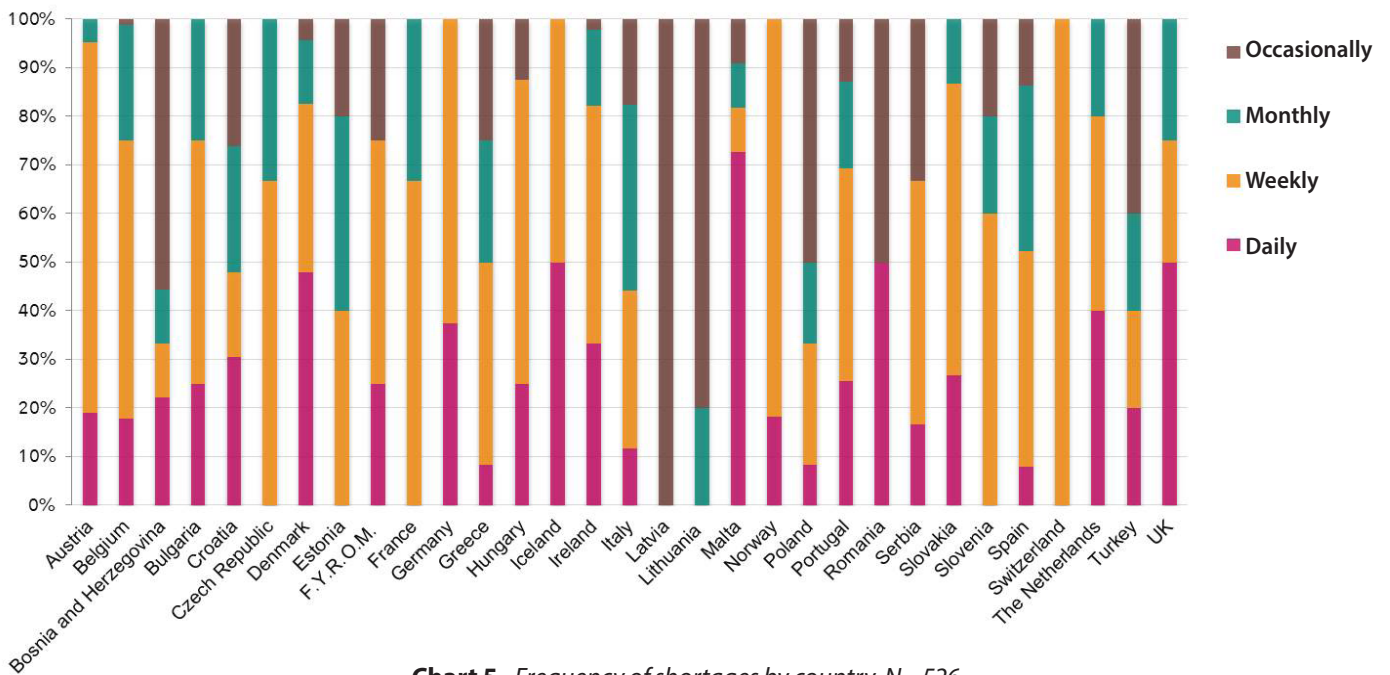


Chart 5 - Frequency of shortages by country. N= 526

The countries with the highest percentage of respondents indicating that medicines shortages are daily occurrence were Malta (72.7%, n=11) and Denmark (47.8%, n=23).

The countries with the highest percentage of respondents indicating that medicines shortages are a weekly occurrence are Norway (81.8%, n=11), Austria (76.2%, n=21) and Slovakia (60%, n=15). Occasional shortages were reported most frequently in Bosnia and Herzegovina (55.6%, n=9) and Croatia (30%, n=23).

Overall, shortages occur on a weekly basis in the majority of countries that were surveyed, but it is also clear that there is great variation within countries and between countries about how often shortages of medicines affect

All medicines have the potential to be in a situation of short supply yet some are at higher risk of doing so, or seem to be reported by hospital pharmacists as in short supply more frequently. Whilst the possible reasons and causes of a shortage may be unique to each situation, hospital pharmacists were asked which medicines were in shortage most frequently in their experience.

We asked hospital pharmacists from what source of supply shortages are most commonly experienced, in which therapeutic areas and which products are affected.

Which type of medicine do you most commonly experience to be in short supply?

According to the respondents they most commonly experience originator (patented) products to be in short supply. 51.8% (n=221) reported them as the most common category of shortage.

Generic products (including branded generics) were affected to a lesser degree, with 36.5% (n=156) of hospital pharmacists stating that they are the most affected category in their experience.

11.7% (n=50) of respondents considered that unlicensed medicines are the most common type of medicines in short supply.

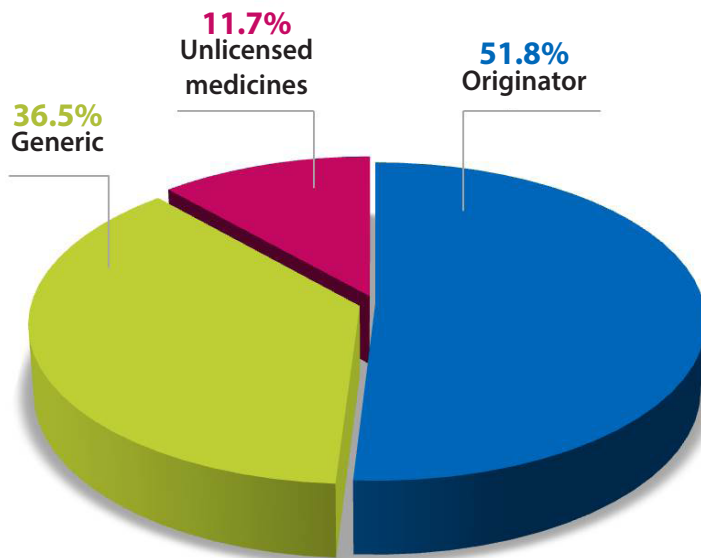


Chart 6 - Nature of the shortages reported from all of the responses. N=427

The countries with the highest recorded prevalence of originator (patented) shortages are Belgium (78.3%, n=69), Spain (64.5%, n=62), Austria (73.3%, n=15) and Slovakia (78.6%, n=14). The pharmaceutical markets of Bulgaria, Ireland, Switzerland, Italy, Norway, France, and Poland also expressed that patented products were the most common category of shortages.

The countries with the highest recorded prevalence of generic shortages (including branded generics) were Denmark (72.2%, n=18), the Netherlands (66%, n=11), Portugal (50%, n=32) and Croatia (50%, n=22). Respondents in the pharmaceutical markets of Germany, Hungary, Latvia, Turkey, the Former Yugoslav Republic of Macedonia (F.Y.R.O.M.), Serbia and the UK expressed that generic products were the most common category of shortages.

Additionally, unlicensed medicines in short supply are reported by respondents from Croatia, Greece, Slovakia, Iceland, Slovenia and Bosnia and Herzegovina. Indeed, in Estonia respondents expressed unlicensed medicines as the most common type of shortage experienced (63.6%, n=11).

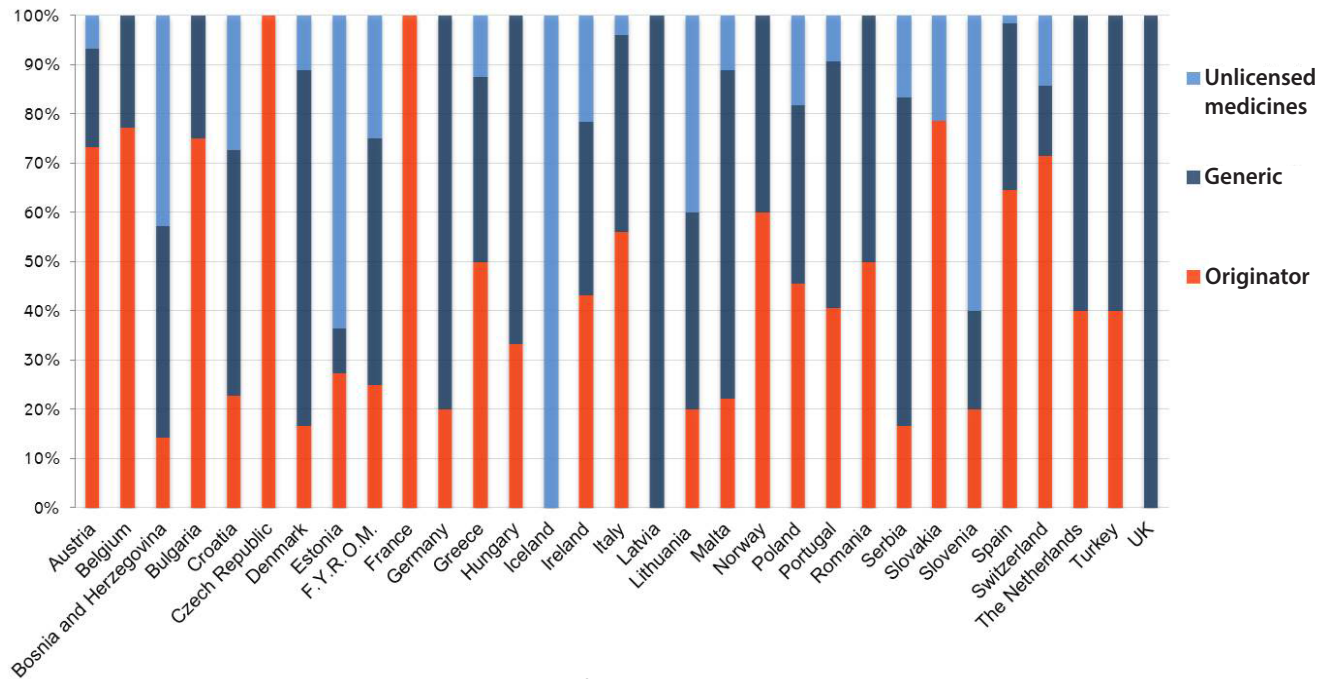


Chart 7 - Type of shortages reported by country. N=424

The results of this question can be compared to results from EAHP’s 2013 survey^[5, 6]

For originator (patented) products there has been an increase from 42.9% (n=139) in the 2013 survey saying that this was the most common kind of shortage, to 51% (n=216) in the 2014 survey.

it should be noted however that the terms of the question in the 2014 survey were amended from the 2013 survey. Respondents to the 2013 survey suggested that “generics” should also be described to include branded generic products. Additionally unlicensed medicines were included as a separate category in the 2014 survey.

This change is one potential factor that may account for a change in the proportion of respondents (%) from 57.1% (n=185) reduced to 37.5% (n=159) that reported generic medicines (including branded generics) as the primary category of shortage.

It is surprising that a reclassification in the question could lead to such a significant change in the expressed experience of categories of shortage. It seems to the authors therefore that hospital pharmacists are more commonly experiencing shortages with originator products than in 2013.

However, overall a similar picture was gained from the 2014 survey as that derived from the 2013 survey: that shortages are affecting both the supply of generic and originator products to a high degree, although the causes, duration and impact for pharmacists, patients and healthcare systems still needs to be further investigated.

In which area of medicine does your hospital experience shortage most commonly?

The areas in which shortages of medicines are most commonly reported are:

- antimicrobial agents (237, 56.7%)
- oncology medicines (228, 54.5%)
- emergency medicines (127, 30.4%)
- cardiovascular medicines (127, 30.4%)
- anaesthetic agents (110, 26.3%)

It is interesting to note that at least 19 (4.5%) reports were received for the lowest affected category: transplant medicines. This indicates the many categories of medicine are affected by shortage.

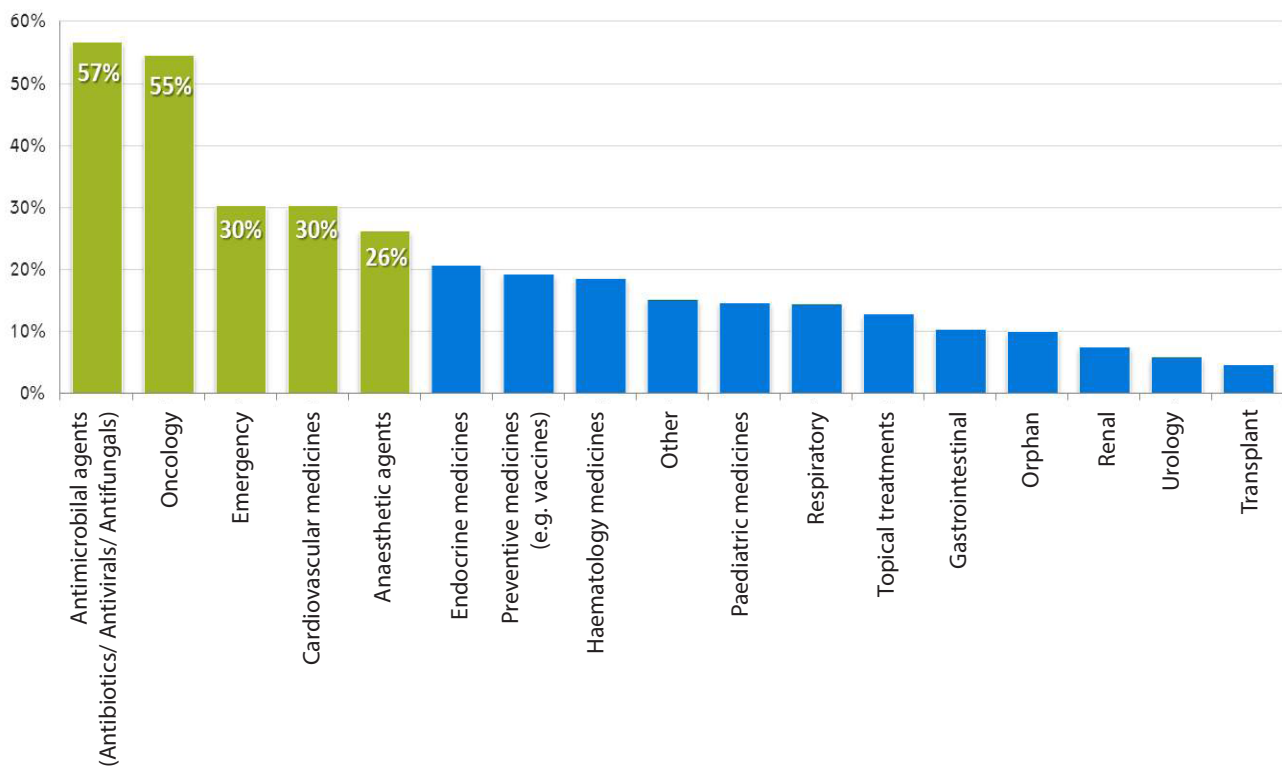


Chart 8 - Category of shortages reported overall. The categories with the highest responds include antimicrobials (56.7%), oncology (54.5%) emergency medicines (30.4%) and cardiovascular medicines (30.4%). N=418

The countries reporting the high prevalence of shortages in cardiovascular medicines are Malta (77.8%, n=7), Lithuania (60%, n=3) and Italy (60%, n=25). In the previous EAHP survey^[5], conducted in 2013, this category was also in the top three categories affected.

It is interesting to note that: preventative medicines (including vaccines) are commonly reported to be in shortage in Switzerland (83%, n=5); emergency medicines in Estonia (63.6%, n=7) and Ireland (69.4%, n=36); transplant medications in the Czech Republic (100%, n=3); and, in Croatia there appears to be an identifiable supply problem with anaesthetic agents (47.6%, n=21).

Examples of other therapeutic areas were provided from a variety of countries in the comments section of the question:

- gynaecological medicines,
- psychiatric drugs,
- ophthalmic medicines
- pain medication
- contrast media used for x rays
- IV formulations
- biologics including monoclonal antibodies
- medicines due to becoming off patent soon
- nutritional products

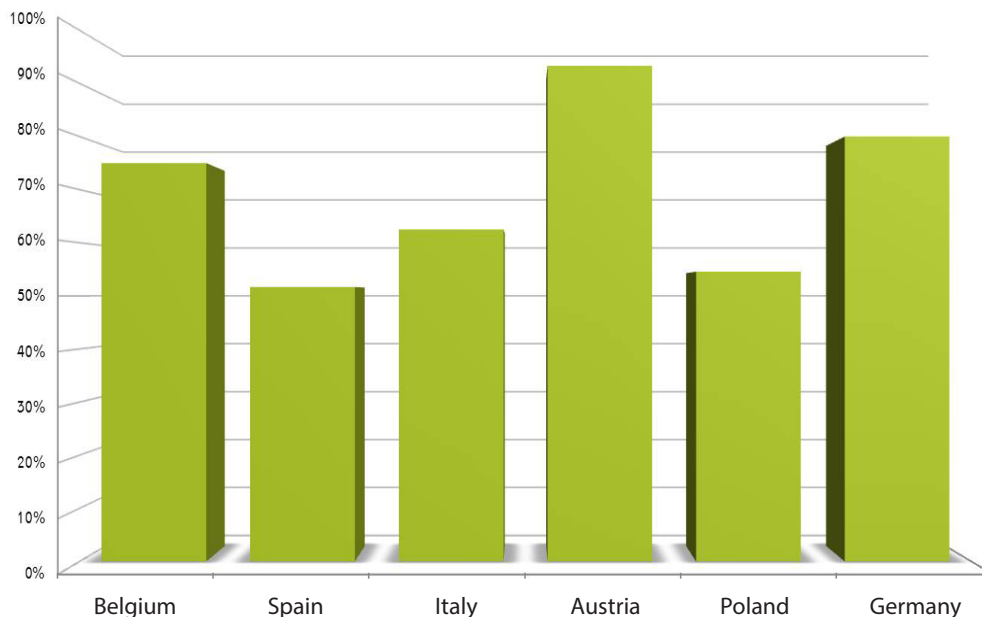


Chart 9 - Countries that reported the highest proportion of shortages relating to antimicrobials (including antivirals and antifungals). Across the x-axis the countries are in the order of the number of responses from Belgium (n=68) to Germany (n=5).

The results correspond to EAHP’s 2013 survey^[5] with oncology, cardiovascular and emergency medicines featuring highly as areas of reported medicine shortage. A new entrant, as the top area of medicine shortage in 2014, is antimicrobial/antiviral/antifungal agents. In the 2013 survey this was not listed as an option, but comments received to that question indicated it was an area of shortage. For similar reasons, the 2014 survey also listed anaesthetic agents as an option, and received a strong response.

The results underline and emphasise the concerns about medicines shortages being raised by health professionals and patients in the cancer sector^[8]. The entry of antimicrobial agents as the top reported area of shortage takes on additional dimension in the context of antimicrobial resistance and the need for better stewardship of these medicines. This evidence indicates the availability challenge that has to be overcome in order to complement efforts on responsible and prudent use of antimicrobials, in the fight to combat antimicrobial resistance.

The areas affected in this European based survey reflect a similar picture to shortages reported elsewhere in the world. In the USA sterile injectable drugs have been widely affected by shortages^[9]; affecting therapeutic areas such as oncology^[10], cardiovascular drugs, pain medication and intravenous (IV) electrolytes^[11].

In Australia there have been reports of antibiotics^[12,13] being in shortage. A newly launched database based on voluntary submissions from market authorisation holders, shows products that have been recently discontinued and resolved including those affecting the alimentary tract, anti-cancer, cardiovascular, antibiotics, and central nervous system (CNS) agents^[14]. Those antibiotics in shortage at the time of writing (September 2014) include cardiovascular agents, dermatological products, CNS agents and various products including vaccines and the diagnostic agent Tetracosactrin^[14].

In South Africa the most common medicines in short supply are anti-retroviral and tuberculosis medication. However shortages in South Africa are not confined to these treatments alone. Shortages have also been reported for vaccines, antibiotics and chronic conditions such as cardiovascular and diabetes^[15].

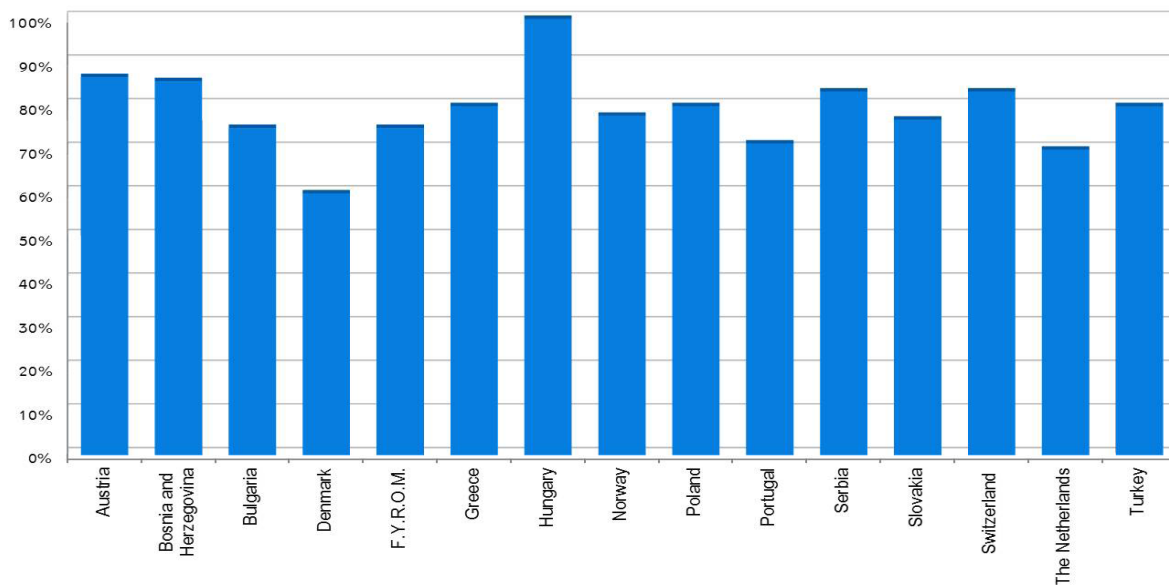







Chart 10 - Countries that reported the highest proportion of shortages relating to oncology



Specific examples of medicines in shortage over the past year

A request was made to obtain examples of shortages that affect hospital pharmacists in different countries in Europe, to see if some shortages of the same medicine are clearly affecting numerous countries, and to make comparison to the catalogue of medicines in shortage held by the European Medicines Agency.

At the time of writing the European Medicines Agency’s drug shortage catalogue contains five current shortages and two resolved shortages (see figure 1). This is based on a definition for inclusion as “*medicine shortages that affect or are likely to affect more than one European Union (EU) Member State, where the European Medicines Agency (EMA) has assessed the shortage and provided recommendations to patients and healthcare professionals across the EU.*”^[16]

Current shortages					
Document(s)	Language	Status	First published	Last updated	Effective Date
 Buccolam (midazolam) supply shortage	(English only)		25/04/2014		
 Cerezyme (imiglucerase) supply shortage	(English only)		04/11/2013		
 Fabrazyme (agalsidase beta) supply shortage	(English only)		04/11/2013		
 Maci (matrix applied characterised autologous cultured chondrocytes) implant supply shortage	(English only)		04/07/2014		
 Vistide (cidofovir) supply shortage	(English only)		04/11/2013		

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Resolved shortages					
Document(s)	Language	Status	First published	Last updated	Effective Date
 Enbrel (etanercept) supply shortage	(English only)		19/02/2014	07/05/2014	
 Increlex (macasermin) shortage resolution	(English only)		20/12/2013		

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Figure 1 – Print screen of the EMA shortages database on 16th July 2014

According to the answers provided by the respondents in this question, medicines shortages that are affecting 3 or more EAHP members (which may include EU and non EU countries) are listed below.

Antibiotics used to treat bacterial infections

- Amoxicillin (Oral) (broad spectrum antibiotic) affecting **Lithuania, the Netherlands and Italy**
- CoAmoxiclav (broad spectrum antibiotic) affecting **Switzerland, Austria, Portugal, Belgium and Spain.**
- Gentamicin (IV) (amino glycoside antibiotic) affecting **Switzerland, Greece and Hungary.**
- Linezolid (oxazolidinone antibiotic) affecting **Italy, Germany, Spain and Portugal.**
- Meropenem (carbapenem antibiotic) affecting **Spain, Austria, Denmark and Belgium.**

Drugs used to treat cancer

- 5-Fluorouracil (anti-metabolite drug used in oncology) affecting **Austria, Portugal and Serbia.**
- Carboplatin (platinum based chemotherapy medicine) affecting **Belgium, Germany, the Netherlands, Denmark, Portugal, Spain and Bosnia/Herzegovina.**
- Cisplatin (platinum based chemotherapy medicine) affecting **Belgium, Italy, Poland, Austria and Hungary.**
- Doxorubicin (Liposomal) (anthracycline antibiotic used as a chemotherapy medicine) affecting **Spain, Croatia, Norway, and Switzerland.**
- Etoposide (anti-neoplastic drug) affecting **Poland, Malta, Portugal and Belgium.**
- Melphalan (alkylating medicine chemotherapy drug) affecting **Greece, Spain and Belgium.**
- Methotrexate (antimetabolite) affecting **Italy, Slovakia and Poland.**
- Oxaliplatin (platinum based anti-neoplastic) affecting the **Netherlands, Belgium and Italy.**
- Vincristine (vinka alkaloid) affecting **Belgium, Italy, Greece and Portugal.**

Medication used in pain relief

- Ibuprofen (IV) (non steroidal anti-inflammatory drug) affecting **Ireland, Italy and Norway.**
- Morphine (opioid analgesic) affecting **Norway, Iceland and Denmark.**
- Tramadol (IV) (opioid analgesic) affecting **Belgium, Bosnia and Herzegovina and Norway.**

Medicines used in cardiology

- Digoxin (cardiac glycoside used in heart failure) affecting the **Netherlands, Greece and Switzerland.**
- Labetalol (IV) (beta-blocker) affecting **Italy, Croatia and Bosnia and Herzegovina.**
- Furosemide (IV) (a loop diuretic used for pulmonary oedema) affecting **Spain, Italy and Bosnia and Herzegovina.**

Various indications

- Dexamethasone (IV) (corticosteroid used for suppression of inflammatory disorders) affecting **Portugal, Spain and Croatia.**
- Levothyroxine (thyroid hormone) affecting **Belgium, Italy, and Germany.**
- Ranitidine (Histamine H2-receptor antagonist) affecting **Croatia, Lithuania and Belgium.**
- Tetracosactide (corticotropin ACTH analogue used to test adrenocortical function) affecting **Croatia, Greece, Spain, Italy and Belgium.**
- Human Immunoglobulin (concentrated antibodies) affecting the **Netherlands, Greece and Italy.**
- Lorazepam (anxiolytics) affecting the **Netherlands, Slovenia, Italy, Switzerland, Iceland and Belgium.**
- Vecuronium (aminosteroid neuromuscular blocking drug used as a muscle relaxant) affecting **Croatia, Norway, UK and Serbia.**

Across Europe hospital pharmacies obtain their medicines from a variety of sources including, but not limited to, the pharmaceutical industry, the generic industry, wholesalers, “specials” companies, other hospitals and their own production. As an update to the 2010 EAHP survey of practice, hospital pharmacists were asked where they obtain their medicines from, and also to try to identify if there is a trend relating to where shortages occur.

Which of the below categories best describes the main external source of supply of medicines to your hospital?

Out of the 367 respondents that answered this question 46.3% (n=170) stated that they obtain medicines mainly from a wholesaler (international/national), with 39.8% (n=146) stating it was direct from the pharmaceutical (originator) company and 12% (n=44) stated that their main external sources of supply was from a generic company.

Only 1.9% (n=7) replied that their main source of supply was from a “specials” company.

A “specials” company describes a manufacturer and supplier of unlicensed medicines or unlicensed formulations which can be purchased by the hospital pharmacy.

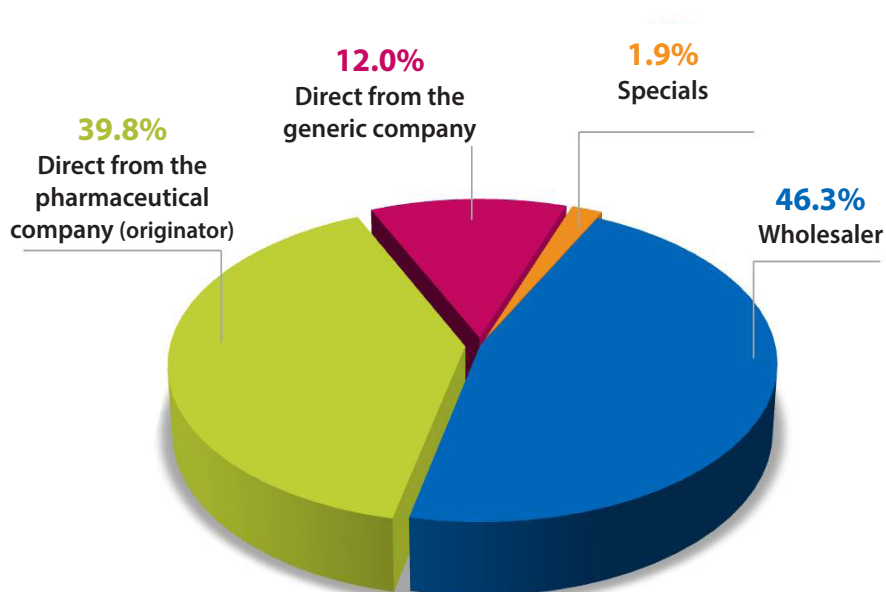


Chart 11 – External source of supply of medicines to the hospital. N=367

The countries indicating direct from the originator company is their principal source of supply were Spain 74.2% (n=54), Belgium 84.4% (n=64), Italy 42.9% (n=21) and Austria 92.9% (n=14).

The countries indicating that direct from the generic company is their principal source of supply were Portugal 44.0% (n=25), Iceland 100% (n=1) and Switzerland 85.7% (n=7).

In addition supply from “specials” companies was also prevalent in Denmark (25%, n=12).

Supply of medicines to hospital pharmacies

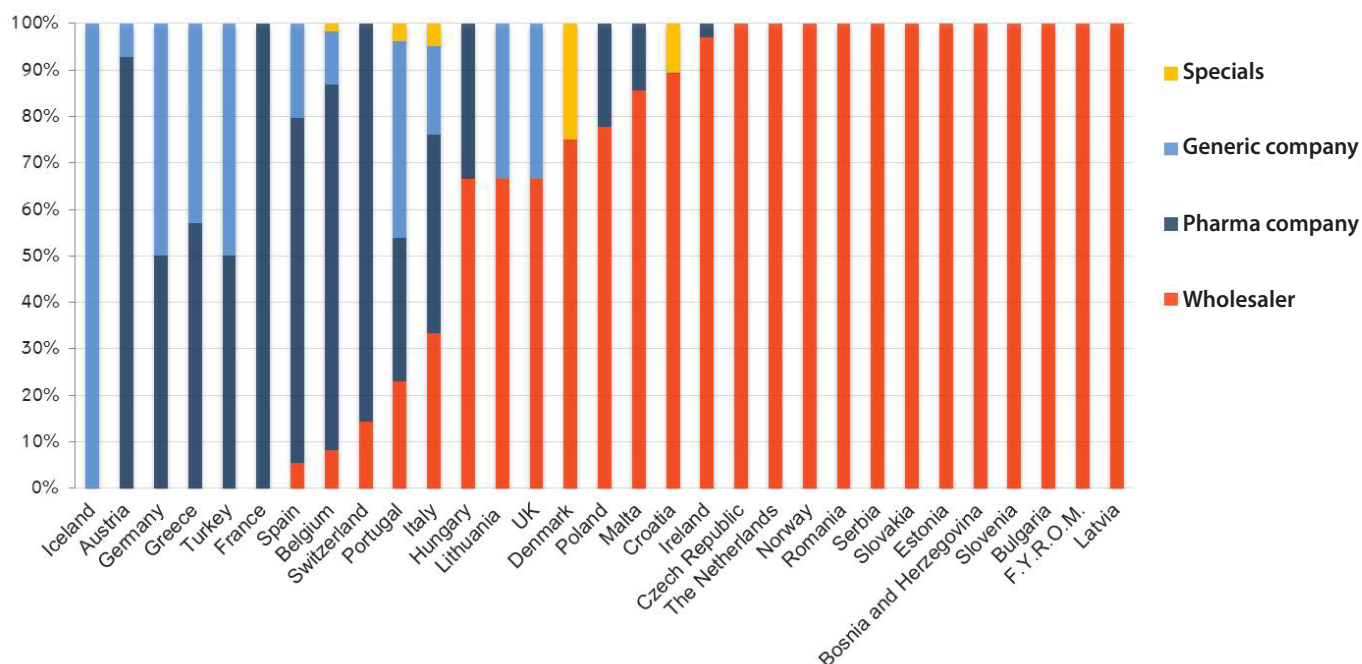


Chart 12 - source of main purchasing by country (% of responses to question 8). N=366
 Countries are listed in the order of the wholesaler % from 0 (Iceland) – 100% (Latvia)

In Denmark, procurement of medicines supply is described as a joint collaboration between the hospitals and the industry, called Amgros. Amgros is the pharmaceutical procurement service for the five regional authorities in Denmark, a public sector organisation responsible for the supply of pharmaceuticals used in public hospitals in Denmark^[18].

Overall, wholesaler supply was indicated by hospital pharmacists in Europe to be the most common source of medicines supply, followed by direct from the pharmaceutical (originator) company and then the generic company.

In a previous EAHP Survey of Practice in 2010 the supply of pharmaceutical products to hospitals was analysed^[17]. In this study most hospital pharmacies were supplied by wholesalers (51%, n=454) followed by the pharmaceutical industry (46%, n=410). This leaves a small proportion of supply coming from other hospitals, specialised production and “in house” production. It is important to note here that there was no distinction in the 2010 Survey of Practice between pharmaceutical companies producing originator (patented medication) and generic companies. Larger hospitals tend to obtain their supply directly from the pharmaceutical industry, and less from wholesalers, and smaller hospitals tend to obtain their supply through wholesalers, with less from the pharmaceutical industry^[17].

Within Europe there is a geographical division regarding supply between north-eastern Europe and south-western Europe. The difference is that supply directly from the pharmaceutical industry is more common in north-eastern Europe and in the south-western part of Europe supply is more commonly from wholesalers^[17]. It was commented that possible reasons for this could include the concentration of the pharmaceutical industry in western Europe, and potential pricing structures in eastern Europe which favour wholesale supply^[17]. In this 2014 survey the respondents again stated that wholesaler was a significant source of supply but slightly lower at 46.2% (n=170) compared to 51% (n=190) than in 2010^[17].

The supply from the pharmaceutical and generic industry is a combined 52% (n=190), increased from 46% (n=410) in the previous survey^[17] It is interesting that the supply direct from pharmaceutical industry seems to be increasing in European hospitals. Overall the answers show the varied sources of supply across Europe illustrating the diversity of involved parties in the medicines shortage problem.

From which category of external supply does your hospital most frequently encounter problems with sourcing specific required medicines?

43.6% (n=155) of respondents said that most problems with supply come from the wholesaler source. 13.5% (n=48) identified generic companies as the most common source of shortages. 38.4% (n=137) said direct from originator companies was the most prevalent source of shortages. 4.5% (n=16) said shortages were most often experienced from “specials” manufacturers.

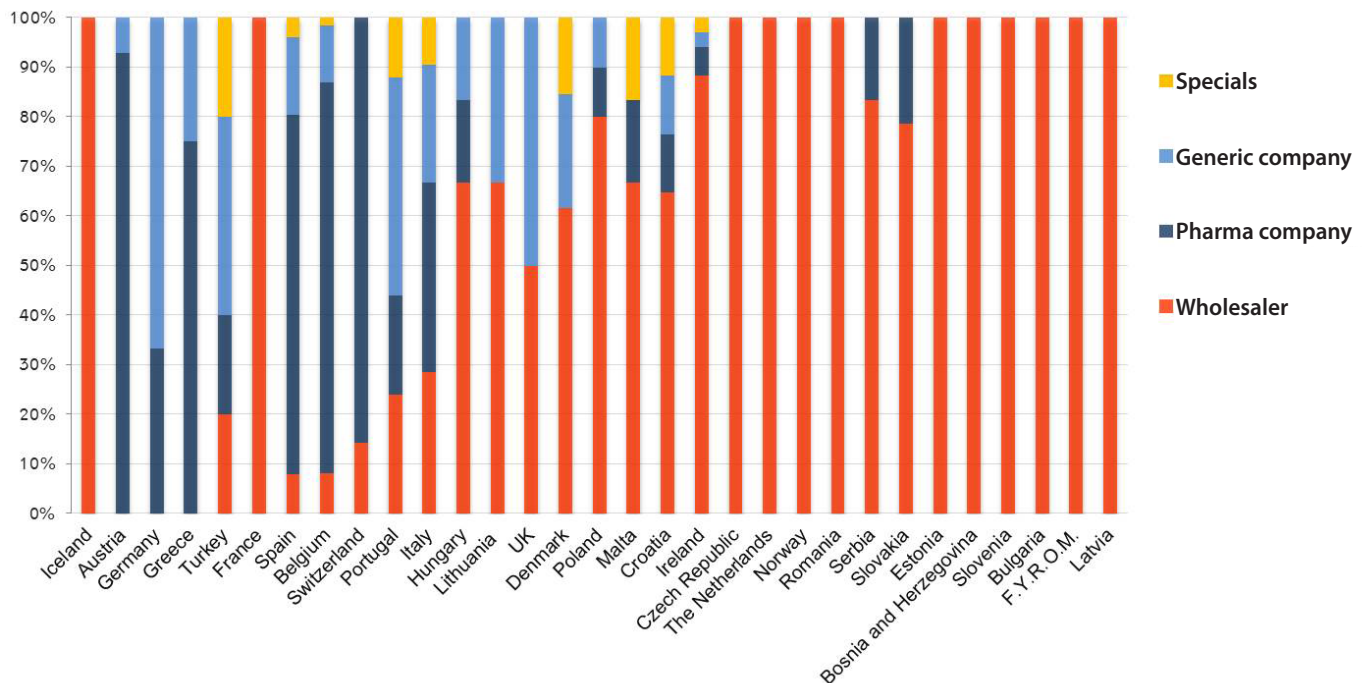


Chart 13 – Countries and which source of supply shortages are most commonly associated with. N=356

Countries with the greatest number of responses and highest prevalence of supply difficulty from wholesalers included Ireland (88.2%, n=30), Serbia (78.7%, n=14), Estonia (100%, n=10), Poland (77.8%, n=9), and Norway (100%, n=9). Wholesalers were also considered to be the source of supply most frequently presenting shortage problems in the countries of the Czech Republic, the Netherlands, Malta, Bosnia and Herzegovina, Slovenia, Bulgaria, Croatia, Denmark, and Hungary.

Countries with the greatest reported prevalence of supply difficulty from originator companies included Spain (72.6%, n=51), Belgium (78.7%, n=61), Austria (92.9%, n=14), Greece (75%, n=8), Poland (80%, n=10), Serbia (83.3%, n=6), and Italy (38.10%, n=21).

Countries with the greatest prevalence of supply difficulty from generic companies included Germany (66.7%, n=3) and Switzerland (85.7%, n=7).

Medicines shortages were reported from a variety of sources in Croatia, Denmark, Turkey and the UK.

Supply of medicines to hospital pharmacies

To our knowledge, this is the first review of the source of medicines shortages affecting hospital pharmacies in Europe. With reference to the previous question, the overall main source of supply of medicines to hospital pharmacies in Europe is from wholesalers and this logically corresponds with a larger proportion of shortages being experienced from this source.

Direct from the pharmaceutical company is the predominant source of medicines supply for approximately 40% of the hospital pharmacists surveyed and this corresponds to the proportion of respondents (38.4%) who state shortages are most commonly experienced from this sector. Generic companies are the main source of supply for approximately 12% of the hospital pharmacists surveyed (see previous question) with 13.5% (n=48) of respondents stating they are also the main source from which they experience shortage problems. 2% of respondents stated that their main source of supply was from “specials” companies, with, 4.5% (n=16) of respondents stating this was the source from which the most commonly experience shortage (see Figure 2).

Overall, shortages are reported as slightly higher for the generic and “specials” industry than the proportion of hospital pharmacists saying this is their main source of supply.

However, there are differences regarding the overall supply and the problem of shortages in particular countries. For example, the experience of medicines shortages are proportionally higher from generic companies in Germany, from pharmaceutical companies in Greece, Slovakia and Serbia, and from wholesalers in France. In Turkey there is a very mixed picture with shortages reported from all sectors.

An increase in the proportion of experienced shortages from “specials” companies compared to the proportion of supply from this source is noticeable in Turkey, Portugal, Denmark, Malta and Croatia.

Source of Supply	Main source of supply (%)	Source in which shortages are most commonly experienced (%)
Pharmaceutical (Originator)	39.8	38.4
Generic	12.0	13.5
Wholesaler	46.3	43.6
Specials	1.9	4.5

Figure 2- Source from which shortages are most commonly experienced (%) n=367

COMMENTS

“Usually it is not related to the type of company.”- **Hospital Pharmacist, Spain** (Illes balears)

“Exchange between other hospitals.” - **Hospital Pharmacist, Belgium** (Brussels)

“The problem is manufacturer, not wholesaler.” – **Hospital Pharmacists, Croatia** (Zagreb)

The time that a medicine is unavailable can be a serious problem for important life-saving medication. The effect that the absence of such a treatment will be different for each medicine and for each patient. Often the hospital pharmacist is only aware of a shortage when they first are unable to obtain a medicine. They are not made aware of a shortage in advance and this makes planning and coordinating supply impossible. Additionally they have no certainty about when a medicine may become available again. This is a source of frustration and puts the hospital pharmacist in a helpless situation.

We asked how long shortages typically have lasted for and for any specific examples of medicines that have lasted for longer periods.

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

387 respondents answered this question. 63.3% (n=245) replied that a typical shortage takes a number of weeks to be solved and 7% (n=27) stated that medicines shortages were typically resolved in a number of days. 29.7% (n=115) replied that in their experience a typical shortage would last a number of months.

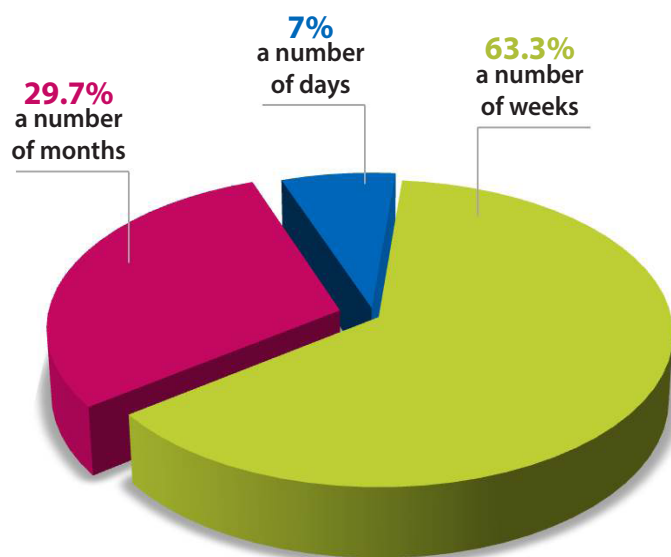


Chart 14 - Typical duration of a medicine shortage according to European hospital pharmacists. N=387

The country in which shortages are most typically reported to be resolved within a number of days is Portugal.

Shortages are reported to be typically resolved within a number of months most commonly in the countries of Turkey, Slovakia and Croatia.

A patient may need his/her prescribed treatment and, in the situation of the hospital pharmacist not being able to obtain, the patient may deteriorate, require alternative treatment or suffer an increase in symptoms.

The impact to patient care from medicines being unavailable for weeks and months at a time occurs to the authors to be a high priority for further research.

Duration of Shortages

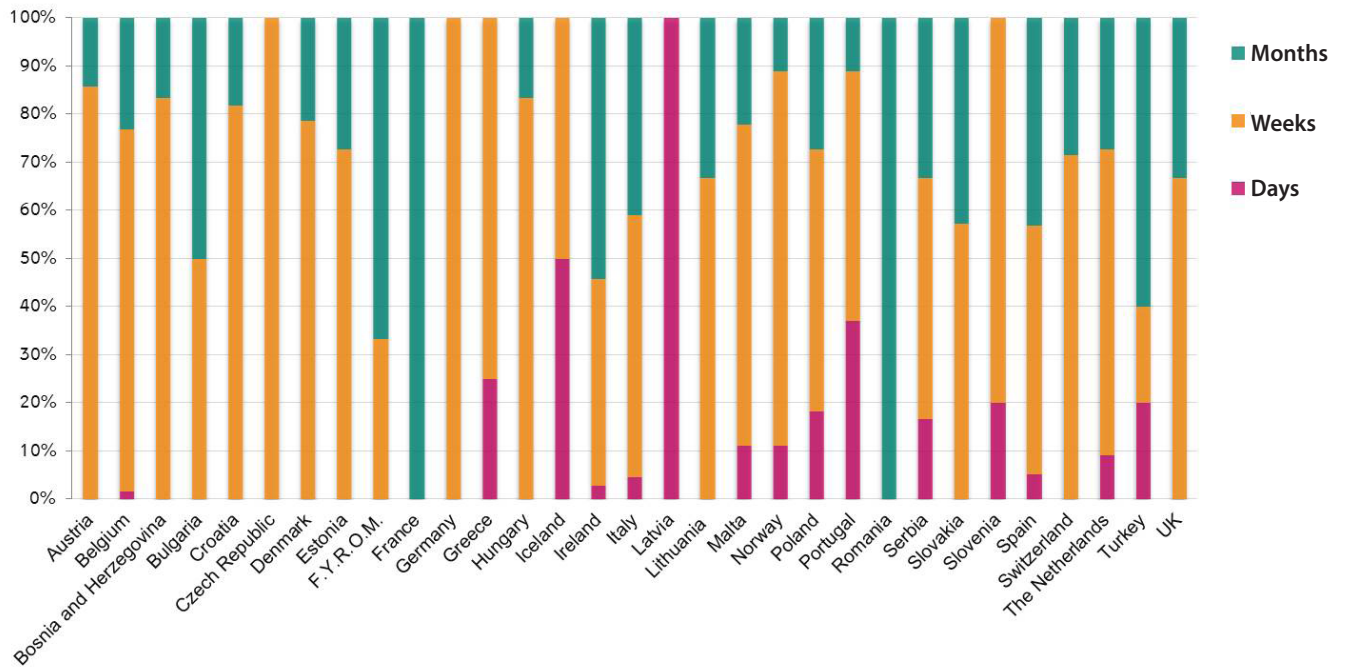


Chart 15 - Typical duration of a shortage per country. N= 387



What is the longest duration that you can recall a medicine being in shortage for?

A shortage of a specific medicine can have a differing severity on the pharmacy service and the treatment of the patient. Medicines with unreliable supply for months or even years can dramatically affect the treatment of a particular patient or the operation of a hospital pharmacy service.

The high number of answers to this open-ended question and the frequent responses about shortages lasting longer than the year is notable. It provides a strong indication that medicines shortages are not of a temporary nature and for some patients can mean long term diversion from the recommended treatment, relying on other, possibly less efficacious or more expensive, alternatives.

COMMENTS

“Caelyx™ [liposomal doxorubicin used in cancer treatment] was affected for over a year and DepoCyte™ [liposomal cytarabine also used in cancer treatment] was in shortage for several months.” - **Hospital Pharmacist, Norway**, (Oslo)

“Halothane [inhaled anaesthetic] was unavailable for 2-3 years.” - **Hospital Pharmacist, Malta**

“Trifluoperazine [dopamine antagonist] and Praziquantel [used to treat hookworms] were unavailable for several years.”
Hospital Pharmacist, Spain (Catalunya)

“Decan multivitamins for parenteral nutrition was unavailable for years.”
Hospital Pharmacist, Spain (Madrid)

“Lorazepam [anxiolytic] was in shortage for more than two years.”
Hospital Pharmacist, Italy

“Fludarabine [antimetabolite used in cancer treatment] was short for more than one year.”
Hospital Pharmacist, Belgium (Antwerp)

“Magnesium sulphate ampoules, dexamethasone IV [acidexam] and colimycin [powder] were all in shortage for over a year.”
Hospital Pharmacist, Belgium (East Flanders)

“Synacthen™ and Nuvacthen™. They have not been available for 9 months. We do not know when they will become available again.” - **Hospital Pharmacist, Spain**

The impact of a shortage can be felt by the hospital pharmacist, the hospital pharmacy department, other healthcare professionals and, most importantly, by the patient. A medicine being unavailable for a long period of time could be a particularly serious issue for patients with life threatening conditions (eg. cancer). The absence of medication such as immunosuppressant therapy, anti-epileptic and treatments for rare diseases can have a significant impact on these patient groups. Real life examples of the impact for patients are shared elsewhere in this report and include delays in surgery, chemotherapy treatment and disease progression.

Impact of Shortages

In the case of a medicine in short supply, how often do you estimate your hospital is able to provide treatment to a patient by providing a therapeutic equivalent or near equivalent medicine, without major disruption to their treatment?

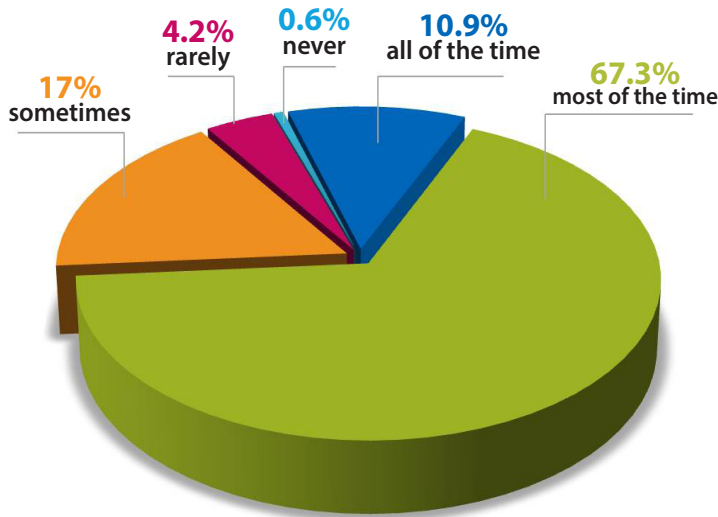


Chart 16 - show the ability of pharmacists to manage shortages in their hospitals. N = 371

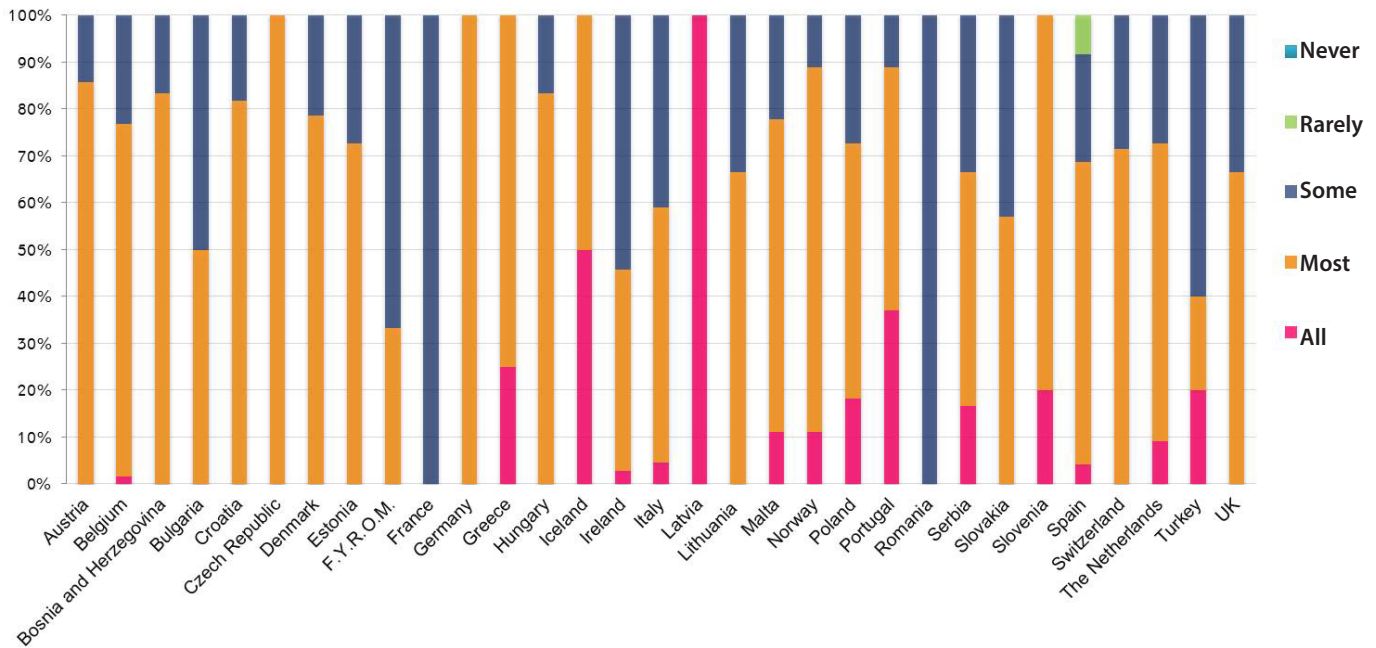


Chart 17 - Ability of pharmacists to manage shortages in each of the countries. N=371

As **chart 16** indicates, a large proportion of hospital pharmacists (78.2%, n=290) in various countries felt that in the event of a medicines shortage they could provide care to patients without major disruption (all of the time or most of the time). Nevertheless, the chart also shows that for nearly all countries there are a proportion of hospital pharmacists who feel that this can only happen some of the time, and therefore some of the time patients do suffer major disruption to their treatment.

In Ireland 54.3% of the responses (n=35) stated that patients can be given pharmaceutical care without major disruption only some of the time. Large responses for this option were also seen from Turkey (60%, n=5), the Former Yugoslav Republic of Macedonia (66.7%, n=3), Slovakia (42.9%, n=14) and Italy (40.9%, n=22).

The results indicate that whilst most of the time the hospital pharmacist is able to take steps to secure a therapeutic alternative for a medicine in shortage, all too often this is not the case. There is a hidden story here of patients not being able to get the medicines they require due to supply shortage that deserves further investigation.

The results also give an indication of the enormous work conducted by hospital pharmacists to track down alternative supplies in order to maintain levels of patient care, highlighted further by the responses received to the subsequent question.

In an average week in your hospital, how much time (staff working time) do you estimate is diverted because of drug shortage problems?

Hospital pharmacists have to work up to 5 hours per week to deal with shortages

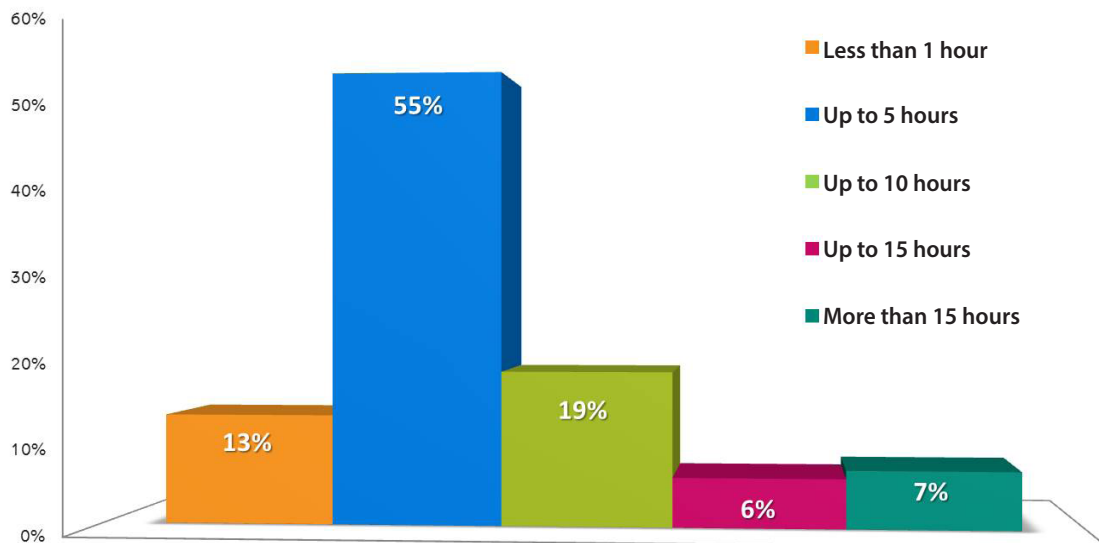


Chart 18 – Amount of time that staff working in the hospital pharmacy have to allocate to dealing with medicine shortages. N=369

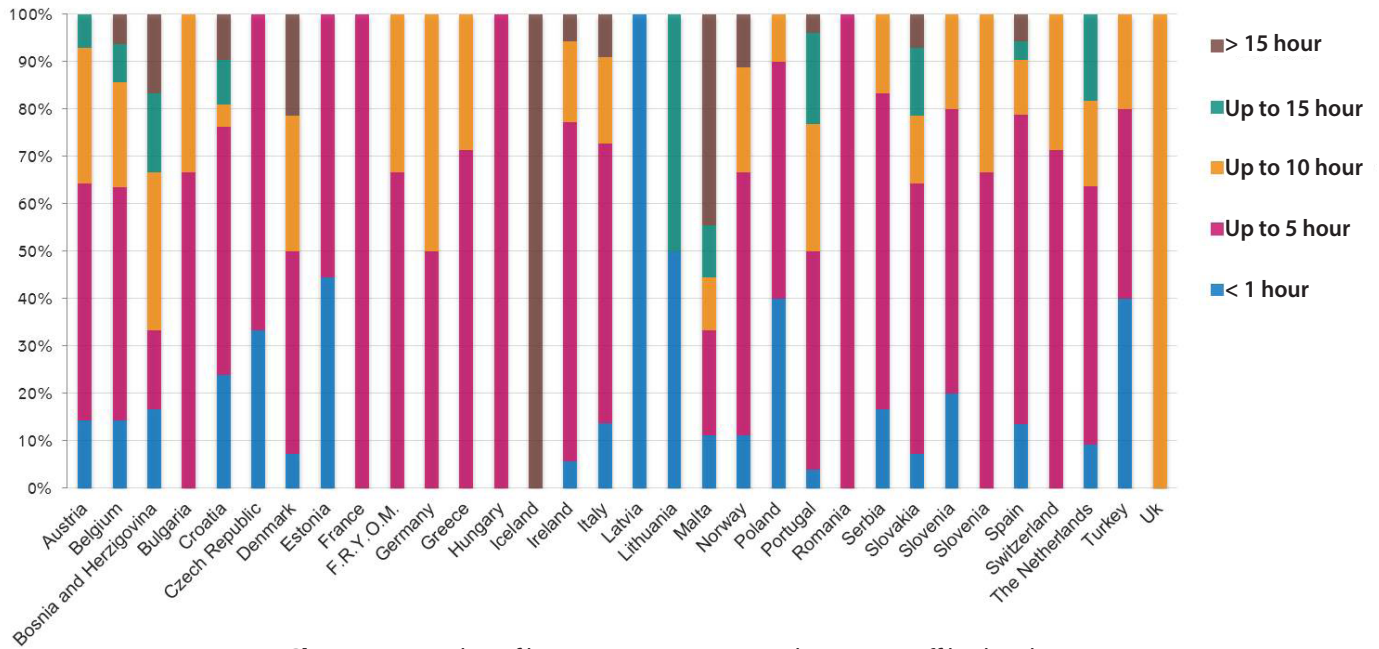


Chart 19 - Number of hours, as a proportion, pharmacy staff had to devote to managing the shortages problem by country. N = 369

COMMENTS

“More than 15 hours – the accumulation of pharmacist, technician and pharmacy assistant would = 19.25 hours.”
Hospital Pharmacist, Belgium (East Flanders)

“More than 15 hours – not personally but as a pharmacy department in general 1.5 FTE [full time equivalent] pharmacists work solely on chasing out-of-stock items.” - **Hospital Pharmacist, Malta**

“15 working hours is only administration of shortages. Unknown number of hours are spent on the wards with information and new routines.” - **Hospital Pharmacist, Norway**

“Up to 10 hours – this applies to the staff only in the hospital pharmacy”
Hospital Pharmacist, Slovenia

The lost and diverted time in the hospital pharmacy given to tracking down medicines to meet a patient’s prescribed needs is one of the most frequent anecdotally reported problems to EAHP of the damaging impact medicines shortages have on the delivery of healthcare. These results confirm that problem and it is well noted that many comments estimated over 15 hours of lost time due to shortages with some hospital pharmacies needing to employ full time equivalents to deal with the problem. In the context of cost-efficient health services, the problem of medicines shortages is creating drag and inefficiencies for the hospital sector and, beyond the patient impact, re emphasises the need for health system managers and political decision makers to take action.

In the USA similar amounts of hospital pharmacist time has been lost due to dealing with medicine shortages, (9 hours per week)^[19] and this EAHP research adds to a picture^[19] of considerable burden being created. Time spent on dealing with shortages is not limited to hospital pharmacists either, with much time lost in the community pharmacy sector as well.^[20]

The medicines shortage problem is thus not only a cross border threat to public health within the EU. It contravenes EU ambitions to create sustainable and efficient healthcare systems.

Do you agree with the following statement? "Medicines shortages in my hospital are having a negative impact on patient care."

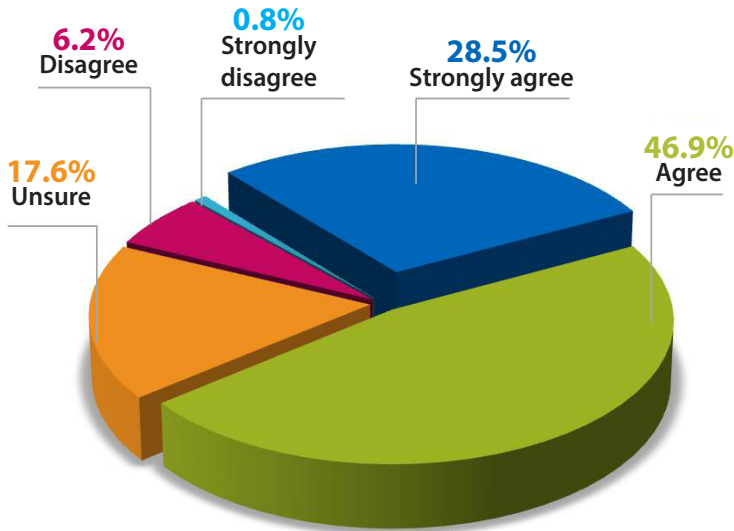


Chart 20 – Level of agreement with the statement "Medicines shortages in my hospital are having a negative impact on patient care". N=369

The countries agreeing most strongly with this statement are:

Strongly agree: UK (100%, n=3), Malta (66.6%, n=9), the Former Yugoslav Republic of Macedonia (66.6%, n=3), the Netherlands (62.5%, n=8) and Hungary (60%, n=5)

Agree: Czech Republic (100%, n=3), Lithuania (100%, n=2), France (100%, n=1), Iceland (100%, n=1), Switzerland (100%, n=7)

The countries disagreeing most strongly with this statement are:

Strongly disagree - Croatia (4.76%, n=21), Spain (1.92%, n=52)

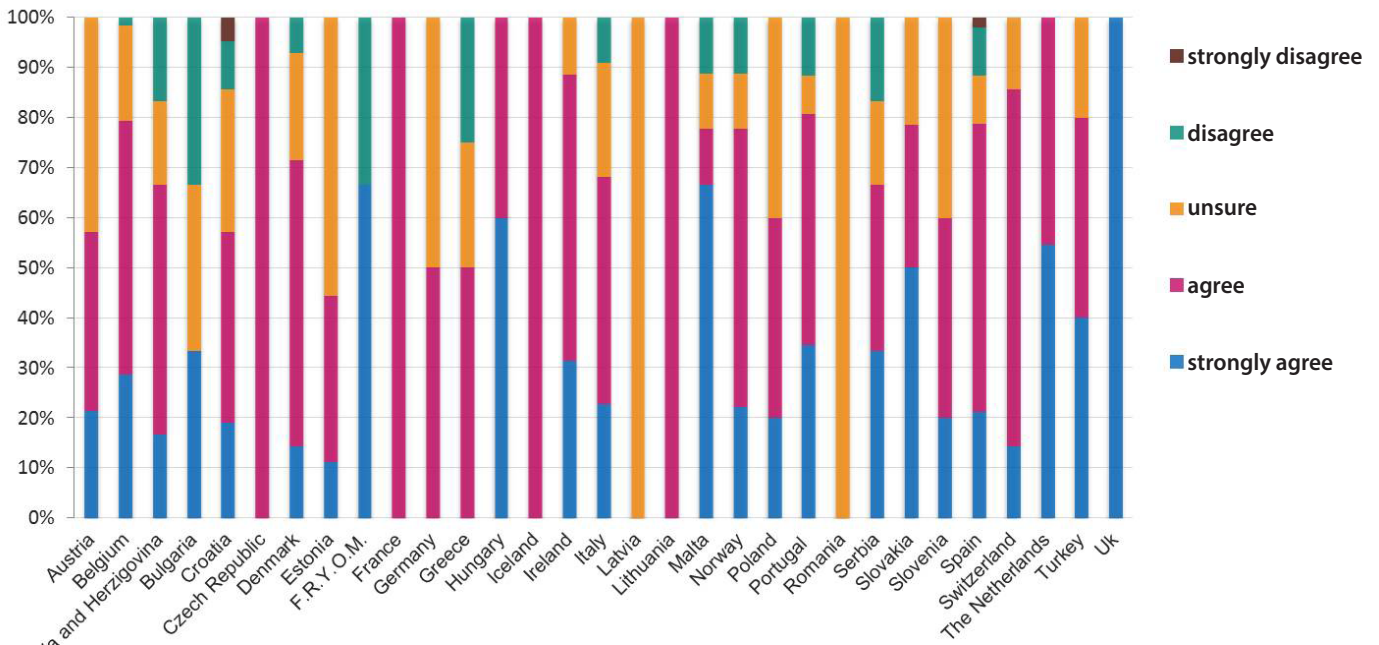


Chart 21 – Showing the level of agreement (as a proportion) with the statement by country. N=369

COMMENTS

"I work as a clinical pharmacist in the gastroenterology department. In the past year mesalazine rectal preparations have always been problematic causing a lot of undue hassle to patients and also to staff working within this fields."

Hospital Pharmacist, Malta

"Cifovir IV: treatment had to be postponed. Melfalan IV: treatment had to be divided in two IV administrations instead of one and using an alternative drug often creates confusion with staff nursing and doctors."

Hospital Pharmacist, Belgium (Leuven)

"When there is a medicine shortage, we try to obtain the same product from another country, mostly against a higher price. Sometimes the hospital is taking these costs, mostly the patient." - **Hospital Pharmacist, Belgium (Antwerp)**

"Patients need to come to the hospital to get medications, when it is not necessary for them, so they lose time and also they are never sure they are going to get enough medication." - **Hospital Pharmacist, Spain**

The strong agreement with the statement indicates the general perception of hospital pharmacists on the question. This corresponds with the previous EAHP survey in 2013^[6] in which 50.7% of pharmacists surveyed (n=266) stated that there had been a negative impact to patient care. In this new study the agreement as to the negative effect medicines shortages have on patient care has increased to 75.3% (n=278) either strongly agreeing (28.5%, n=105) or agreeing (46.9%, n=173) with the statement presented.

Possible reasons for how shortages negatively impact patient care are explained in other parts of EAHP's 2014 survey but include: not being able to provide the patient with a therapeutic equivalent; delays in the getting the medicine to the patient; diversion of hospital pharmacist time from other tasks important to patient care; and increased stress levels in a safety critical environment.



Examples of the impact of shortages on patient welfare

COMMENTS

"A shortage of Kwells™ [hyoscine] has meant our clozapine [used for schizophrenia] patients are suffering from hypersalivation [excessive salivation, known side effect of clozapine] unnecessarily." - **Hospital Pharmacist, UK** (Staffordshire)

"Availability of emergency prefilled devices [adrenaline, atropine] lead to multiple prolonged meeting and advice from resus committee, advice from emergency medicine specialists, re-training of clinical staff that may be required to administer." **Hospital Pharmacist, Ireland**

"Teicoplanin [antibiotic] shortage prompted review and change of antibiotics for many patients in our hospital. These alternative agents had a higher association with clostridium difficile and was not the optimum choice for patients." **Hospital Pharmacist, UK** (Cheshire)

"We had a shortage of bosentan [vasodilator antihypertensive drug] for two months, due to which most patients with pulmonary arterial hypertension had deterioration of their disease." - **Hospital Pharmacist, Bosnia and Herzegovina**

"Change of antimicrobial therapy for less efficient, for example: shortage of amikacin [aminoglycoside antibiotic] caused that for some resistant bacteria (that amikacin showed best efficiency in treatment and antibiotic therapy) had to be changed for less efficient, or the change had to be done in the middle of therapy." - **Hospital Pharmacist, Croatia**

"There were delays in treating patients or having to maintain a patient on intravenous treatment just because the oral alternative was not available. In addition, patients who get their out-patient treatment from an NHS pharmacy sometimes require hospital admission because they are not available." - **Hospital Pharmacist, Malta**

"They result in much higher use of unlicensed medicines which carries an inherent risk." - **Hospital Pharmacist, Ireland**

"Oncology therapy has to be postponed, which is very stressful and sometimes harmful for the patient." **Hospital Pharmacist, The Netherlands**

"Cytarabine (antimetabolite) shortages threaten haematology patients. Fortunately, we did not run out of drugs, but we had to use very small vial sizes for drug preparation. Imagine preparation of 4000mg cytarabine with 40 vials of 100mg vials." **Hospital Pharmacist, Poland**

"Bumetanide tablets and spironolactone [diuretics used in cardiology] were out-of-stock leading to patients being admitted with oedema and exacerbation of heart failure. Also a ketoconazole shortage has led to a patient readmitted with Cushing's symptoms." - **Hospital Pharmacist, Malta**

"Shortages of intravenous immunoglobulin [concentrated antibodies] create several problems concerning patient safety." **Hospital Pharmacist, Greece**

How is a medicine in short supply usually dealt with to minimise the impact on patient safety?

Possible answers were:

- substitute (without consultation with the prescriber/the patient)
- inform prescriber and recommend an alternative
- inform prescriber of the shortage
- investigate when supply will be restored and plan stock accordingly.
- attempt to source the medicine from an alternative supplier (including another country)
- change the formulary based on the information provided

Multiple answers and additional comments could have been provided when answering this question.

The most common action that was taken practically was “informing the prescriber and recommend an alternative” with 82.9% (n=286) selecting this option.

35.1% (n=121) of the respondents said they typically substituted the medicine with an available alternative without consulting the prescriber or the patient.

58% (n=200) informed the prescriber of the shortage.

65.8% (n=227) investigated when supply would be restored and planned accordingly.

67% (n=231) attempted to source the medicine from an alternative supplier (including another country).

The least common action was changing the formulary based on the available information with only 17.1% (n=59) choosing this action.

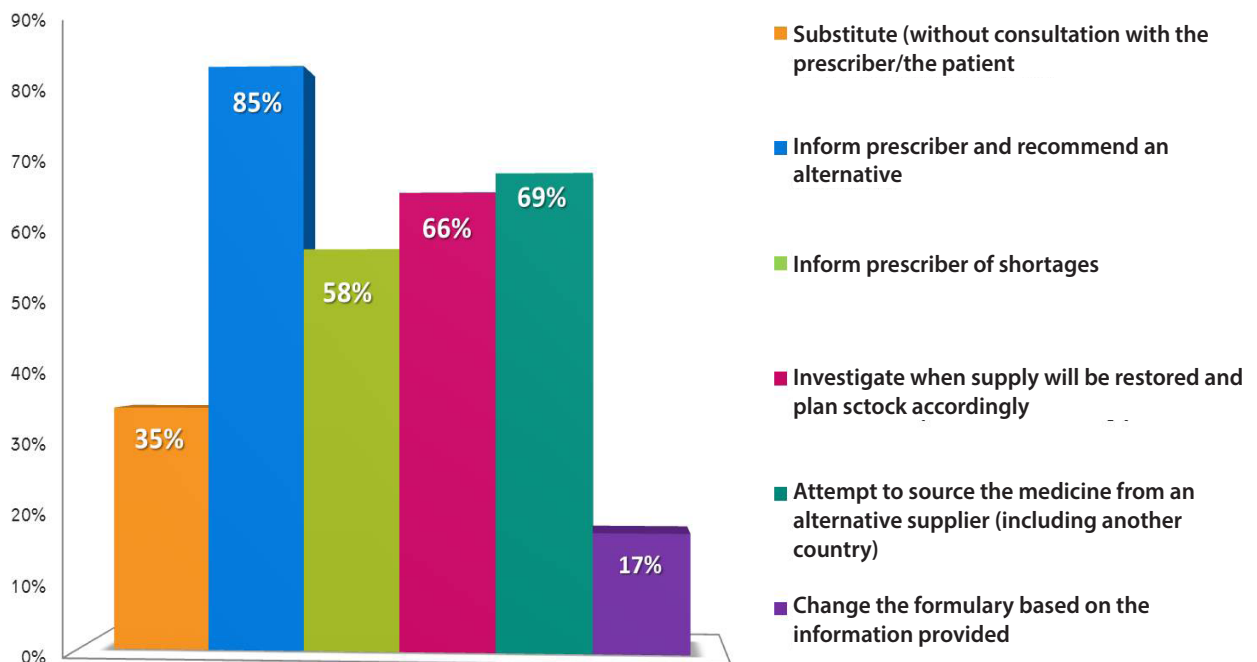


Chart 22 - Typical actions hospital pharmacists undertake in the event of a shortage. N=345

COMMENTS

“Changes may be needed to the IV Guidelines.”

Hospital Pharmacist, Ireland (Dublin)

“Borrow from other hospitals if possible.”

Hospital Pharmacist, Portugal (Lisbon) and **Croatia** (Zagreb)

“Discussion in the Pharmacy and Therapeutic Committee.”

Hospital Pharmacist, Portugal (Lisbon)

“Change formulary only if no other solution.”

Hospital Pharmacists, Greece (Athens)

“Due to shortage of labetalol injection, we had to relocate the last packages through hospitals within the region in order to treat patients who did not respond on alternative therapies.” - **Hospital Pharmacist, Norway**

When asked how a medicine shortage is handled within a hospital pharmacy it is clear that a combination of measures are used to varying degree, although all the proposed solutions at a local level were described by respondents.

The difference seen with recommending an alternative and just informing the prescriber shows that hospital pharmacists are taking responsibility for proactively advising the prescribers of the available products, and what would be appropriate for individual patients. This shows the skill and importance of hospital pharmacists as experts in medication management.

The topic of how to deal with shortages has led to various guidelines being produced from professional organisations. These include:

The **American Society of Health-System Pharmacists (ASHP)** produced guidance including a description of the contributing factors to the problem of shortages, a phased approach to planning for drug product shortages, strategies for prevention and explaining some of the government intervention at the time^[21].

Best practice guidance for ensuring the efficient supply and distribution of medicines to patients has been jointly published by the representative bodies of the supply chain along with the **UK Government and regulators**^[22]. Key points include: an expectation that, under normal circumstances, pharmacies should receive medicines within 24 hours; the importance of regular communication between manufacturers and wholesalers so that all parties have a good understanding of the supply and demand for particular products; and, the need for all in the supply chain to have contingency arrangements in place to source supply where there are supply difficulties.

The **Royal Pharmaceutical Society (RPS)**, the professional body for pharmacists in the UK has also published guidance specifically looking at the problem of medicine shortages in the hospital environment^[23]. The leadership role of the chief pharmacist is highlighted here, ensuring policies are in place to deal with shortages including a risk assessment and a managed allocation of limited stock together with medical colleagues.

This guidance was further explored in articles in the *European Journal of Hospital Pharmacy*^[24] and the *Pharmaceutical Journal*^[25].

Actions taken to minimise the impact on patient care within the hospital

Possible answers were:

- reassign staff work profiles and job descriptions (i.e. devote staff resources more specifically to dealing with shortages)
- create new communication systems and tools to alert prescribers and other hospital staff about the presence of shortages and the need to substitute replacement therapies
- readjust budget plans due to additional expenditure caused by shortages (e.g. needing to use more expensive replacement therapies)
- cancel practice improvement and development initiatives due to resources having to be reassigned to dealing with the shortage problem
- no changes required

The most common change in practice was the creation of communication tools to inform prescribers and other healthcare professionals of the situation. This was selected by 62.5% (n=205) and was followed by a review of the budget 34.8% (n=114).

29.9% (n=98) said they had reassigned staff to cope with medicine shortage problems and 20.1% (n=66) cancelled service improvement, with 13.4% (n=44) not requiring any change in practice to cope.

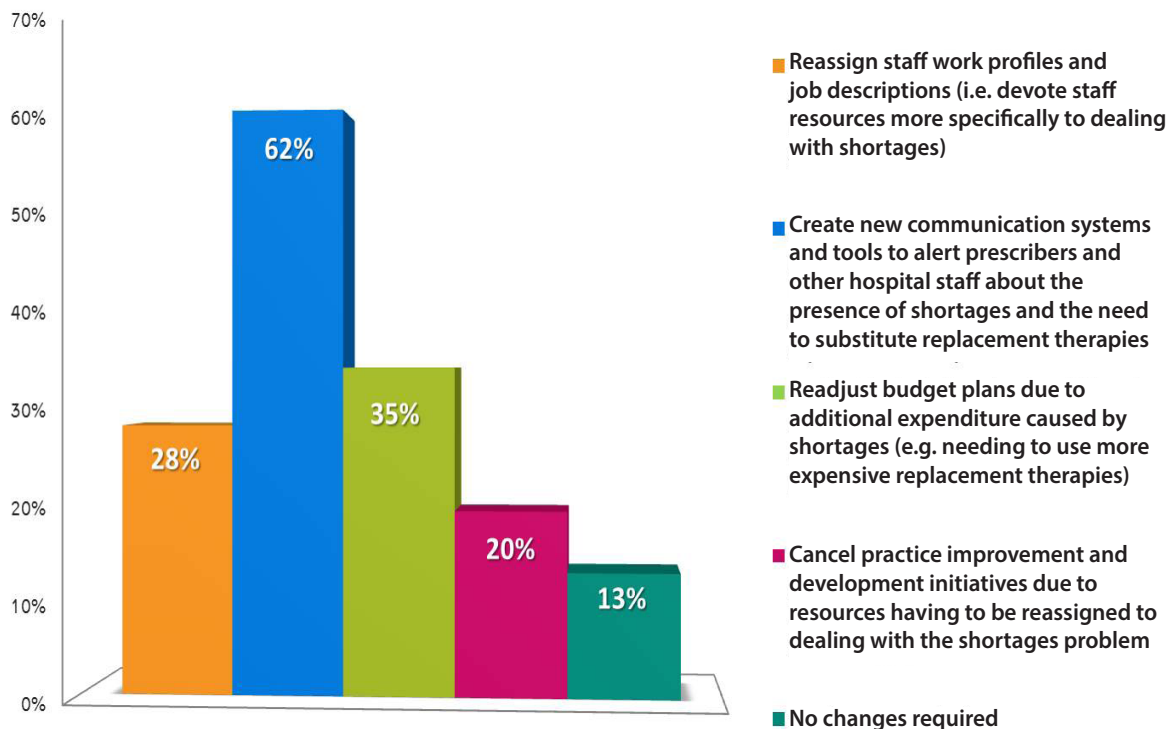


Chart 23 - New actions required of hospital pharmacists in the event of a shortage. N=328

COMMENTS

“No changes required because it has been like this forever, we just adjusted to it.”

Hospital Pharmacist, Belgium (Brussels)

“Increased the role of hospital pharmacy in the supply of medicines and decision making process.”

Hospital Pharmacist, Portugal (Lisbon)

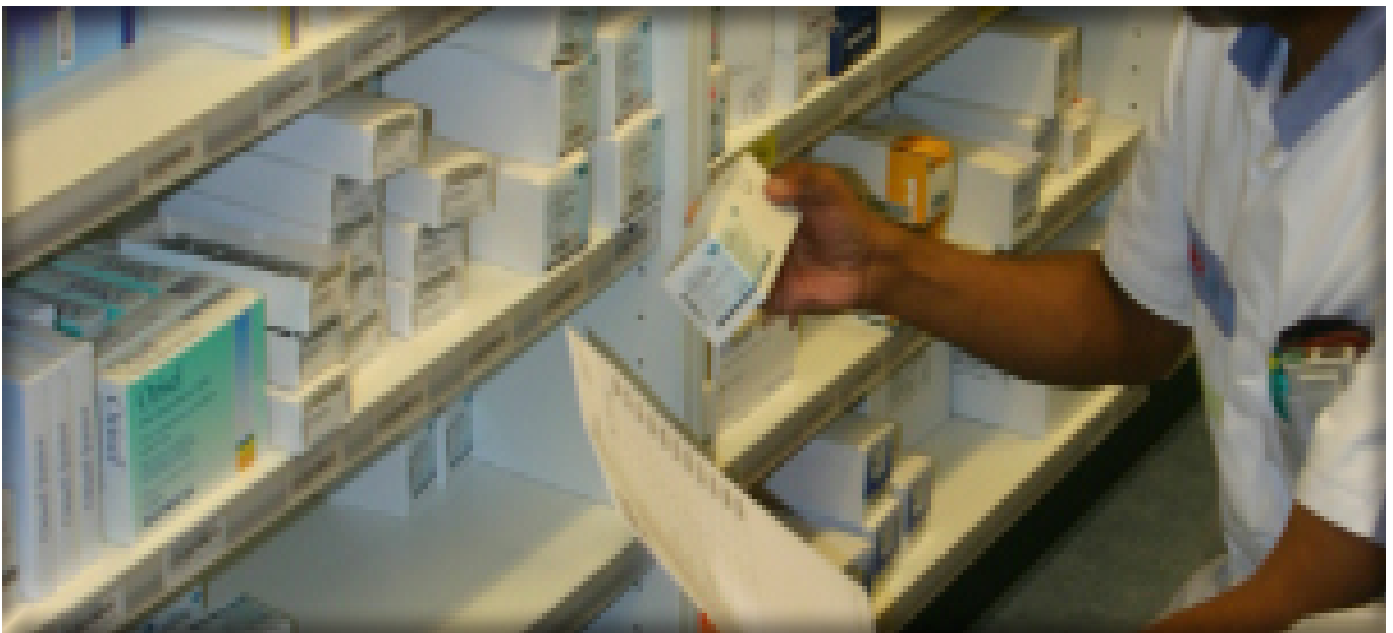
“We needed to increase production of medicines.”

Hospital Pharmacist, Poland (Wroclaw)

The responses to this question underline the communication challenges posed by medicines shortages. This applies to both the need for pharmacists to get the right information to prescribers, nurses, patients and others, but also to receive the right information to pass on, for example why the shortage is in occurrence, how long it may last, and what alternatives are available. Only a few countries have national databases to support this activity, including Italy and the Netherlands. Such informational databases have been in existence in the USA for some time however. EAHP and its members are calling for a European wide database of current shortages, their causes and available alternatives, to be run by the European Medicines Agency on a similar basis to the FDA database in the USA. This would go a long way towards addressing the current ‘information gap’ about pan-European medicines shortages and greatly inform the much-needed EU-led response.

The results also underline the deleterious impact shortages have on hospital budgets, with often more expensive medicines needing to be procured as an alternative, and an additional drain being placed on staff resourcing.

A high percentage of respondents also indicated that other services offered by hospital pharmacy (such as clinical pharmacy services) have suffered as a consequence of shortage problems.



Examples of the impact medicines shortages have on patient welfare

COMMENTS

"Lack of etoposide [anti-cancer drug] forced us to change doctor's treatment of choice in many oncology malignancies [conditions]. Irregular daunorubicin [another anticancer drug] consignments force us to dose reductions, or treatment change. Currently we're expecting shortages of thalidomide [used for a specific cancer], which will probably force us to put patients on different treatment for multiple myeloma." - **Hospital Pharmacist, Poland**

"Hospital pharmacies are usually not informed about the shortage until they try to order and are already low on stock." **Hospital Pharmacist, Switzerland**

"Rabies vaccine only reserved for patients requiring vaccine after being bitten and not for prevention." **Hospital Pharmacist, Switzerland**

"Shortage of some transplant drugs implied delay of bone marrow transplant. Shortage of lyothronine implies use of an alternative, much more expensive, shortage of larger dosage forms of dexamethasone [steroid] implies patients having to take 16 tablets for each dose." - **Hospital Pharmacist, Portugal**

"The amoxicillin/clavulanic acid shortage [antibiotic] affected all of our departments, while the current benzylpenicillin [antibiotic] issue strongly hinders the capacity of our toxicology department. The status and availability of the botulism antitoxin in the region is clearly worrying." - **Hospital Pharmacist, Hungary (Budapest)**

"Having difficulty maintaining calcium levels in infants due to calcium Sandoz™ shortage." - **Hospital Pharmacist, Ireland**

"When there is a shortage on medicines for ambulatory patients, we do not give them the treatment for one month as it should, and they have to come often to the hospital pharmacy (we do this to avoid any intermission on the treatment of any patient)." - **Hospital Pharmacist, Portugal**

"Commencing antidepressants [nortriptyline, clomipramine] whilst in patient and then not being able to source suppliers or delays in treatment whilst in community - negating any benefit and in some circumstance requiring either journey to hospital for supplies (up to 5 hours) or even relapse in condition and further hospital stays." - **Hospital Pharmacist, Ireland**

"There is insufficient knowledge of near equivalent medicines or medicines with no equivalent medicine. This leads to therapy with lower dosage or providing the equivalent medicine too late." - **Hospital Pharmacist, Belgium (Antwerp)**

"Depocyte™ [liposomal cytarabine™ – anticancer drug] was unavailable for several months. It is used for patients with lymphoma and CNS infections. Alternative therapy is cytarabine [different formulation] which has to be given more often. Maybe the effect will be the same, but it has to be injected more often and it is painful for the patients." - **Hospital Pharmacist, Norway**

Specific examples of medicines in shortage experienced in the past year.

The products listed below were reported as currently still in shortage or still affecting patients who require them:

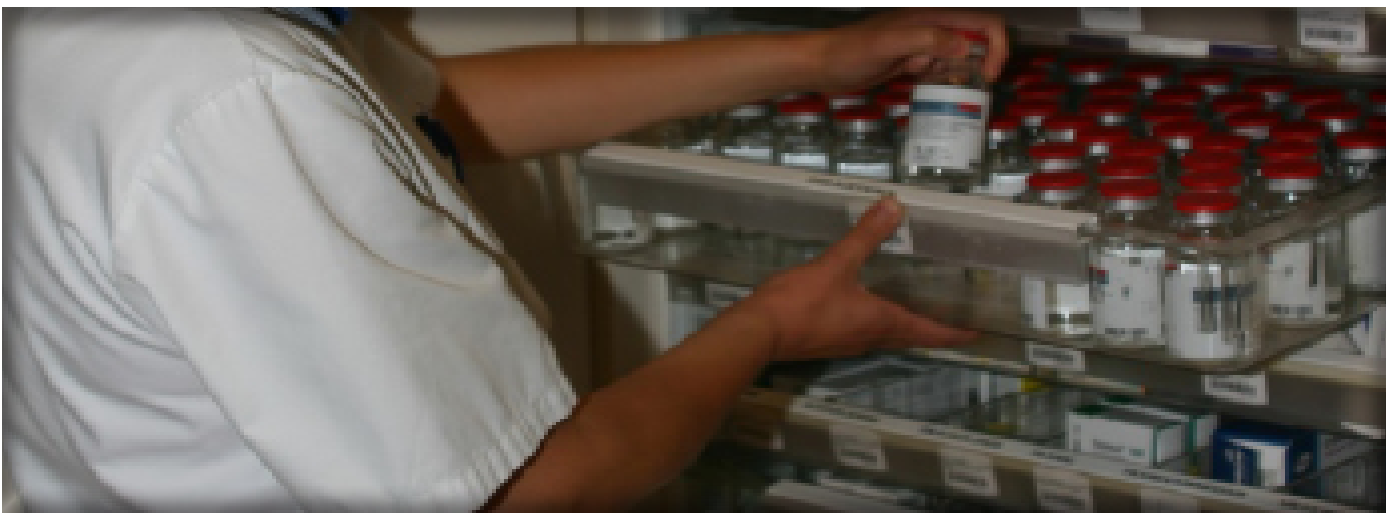
- 5-Fluorouracil
- Amoxicillin (Oral)
- Carboplatin
- Cisplatin
- CoAmoxiclav
- Dexamethasone (Intravenous - IV)
- Digoxin
- Doxorubicin (Liposomal)
- Etoposide
- Furosemide (IV)
- Gentamicin (IV)
- Ibuprofen (IV)
- Human Immunoglobulin
- Labetalol (IV)
- Levothyroxine
- Linezolid
- Lorazepam (IV)
- Melphalan
- Meropenem
- Methotrexate
- Morphine
- Oxaliplatin
- Ranitidine
- Tetracosactide
- Tramadol (IV)
- Vecuronium
- Vincristine

Those highlighted in blue are listed in the shortage catalogue of the FDA at the time of writing^[26]

Those listed in green are listed in the WHO Essential medicines list (2013)^[27].

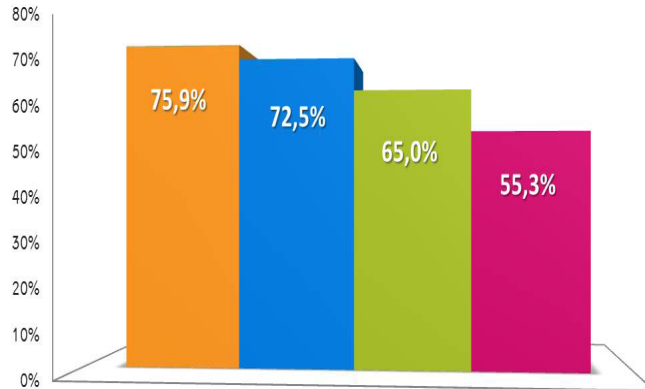
The medicines in red are listed in both.

The medications listed above include antibiotics, chemotherapy agents, cardiology products and pain medication. Investigations into the current shortages should be conducted by both national and European regulatory bodies.



Proposed policy solutions on medicines shortages

The problem of medicines shortages has many causes and therefore it is sensible to suggest that a multitude of policy solutions will be required to address this issue. Participants were asked to select and comment on a number of policy options which could be implemented to tackle the medicines shortages problem. It was possible to select more than one option.



■ Greater legal clarity on the responsibility of manufacturers

■ A comprehensive database, run by the European Medicines Agency, of all medicines reported to be in current shortage in at least 5 EU Member States

■ A high level investigation, led by the European Commission, of the holistic causes of medicine shortages in Europe

■ Annual reporting of the extent of the medicines shortage problem by the European Medicines Agency

Chart 24 - Level of support for the proposed solutions/improvements in dealing with shortages. N = 327

The two most popular options (over 70% of those who responded) are a) more legal clarity on the responsibility of manufacturers to openly report forthcoming disruption, and b) a central database hospital pharmacists could consult with recommendations.

Once more, the results underline the communication challenge hospital pharmacists face in advising prescribers, patients and others about shortages problems, and receiving far too little information about the cause and likely length of medicines shortages to make robust contingency plans.

The results underline the strong support from the profession for EAHP's principal advocacy messages about medicines shortages at the European level – the need for a European database of medicines in shortage across Europe, managed and overseen by the European Medicines Agency, including information on the likely duration of the shortage, and available alternatives. This should be underpinned by strengthened legal requirements on manufacturers to report forthcoming disruptions in supply. Such actions have been taken in the United States of America (USA) with positive impact^[28] and should be replicated in the European Union.

According to the *European Commission directive 2001/83/EC, Article 23a*, market authorisation holders for products marketed in Europe Union member states are required to give two months notification to regulatory authorities when market access to a product will be temporarily or permanently interrupted^[29,30]. EAHP considers investigation is required on the extent to which these legal requirements are being met in actuality.

COMMENTS

“Hospital pharmacists should not only go for the lowest possible price during the acquisition of medicines. Companies that can guarantee a reliable and better supply should be rewarded with a better price!”

Hospital Pharmacist, the Netherlands (Limburg)

“In this case we increase the purchasing and define the safe procedure (LASA, High risk meds and so on). Sometimes it is a big problem to ensure the continuity of care.” - **Hospital Pharmacist, Italy** (Sicily)

“Every country needs to have a form of national registry of medicine shortage online, where a certain medicine shortage can be registered at least one month before the shortage, so that medical institutions could secure themselves from the shortage. Drug manufacturers are aware of the medicine shortage before it happens and there should be legal obligations to post it online, preferably on site that is meant for it, or at least on the site of national drug agency. Hospitals should have a form in which can be reported how a medicine shortage affects a patient’s therapy.”

Hospital Pharmacist, Bosnia and Herzegovina

“In my hospital, we spend too much time to managing drugs shortage: it is a recurring problem. A solution: an European network.” - **Hospital Pharmacist, Italy**

National level approaches to address the medicines shortage problem e.g. websites with information about current shortages

A summary of the responses highlighting the national attempts to solve the shortages problem can be found below. These vary from: no obvious national system in place; a method to report shortages to the national agency; a publicly available database; and, members of staff actively investigating and attempting to resolve the shortage.

In **Austria** shortages can be reported on the national ministry of health’s website www.basg.gv.at. This website has been launched this year (2014) and can be used to share news about shortages in Austria.

In **Belgium** hospital pharmacists can send an email to stockbreuken@vza.be which will alert other colleagues working in the Flemish region of Belgium about this shortage.

Additionally the website of the *Agence fédérale des médicaments et des produits de santé (AFMPS)* indicates medicines in short supply and reasons if it is aware of them: http://www.fagg-afmps.be/fr/items-HOME/indisponibilites_de_medicaments/

The Belgian authorities make recommendations to healthcare professionals in the event of a discontinuation regarding the treatment of patients prescribed that product regarding therapeutic alternatives.

Liste des médicaments à usage humain et vétérinaire indisponibles 15/09/2014

Nom du médicament	Forme pharmaceutique	Emballage	Conditionnement	CNK	Titulaire de l'autorisation	Date supposée de la fin de l'indisponibilité	Raison de l'indisponibilité	H = à usage humain V = à usage vétérinaire
Aacifemine 0,5 mg	Ovule	Plaquette thermoformée	15	0860932	Aspen Pharma Trading	26/09/2014	Autre raison	H
Aceclofenac Mylan 100 mg	Comprimé pelliculé	Plaquette thermoformée	20	2650265	Mylan	1/10/2014	Nouveaux lots pas encore disponibles	H
Aceclofenac Mylan 100 mg	Comprimé pelliculé	Plaquette thermoformée	60	2650273	Mylan	1/10/2014	Nouveaux lots pas encore disponibles	H
Acepe 10 mg	Comprimé	Plaquette thermoformée	2 x 10	0864686	Eurovet	31/08/2014		V
Aldactone 50 mg	Comprimé pelliculé	Plaquette thermoformée	30	1337286	Continental Pharma	30/03/2014		H
Amoxypen 500 mg	Gélule	Plaquette thermoformée	16	0688176	Socobom			H
Atorvastatin Calcium Actavis 10 mg	Comprimé pelliculé	Plaquette thermoformée	28	3042231	Actavis Group Ptc Ehf	1/09/2014		H
Atorvastatin Calcium Actavis 20 mg	Comprimé pelliculé	Plaquette thermoformée	28	3042256	Actavis Group Ptc Ehf	1/09/2014		H
Atorvastatine Mylan Pharma 10 mg	Comprimé pelliculé	Plaquette thermoformée	28	2922136	Impexeco	15/12/2013		H
Augmentin 500 mg - 125 mg	Comprimé pelliculé	Plaquette thermoformée	16	0029025	Glaxosmithkline Pharmaceuticals	30/09/2014	Problème de production	H
Augmentin 875 mg - 125 mg	Comprimé pelliculé	Plaquette thermoformée	20	1705789	Glaxosmithkline Pharmaceuticals	30/09/2014	Problème de production	H
Augmentin 875 mg - 125 mg	Comprimé pelliculé	Plaquette thermoformée	10	1458736	Glaxosmithkline Pharmaceuticals	30/09/2014	Problème de production	H
Bactroban 2 %	Pommade nasale	Tube	1	1036466	Glaxosmithkline Pharmaceuticals	1/10/2014	Problème de production	H
Baytril Flavour 25 mg/ml	Suspension buvable	Flacon	8,5 ml	2886943	Bayer	1/10/2014	Problème de production	V
Baytril pigeon/rabbit 25 mg/ml	Solution buvable	Flacon	100 ml	2399681	Bayer	19/08/2014	Nouveaux lots pas encore disponibles	V
Bethahistine IPS 16 mg	Comprimé	Plaquette thermoformée	84	2725901	I.P.S. (Intern.Pharmac.Services)		Autre raison	H
Betnesol 0,5 mg	Comprimé effervescent	Pilulier	30	0025403	Sigma-Tau Industrie Farmac. Riunite			H
Betnesol 5,3 mg	Solution injectable	Ampoule	6	0025395	Sigma-Tau Industrie Farmac. Riunite			H
Bromazepam Mylan 12 mg	Comprimé	Plaquette thermoformée	50	1480755	Mylan	2/12/2014	Nouveaux lots pas encore disponibles	H
Bromazepam Mylan 6 mg	Comprimé	Plaquette thermoformée	50	1480748	Mylan	1/09/2014	Nouveaux lots pas encore disponibles	H
Bronchocil 200 mg	Solution buvable	Flacon	10	2681385	Menarini Benelux	1/07/2015	Autre raison	H
ByeMite 500 mg/ml	Emulsion à diluer pour pulvérisation cutanée	Flacon	250 ml	2581965	Bayer	18/09/2014	Problème de production	V
Caelyx 2 mg/2 ml	Solution à diluer pour perfusion	Flacon	1 x 25 ml	2735876	Janssen-Cilag International			H
Calisvit 1200 mg - 800 IU	Poudre orale	Sachet	30	2662138	Menarini Int.Operations	1/05/2016	Autre raison	H
Candepharm 16 mg	Comprimé	Plaquette thermoformée	98	2880821	Teva Pharma Belgium	1/03/2015	Autre raison	H
Candesartan Apotex 8 mg	Comprimé	Plaquette thermoformée	28	2926665	Apotex Europe	30/04/2014		H

Figure 2 - Screenshot of the unavailable medicines list in Belgium on the 15th September 2014. This was the first page of 9. The name of the drug, pharmaceutical form, packaging, authorization holder, estimated cessation of the shortage and the reason is listed. Taken from http://www.fagg-afmps.be/fr/binaries/R_Supply_ProblemsFR20140915_tcm291-240637.pdf

In **Portugal** the National Authority of Medicines and Health Products (Infarmed) updates a website with shortage information. Members of the public and healthcare professionals can report shortages by phone, email or an online form found here: <http://www.infarmed.pt/portal/page/portal/INFARMED>.

In **Poland** the pharmaceutical inspectorate sends messages by email about the shortages that they are aware of (planned shortages). A section of the Ministry of Health's website also provides information, and pharmacists are encouraged to report shortages. Representatives may contact hospital pharmacists to assess the situation and recommend alternative sources of supply. Marketing authorisations holders must inform the national agency of prospective shortages.

In **the UK** the PSNC (Pharmaceutical Services Negotiating Committee) maintains a list of shortages of branded medicines only. A similar list of generic medicines is not operational, yet for reimbursement purposes only there is a list available^[31]. Various guidance and reports have been issued such as the report "Shortages and Supply Chain Obligations" in January 2013 by the Department of Health. In addition, the APPG (All Party Pharmacy Group) issued a report which highlights the issue^[32] discussed further this year^[33]. Regulations in the UK also build upon European legislation with the Human Medicines Regulations 2012 (SI 2012/1916) explaining the responsibilities of marketing authorisation holders.

In **France** the website of the Agence Nationale de Sécurité du Médicament et de produits de santé (ANSM) provides a current list of medicine shortages. The Article R 5115-13 (Code de la Santé Publique) requires every wholesaler to inform the ANSM of the relevant details of their product and hold 90% of all medicines used, with a 2 week capacity of their usual supply^[34].

In **Greece** current shortages can be found on the website of the National Organization for Medicines (EOF), with

Nazwa handlowa	Nr pozwolenia	Firma informująca	Informacja	Odpowiedniki	Źródło/ Data
Deslodyna	19962 kod EAN: 5909990964581	PPF HASCO-LEK S.A.	Wstrzymanie obrotu czasowe/ stale z dniem: czasowe z dniem dzisiejszym 05.08.14. Termin planowego wznowienia obrotu: do odwołania	są odpowiedniki	Dokument z dn. 2014-08-12
CHORAGON 5000	8608 kod EAN: 5909990860814	Ferring GmbH	Wstrzymanie obrotu czasowe/ stale z dniem: stale z dn.: 2014-09-01	brak odpowiedników	Dokument z dn. 2014-08-12
Glypressin	11915 kod EAN: 5909990420735	Ferring GmbH	Wstrzymanie obrotu czasowe/ stale z dniem: 2013-04-01. Termin planowego wznowienia obrotu: 2016-02-28	brak odpowiedników	Dokument z dn. 2014-08-12
Bactroban	R/0714 kod EAN: 5909990071418	GlaxoSmithKline Export Ltd	Wstrzymanie obrotu czasowe/ stale z dniem: 2014-08-08. Termin planowego wznowienia obrotu: 2014-08-15	są odpowiedniki	Dokument z dn. 2014-08-12

Figure 3 - Screenshot of the shortages displayed on www.leki-informacje.pl for August 2014. The brand name of the medicine, unique identifier, marketing authorisation holder, information such reason for shortage and estimated date of resolution are displayed.

In **Germany** regular reports of shortages can be found on the ministry of health's website and the website of the Federal Institute for Drugs and Medical Devices (BfArM) after receiving voluntary reports from the marketing authorisation holders. The list of prescription only medicines is primarily intended for healthcare professionals and includes treatments for life-threatening and serious diseases such as oncology, antibiotics, emergency medicines and those used in surgery.

In the **Netherlands**, since 2011 the website www.farmanco.knmp.nl has recorded shortages reported by pharmacists and the public. Developed by the Dutch Association of Pharmacists (KNMP) this website contains information regarding medication available in community and hospital pharmacies, and staff attempt to resolve them by contacting the manufacturer directly. The scale of shortages in the Netherlands has previously been reported at the 18th EAHP Annual Congress in Paris in 2013^[4].

In **Ireland**, guidance has been produced highlighting the various requirements that pharmaceutical companies have to meet under legislation and good practice guidance in relation to the notification of medicine shortages. This was produced by the Irish Pharmaceutical Healthcare Association, representing the pharmaceutical companies of Ireland and can be found at <http://www.ipha.ie/alist/ipha-hse-agreement.aspx?article=62e200ce-6d45-40d8-9750-3692fcd08538>.

In **Italy**, the website of the National Medicines Agency (AIFA) regularly issues reports on shortages. It provides monthly bulletins of the medicines in shortage, including information such as the brand name, generic name, formulation, marketing authorisation holder, date the shortage was reported, estimated date of resolution, a rasonel (category) and whether there is an alternative or not.

NOME COMMERCIALE	AIC	PRINCIPIO ATTIVO	FORMA FARMACEUTICA E DOSAGGIO	TITOLARE A.I.C.	DATA INIZIO	DATA DI FINE PRESUNTA	ALTERNATIVA	MOTIVAZIONI	SUGGERIMENTI
AC. URSODEOSSICOLICO DOROM	034317014/M	AC. URSODEOSSICOLICO	300 MG 20 CPS RIGIDE	TEVA ITALIA S.r.l.	01/03/2013		SI	Sospensione commercializzazione	Per trattamento alternativo si consiglia di rivolgersi allo specialista o al M.M.G
AC. URSODEOSSICOLICO DOROM	034317038/M	AC. URSODEOSSICOLICO	450 MG 20 CPS RIGIDE	TEVA ITALIA S.r.l.	01/07/2013		SI	Sospensione commercializzazione	Per trattamento alternativo si consiglia di rivolgersi allo specialista o al M.M.G
ACUMEL	035901014/M	POLIAMMINOACIDI + GLUCOSIO MONOidrato + OLIO DI OLIVA+ OLIO DI SOIA PER USO PARENTERALE	4 SACCHE 2000 ML A 3 COMPONENTI	BAXTER	18/01/2013		SI	Cessata commercializzazione	Per trattamento alternativo si consiglia di rivolgersi allo specialista o al M.M.G
ADENOPLEX RICHTER EG	012352023	COCARBOSSILASI/PIRIDOSI NA/IDROSSICOBALAMINA	POLVERE E SOLVENTE IM 5 FL/2ML	EG S.P.A.	18/04/2012		SI	Cessata commercializzazione	Per trattamento alternativo si consiglia di rivolgersi allo specialista o al M.M.G

Figure 4 - Screenshot of the shortages list on the AIFA website for April 2014. The list continues for 67 pages. Taken from: http://www.agenziafarmaco.aov.it/sites/default/files/ELENCO_DEI_MEDICINALI_CARENTI_22.04.2014.pdf

In **Croatia**, information can be found on the national agency's website (<http://halmed.hr/>) about current shortages and advice on how long the shortage may last. Additionally the website of the agency for medicines and medical devices has information about current shortages with advice about available replacement therapies.

In **Spain** the Ministry of Health's website maintains a database of medicines in shortage which is continually updated.

LISTADO DE MEDICAMENTOS CON PROBLEMAS DE SUMINISTRO A FECHA 27/08/2014						
172 rows, displaying from 1 to 25. [<</<] 1, 2, 3, 4, 5, 6, 7 [>/>>]						
Puede cambiar el orden en el que figuran los datos utilizando las flechas que existen en las cabeceras de cada columna						
National Code	Medicinal product's presentation name	Marketing Authorisation Holder	Initial Date	End Date	Observations	
690154	TOLTERODINA NEO MYLAN 4 mg CÁPSULAS DURAS DE LIBERACIÓN PROLONGADA EFG, 28 cápsulas	MYLAN PHARMACEUTICALS, S.L.	22/08/2014	17/11/2014	Existen otros medicamentos con el mismo principio activo y para la misma vía de administración	
688247	RIVASTIGMINA KERN PHARMA 6 mg CAPSULAS DURAS EFG, 56 cápsulas	KERN PHARMA, S.L.	22/08/2014	19/09/2014	Existen otros medicamentos con el mismo principio activo y para la misma vía de administración	
694930	RISPERIDONA MYLAN PHARMACEUTICALS 6 MG COMPRIMIDOS RECUBIERTOS CON PELICULA EFG , 30 comprimidos	MYLAN PHARMACEUTICALS, S.L.	22/08/2014	22/09/2014	Existen otros medicamentos con el mismo principio activo y para la misma vía de administración	

Figure 5 - Screenshot of the shortage list from the Ministry of Health in Spain on 27th August 2014. New shortages are listed first, accompanied by an estimated end date and details relating to each shortage. Taken from: <http://www.aemps.gob.es/cima/fichasTecnicas.do?metodo=buscarDesabastecidos>

In **Hungary**, the National Institute of Pharmacy is the responsible authority to manage medicine shortages on a national level. On its website the Institute provides exact guidelines and contingency plans (http://www.ogyi.hu/gyogyszerhiany_kezelese/). Current shortages are also listed (http://www.ogyi.hu/_atmeneti-termekhiany_/) with detailed information about each product (dates, reason of shortage, expected end of shortage, recommended countermeasures). In case of emergency medicines and severe shortages, the national authority also monitors the stock sizes of every drug in question, including manufacturer, wholesaler and hospital stocks as well.

In **Estonia**, information about current shortages and estimated duration of shortages can be found on the national agency's website (www.ravimiamet.ee). According to the legislation (Medicinal Products Act §64, entered into force in April 2013) marketing authorisation holders must give to the State Agency of Medicines at least two months advanced notice if the distribution of the medicinal product in Estonia is to be terminated or the supply thereof is to be suspended.

In **Finland**, pharmaceutical companies should inform the National Medicines Agency (www.fimea.fi) about likely disruptions to supply. In Finland there is a law about "mandatory reserve supplies" that means that both pharmaceutical companies, importers and hospital pharmacies should have 3-6 month stock about those medicines that the National Medicines Agency has considered essential for patient safety (http://www.fimea.fi/supervision/mandatory_reserve_supplies).

In **Denmark** there is a national database available for the hospital pharmacies where they can find information about current shortages and expected dates for return of the drug on the market. The database is updated on a daily basis and in some cases it also gives guidelines to what drug substitution should be used. The database only holds information about drugs that have been put out for tender – which is the major part of drugs used at Danish hospitals.

In **Serbia**, there is a system created by the National Health Insurance Fund (RFZO) which provides weekly updates for shortages. The Ministry of Health and the National Health Insurance Fund (RFZO) are in charge of giving any recommendations to hospital managers and pharmacists related to the potential alternatives and solutions for overcoming problems caused by medicines shortages. Information contained in the table includes, brand name of the medicine, unique identifier and information on the reason for shortage.

In **Slovakia** the national agency SUKL (<http://www.sukl.sk>) provides and maintains the current list of shortages with advice how long the shortage will last. According to the Act of Medicine and Medical Devices (No 362/2011) it is compulsory for every marketing authorisation holder to inform this national agency about any shortage.

In **Malta** the National Health Service provides a list which is accessible to patients on https://ehealth.gov.mt/HealthPortal/health_institutions/pharmacy_services/poyc/poyc_out_of_stock/information.aspx. The list provides the public with shortages of items which are usually supplied for free to patients who are entitled via the national medicines entitlement act. The list is published weekly and binds the purchasing unit (CPSU) to give reasons why the particular item is unavailable. This does not mean the item is not available via the retail sector, where the patient could purchase the medication. Unfortunately there is no national initiative which provides information regarding national shortages.

Shortages are also reported on the national medicine agencies website of **Lithuania, Bosnia and Herzegovina and the Former Yugoslav Republic of Macedonia (F.Y.R.O.M.)**. Respondents were unaware of any national approaches to address the medicine shortages problem in **Cyprus, Bulgaria, the Czech Republic, Iceland, Latvia, Slovenia, Romania, or Turkey**.

COMMENTS

“This website works very well and provides you with alternatives, if possible” - **Hospital Pharmacist, the Netherlands**

“www.farmanco.knmp.nl is a website that provides all information about shortage, duration and replacement therapies. (initiated by KNMP, the Dutch Association of pharmacists). The information provided is very accurate and helpful in our hospital.” - **Hospital Pharmacist, the Netherlands**

“The main problem is that the shortages are not communicated to the agency on time, so the website has a delay of several days, even weeks.” - **Hospital Pharmacist, Spain**

“We can write to the Ministry of Health.” – **Hospital Pharmacist, Bulgaria**

“There is a national coordinator for information on drug shortages in hospitals. Information is supplied to all hospitals and hospital pharmacies on a regular basis. A medicine shortage team consisting of pharmacists and doctors meet with the Medical Agency once a month.” – **Hospital Pharmacist, Norway**

“The National medicines authority in Norway - “Statens legemiddelverk” provides information that is ok and alternatives are often provided. However the information comes too late.” – **Hospital Pharmacist, Norway**

“National-health-fund (RFZO - Republički fonda za zdravstveno osiguranje) is receiving information about shortages from pharmacies regularly, and the only step that RFZO is making is putting occasionally the shortage drug (INN, way of administration and quantitative information) on a “D-List”. This is a list of drugs which are not registered in our country and may be imported with special licence from Agency for drugs and medical supplies (ALIM - Agencija za lekove i medicinska sredstva).” – **Hospital Pharmacist, Serbia**

“The website of the Croatian medical agency has information about current shortages and communication from the wholesaler. It should also have the information of the solution of the problem (alternative drug or what to do if there is not any alternative).” – **Hospital Pharmacist, Croatia**

“The Irish Pharmacy Union, which represents community pharmacists, maintains a list of short items on their website. However, this has a community focus and often does not include the products, which have the most impact on hospital practice when they are short. There is no national initiative that I am aware of.” – **Hospital Pharmacist, Ireland**

“There does not appear to be any comprehensive plan to address shortages in Ireland nor any consistent approach to the requirement of manufacturers or suppliers to notify customers of shortage or make substitute available.”
Hospital Pharmacist, Ireland (Cork)

List of websites with drug shortage information available in national countries

Austria: www.basg.gv.at

Belgium: http://www.fagg-afmps.be/fr/items-HOME/indisponibilites_de_medicaments/

Germany: http://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/Risikoinformationen/Lieferengpaesse/_node.html

France: <http://www.ansm.sante.fr/>

Hungary: http://www.ogyi.hu/gyogyszerhiany_kezelese/

Italy: <http://www.agenziafarmaco.gov.it/it/content/carenze-dei-medicinali>

Lithuania: www.vvkt.lt

Poland: www.leki-informacje.pl

Portugal: <http://www.infarmed.pt/portal/page/portal/INFARMED>

The Netherlands: www.farmanco.knmp.nl

Slovakia: <http://www.sukl.sk>

Spain: <http://www.aemps.gob.es/cima/fichasTecnicas.do?metodo=buscarDesabastecidos>

Switzerland: <https://www.swissmedic.ch/marktueberwachung/00135/00136/00140/00142/index.html?lang=fr>

UK: <http://psnc.org.uk/dispensing-supply/supply-chain/branded-shortages/> (Branded) and <http://psnc.org.uk/dispensing-supply/supply-chain/generic-shortages/> (Generic)

1. PGEU. *Statement: Medicine Shortages in European Community Pharmacies*. 2012 [cited 21.03.2014]; Available from: <http://www.pgeu.eu/en/policy/20-medicine-shortages.html>.
2. *FIP calls attention to medicines shortages*. 2012 [cited 08/03/2014]; Available from: http://www.fip.org/www/index.php?page=news_publications&news=newsitem&newsitem=118.
3. *The White House. Executive Order 13588 – Reducing Prescription Drug Shortages*. [cited 14.04.2013]; Available from: <http://www.whitehouse.gov/the-press-office/2011/10/31/executive-order-reducing-prescription-drug-shortages>.
4. Postma, D. and d.W. L., *Royal Dutch Pharmacists Association KNMP. Drug shortages in The Netherlands: monitored by Farmanco*. <http://www.farmanco.knmp.nl>. *Eur J Hospital Pharmacy – Science and Practice* 2013, 2013. 20 (suppl 1): p. A90.
5. Preece, D.G. and R.P. Price, *PS-076 The problem of medicines shortages in hospitals across Europe: The European Association of Hospital Pharmacists (EAHP) Survey*. *European Journal of Hospital Pharmacy: Science and Practice*, 2014. 21(Suppl 1): p. A174-A175.
6. EAHP. *99% of HPs experience medicines shortages in past year*. 2013 [cited 14/04/2014]; Available from: <http://www.eahp.eu/press-room/99-hps-experience-medicines-shortages-past-year>.
7. McLaughlin, M., et al., *Empty Shelves, Full of Frustration: Consequences of Drug Shortages and the Need for Action*. *Hospital Pharmacy*, 2013. 48(8): p. 617-618.
8. Printz, C., *Medication shortages threaten cancer care*. *Cancer*, 2012. 118(2): p. 289-291.
9. Woodcock, J. and M. Wosinska, *Economic and Technological Drivers of Generic Sterile Injectable Drug Shortages*. *Clin Pharmacol Ther*, 2013. 93(2): p. 170-176.
10. Gatesman, M.L. and T.J. Smith, *The Shortage of Essential Chemotherapy Drugs in the United States*. *New England Journal of Medicine*, 2011. 365(18): p. 1653-1655.
11. Jenks, S., *Efforts Underway To Curb Drug Shortages*. *Journal of the National Cancer Institute*, 2011. 103(12): p. 914-915.
12. Quilty, S., *Medicines shortages in Australia - the reality*. *The Australasian Medical Journal*, 2014. 7(6): p. 240-242.
13. Chaar, B.B., *Medicine Shortages: Implications for the Australian healthcare system*. *The Australasian Medical Journal*, 2014. 7(3): p. 161-163.
14. *Medicines Shortages Information Initiative*. [cited 25/08/2014]; Available from: http://www.tga.gov.au/hp/information-msi.htm#_U_sD-PmSySo.
15. Bateman, C., *Drug stock-outs: Inept supply-chain management and corruption*. *SAMJ: South African Medical Journal*, 2013. 103: p. 600-602.
16. EMA. *Shortages Catalogue*. [cited 16/07/2014]; Available from: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000376.jsp&mid=WC0b01ac05807477a6.
17. Frontini, R., T. Miharija-Gala, and J. Sykora, *EAHP Survey 2010 on hospital pharmacy in Europe: Part 2 Procurement and distribution*. *European Journal of Hospital Pharmacy: Science and Practice*, 2012. 19(5): p. 460-463.
18. Amgros. 2014 [cited 25/08/2014]; Available from: <http://amgros.dk/en/about-amgros.aspx>.
19. Charatan, F., *Prescription drug shortages plague US*. *British Medical Journal*, 2001. 322(7279): p. 130.
20. Woodend, A.K., J. Poston, and K. Weir, *Drug Shortages: Risk or Reality?* *Canadian Pharmacists Journal / Revue des Pharmaciens du Canada*, 2005. 138(1): p. 27-30.
21. Fox, E.R., et al., *ASHP Guidelines on Managing Drug Product Shortages in Hospitals and Health Systems*. *American Journal of Health-System Pharmacy*, 2009. 66(15): p. 1399-1406.
22. *Best Practice for Ensuring the Efficient Supply and Distribution of Medicines to Patients*. 2013 [cited 25/05/2014]; Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213290/distribution_medicines_V2.pdf.
23. *Best Practice Standards for managing Medicines Shortages in Secondary Care in England* [cited 25/05/2014]; Available from: <http://www.rpharms.com/support-pdfs/managing-medicines-shortages-in-secondary-care.pdf>.
24. Stead, D., *Best practice standards for managing medicines shortages in hospitals*. *European Journal of Hospital Pharmacy: Science and Practice*, 2013. 20(4): p. 251-252.
25. Cousins, D., M. Evans, and K. Wind, *Managing risks arising from medicine shortages in NHS hospitals*. *The Pharmaceutical Journal*, 2012. 289: p. 306.
26. *Current and Resolved Drug Shortages and Discontinuations Reported to FDA*. [cited 01/09/2014]; Available from: <http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>.

27. WHO. *Model List of Essential Medicines*. 2013, The World Health Organisation.
28. Gupta, D.K. and S.M. Huang, *Drug Shortages in the United States: A Critical Evaluation of Root Causes and the Need for Action*. *Clin Pharmacol Ther*, 2013. 93(2): p. 133-135.
29. *Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use* E. Commission, Editor. 2001: Brussels. p. 67.
30. Morrison, A., *Drug Supply Disruptions 2011*, Canadian Agency for Drugs and Technologies in Health.
31. *Generic Shortages (NCSO & Price Concessions)*. [cited 27/08/2014]; Available from: <http://psnc.org.uk/dispensing-supply/supply-chain/generic-shortages/>.
32. Barron, K., et al., *Report of the APPG Inquiry into Medicines Shortages*. 2012, All Party Pharmacy Group.
33. *Medicine shortage problem is far from solved, warns APPG*. *The Pharmaceutical Journal*, 2014. 293.
34. Lucchini, C. *Medicines shortages: an European overview?* *PharmaWorld Magazine* 2014 [cited 25/08/2014]; Available from: <http://www.pharmaworldmagazine.com/medicines-shortages-an-european-overview/>

Further information

This report was produced by the EAHP secretariat. EAHP would be delighted to provide further information on the results of the survey on request, and/or to have discussions with other interested stakeholder/ individuals in relation to partnership activity on securing solutions to the medicine shortage problem.

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