



# Medicines Shortages in European Hospitals

The evidence and case for action

Dr. Roberto Frontini, President EAHP

[president@eahp.eu](mailto:president@eahp.eu)



making the difference in medication



# Conflict of interest

No commercial conflict of  
interest to disclose

# What does a medicine shortage REALLY mean? (it happened in a German hospital)

Patient N.N. was admitted to the hospital with an epileptic emergency



Standard medication for status epilepticus was in the hospital Lorazepam 4mg i.v. 4 (Tavor Pro Injektione® **2 amp**)

Due to a shortage the Pharmacy advised 3 alternatives:

- Diazepam i.v. 10mg (Diazepam Rotexmedica® **1 amp**)
- Diazepam rectal 10mg (Diazepam Desitin rect. 10mg®)
- Lorazepam smelting Tbl. 5.0mg (Tavor expidet®, **off label**)

## What does a medicine shortage REALLY mean? (it happened in a German hospital)

Despite proper communication by the pharmacy in the emergency situation the doctor was not able to find the i.v. medication (oral or rectal application was not possible)

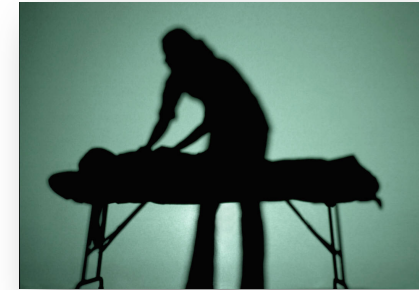


The reason was Tavor Pro Injektione® being stored in the refrigerator unlike Diazepam Rotexmedica®

After more than 15min the alternative Diazepam i.v. was found but the doctor administered as usual **2** instead of **1** amp causing an overdose of 100%

# What does a medicine shortage REALLY mean? (it happened in a German hospital)

The patient remained untreated significantly longer than unavoidable



Due to the overdose sedation remained for more than 48h making a neurological assessment impossible

The stay in hospital was prolonged by ca 2 days

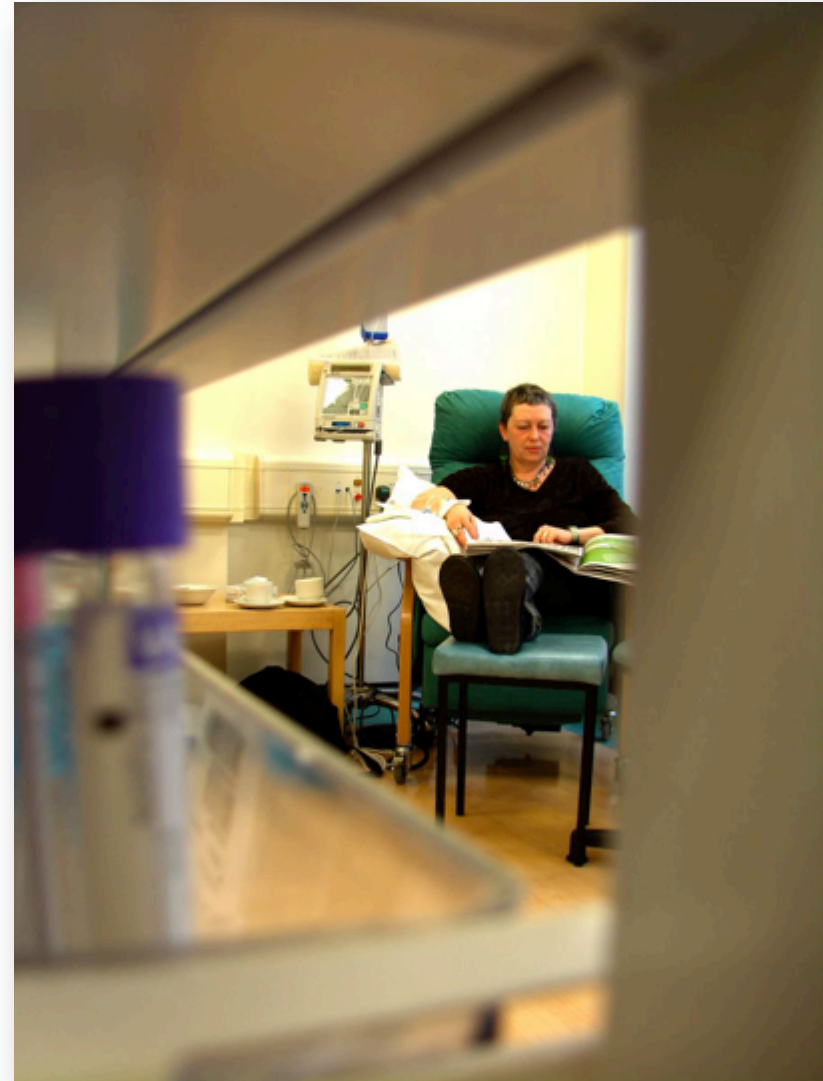
# The EAHP survey



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

## Why a survey?

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





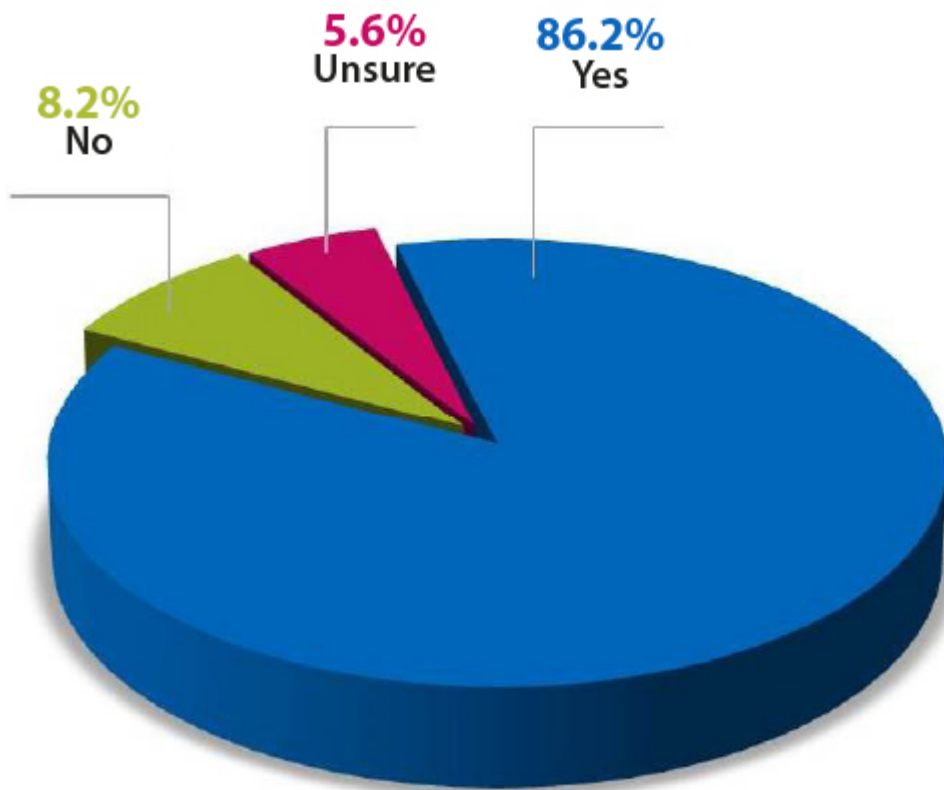
# Level of response – the largest survey of its kind

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.



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



**Chart 2: proportion of hospital pharmacists (%) stating that medicines shortages were a current problem in their county. (N=537)**



## Comments include

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

***Hospital Pharmacist (Ireland)***

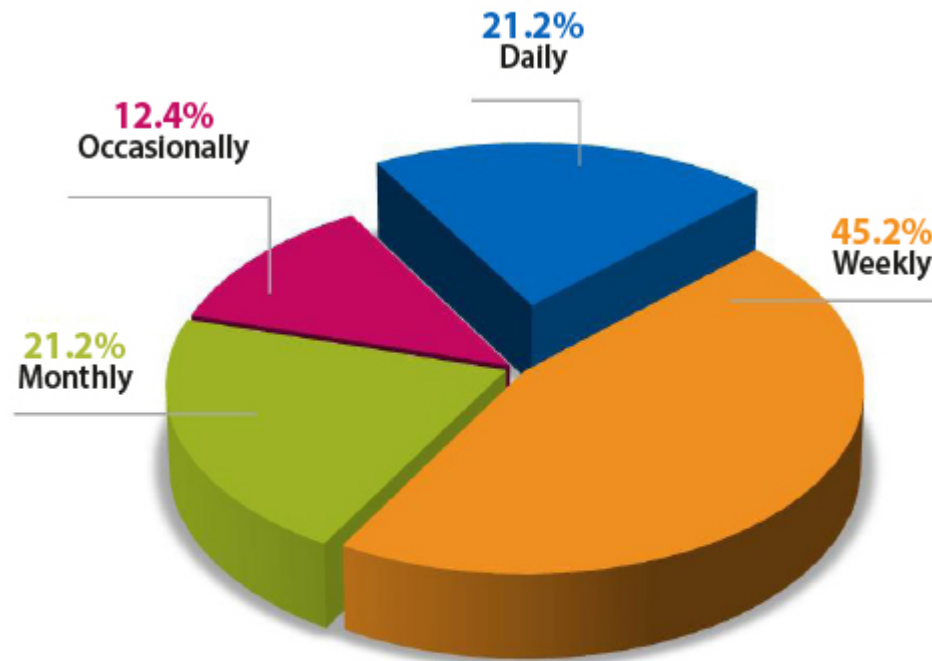
“In the last year shortages have become more current ”

***Hospital Pharmacist, (Belgium)***

“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)***

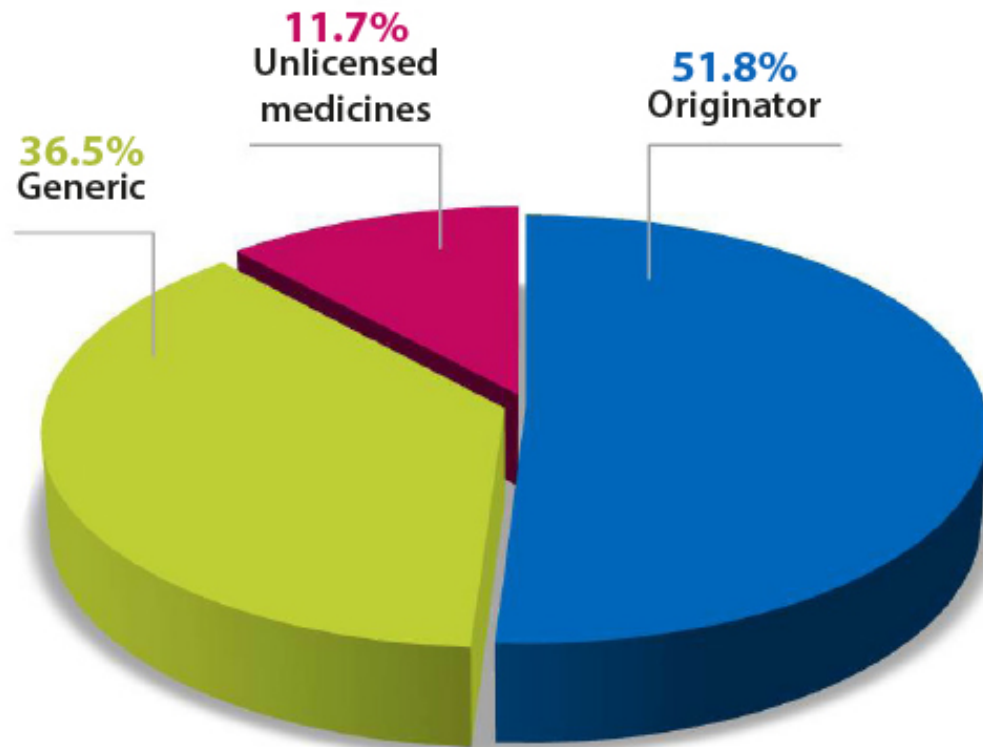
## How often does your hospital pharmacy experience shortages?



**Chart 3: Shortages Frequency.**  
(n=526)

- **66%** of all respondents are affected on a **daily or weekly** basis.
- An increase from 63% in 2013 saying it was daily or weekly problem
- Highest daily occurrence in Malta and Denmark.
- 100% of Norwegian responses stated it was a weekly or daily problem.

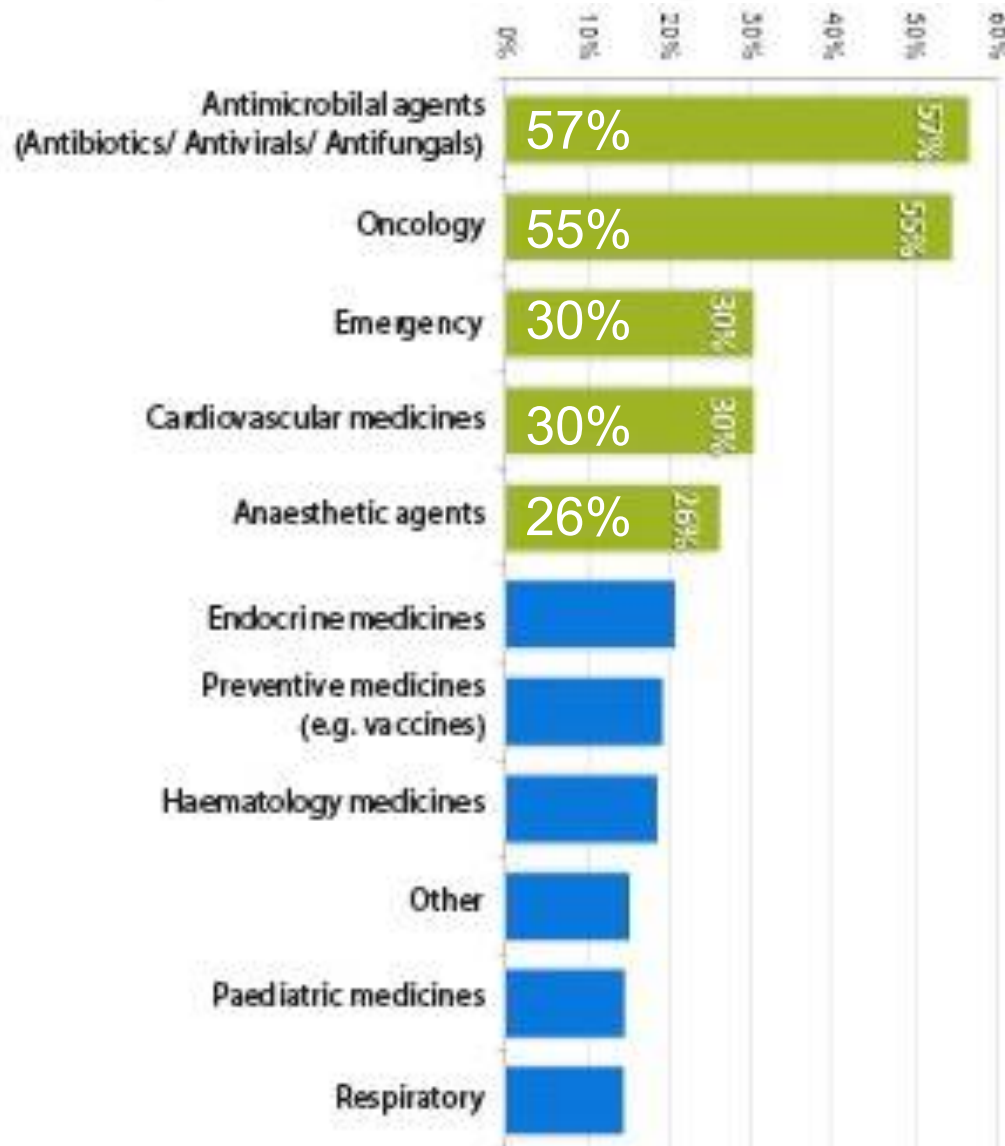
# Which type of medicine do you most commonly experience to be in short supply?



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

- In **2013 42%** said **originator** and **57% generic** – a change in result for 2014 survey
- **Unlicensed products a new option in 2014**
- **High originator shortage responses in Austria, Belgium, Slovakia, Spain & Switzerland**
- **High generic response in Croatia, Denmark, Germany, Hungary, Malta, Netherlands, Portugal**

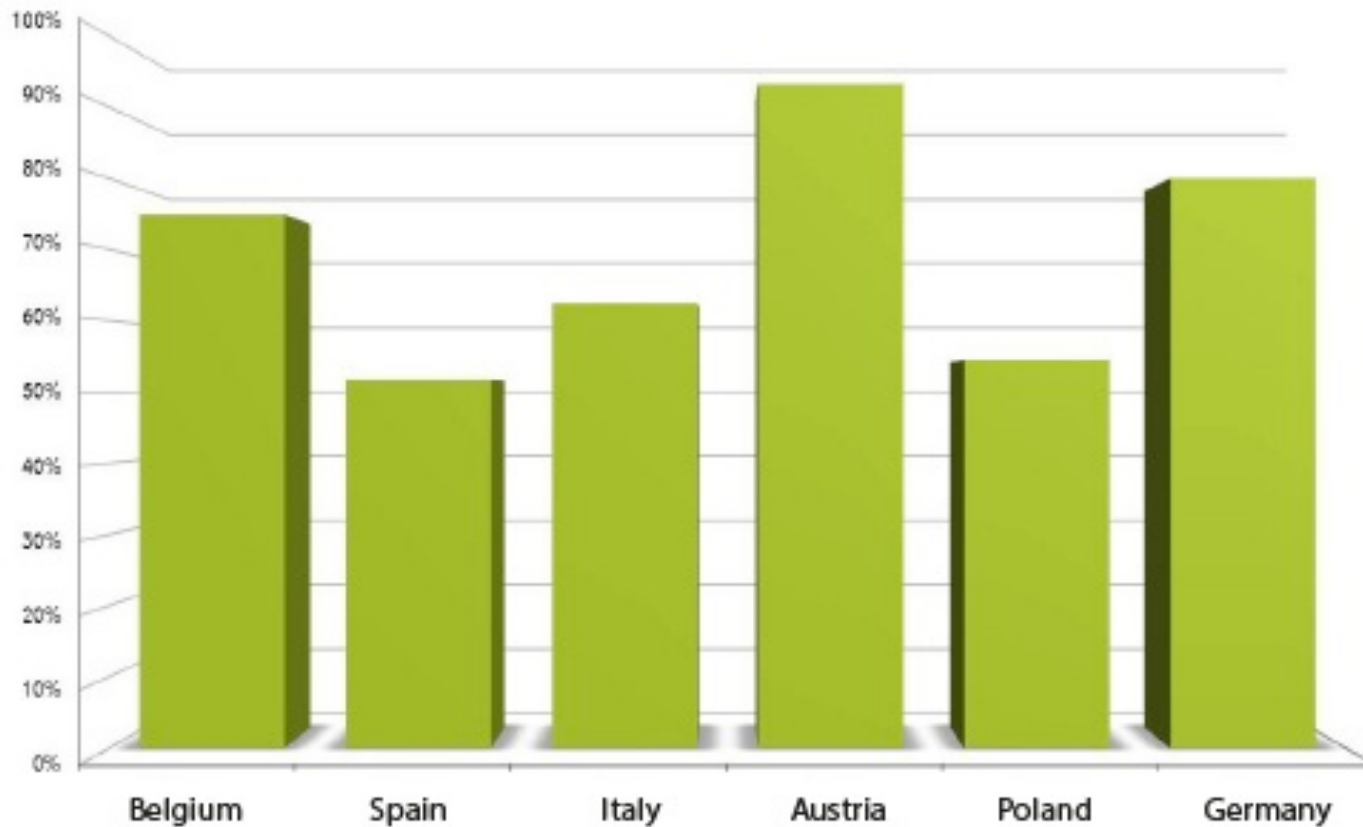
# In which area of medicine does your hospital experience shortage most commonly?



- Corresponds with 2013 survey results with oncology, emergency medicines and cardiovascular medicines featuring highly
- **New categories** with high response in 2014 survey: **antimicrobials and anesthetic** agents due to inclusion following 2013 feedback



# Countries with the strongest levels of response indicating **common antimicrobial** shortages

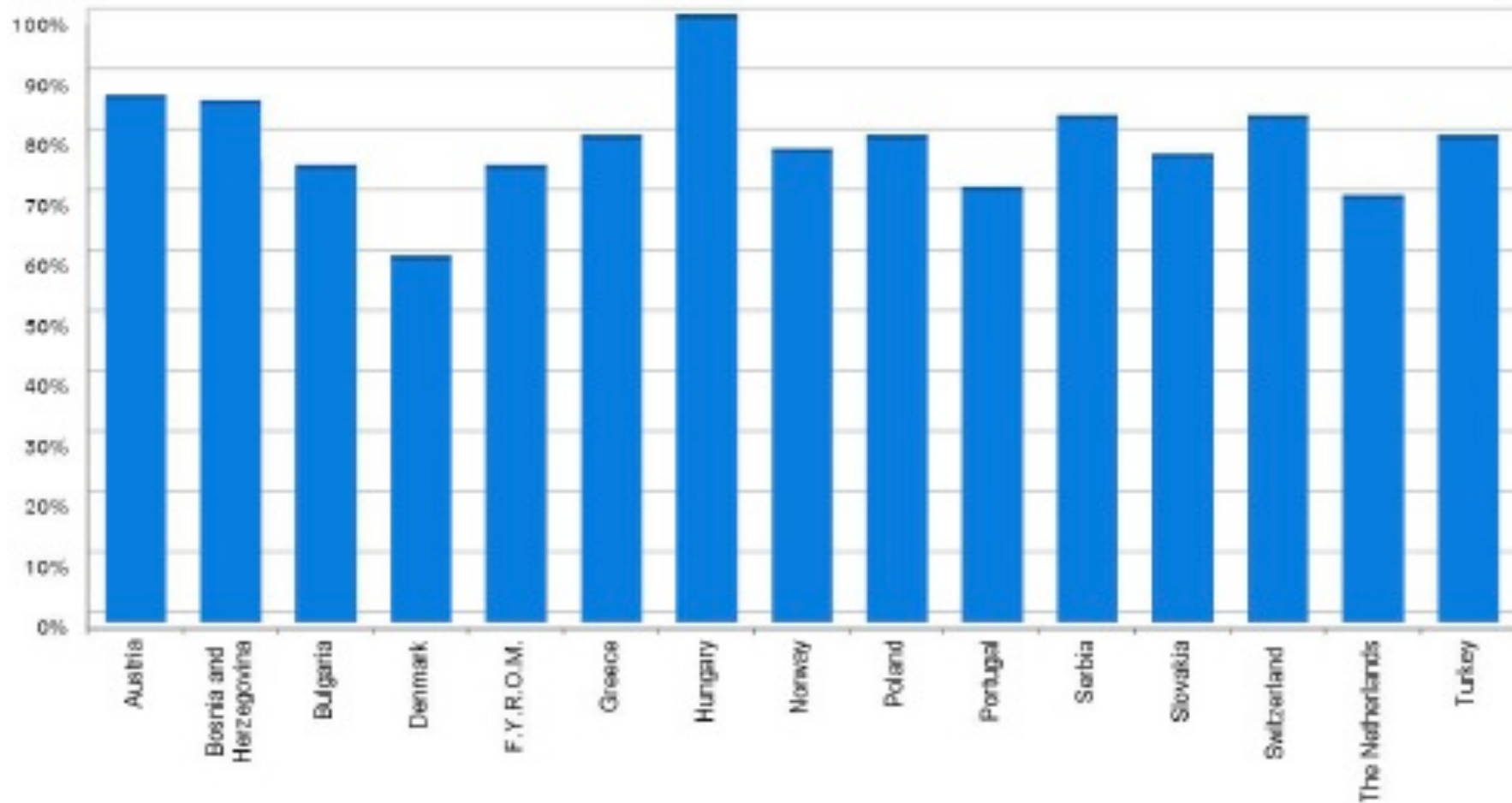


**Chart 9: Countries that reported the highest proportion of shortages relating to antimicrobials (including antivirals and antifungals).**





# Countries with the strongest levels of response indicating **oncology product shortages**








## Specific examples of medicines in shortage provided by respondents in 3 or more countries

- **Antibiotics:** amoxicillin, co-amoxiclav, gentamicin, linezolid & meropenem.
- **Anti-cancer drugs:** 5-Fluorouracil, carboplatin, cisplatin, doxorubicin (liposomal), methotrexate & vincristine.
- **Analgesics (pain relief):** ibuprofen, morphine & tramadol
- **Cardiology drugs:** digoxin, labetalol & furosemide

# Compare this to the current EMA database...

## Current shortages

Document(s)	Status	First published	Last updated
 Buccolam (midazolam) supply shortage	Ongoing	25/04/2014	12/09/2014
 Cerezyme (imiglucerase) supply shortage	Ongoing	04/11/2013	
 Fabrazyme (agalsidase beta) supply shortage	Ongoing	04/11/2013	29/10/2014
 Maci (matrix applied characterised autologous cultured chondrocytes) implant supply shortage	Ongoing	04/07/2014	
 Xofigo (radium-223 dichloride) supply shortage	Ongoing	17/10/2014	

## Resolved shortages

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



## “Essential” Medicines in shortage around Europe

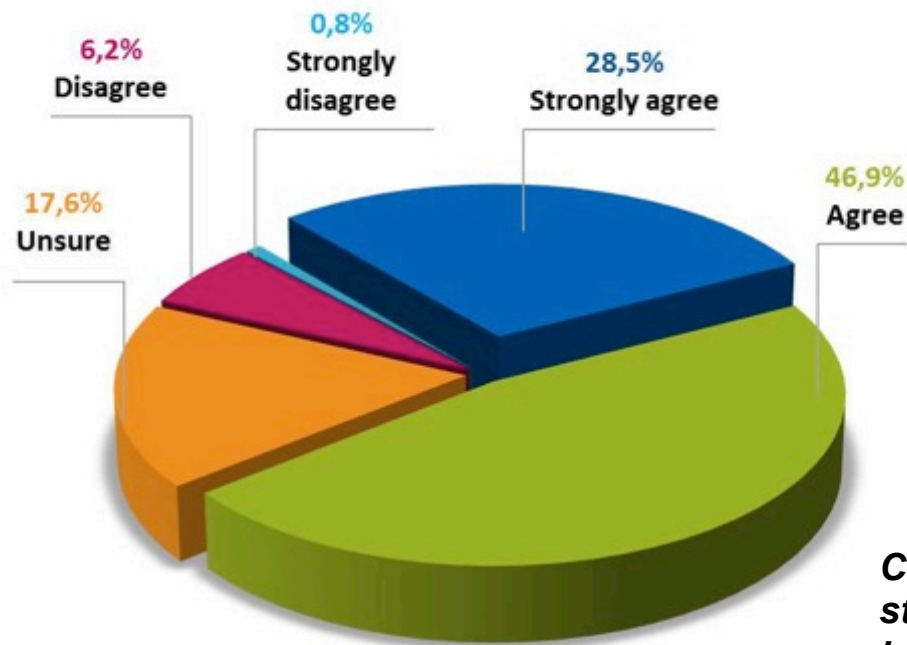
The World Health Organisation maintains a list of **essential medicines**. Our results show many respondents indicating the following essential medicines in shortage in Europe:

**Amoxicillin, Co-amoxiclav, Furosemide**

The Federal Drug Administration (FDA) also maintains a shortages database of **medically necessary** products. Our respondents indicated the following medically necessary products in shortage in Europe:

**Dexamethasone, Doxorubicin (Liposomal), Lorazepam**

Do you agree with the statement “medicines shortages in my hospital are having a negative impact on patient care”



- **75.4%** of all respondents either agree or strongly agree.

*Chart 20: level of agreement with the statement: “Medicines shortages in my hospital are having a negative impact on patient care”. N=369*

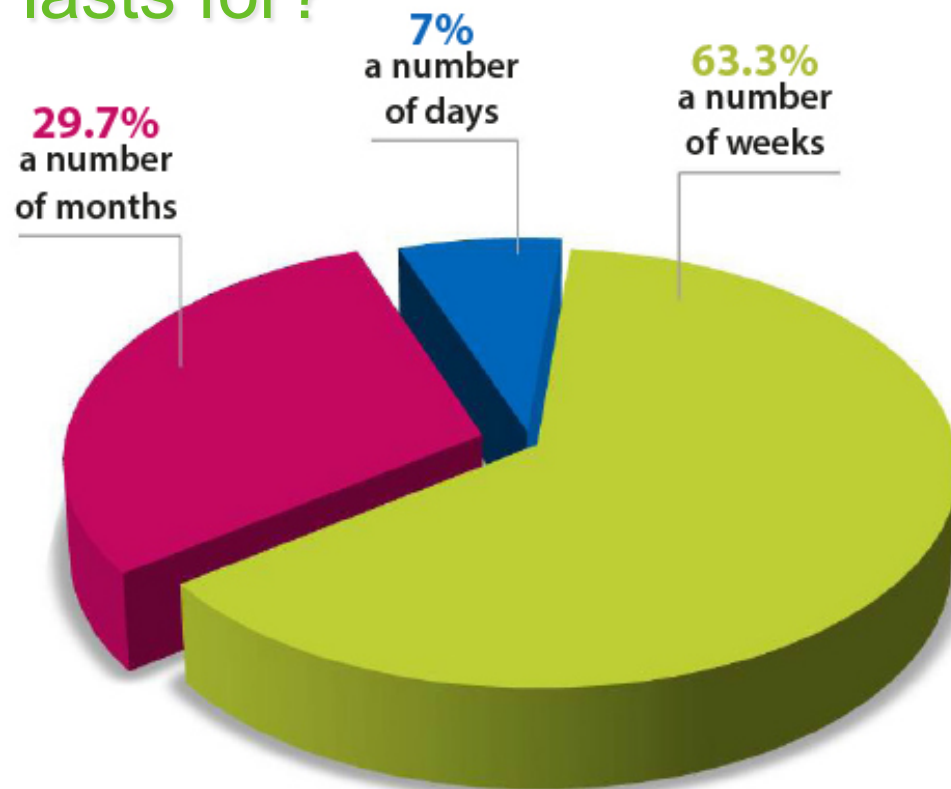
## Impact on patient welfare

“Lack of etoposide forced us to change the treatment in many oncology malignancies. Irregular duanorubicin forced us to reduce doses or change treatment. Shortages of thalidomide will force us to put patients on different treatments.” ***Hospital Pharmacist, Poland.***

“When there is a shortage we do not give them 1 month’s supply as we should. They have to come often to the hospital pharmacy to avoid disruption in treatment.” ***Hospital Pharmacist, Portugal.***



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



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

**Chart 14: Typical duration of a typical medicine shortage according to European Hospital Pharmacists (n=387)**

## Comments from respondents included:

“Liposomal doxorubicin [**cancer drug**] was affected for over a year and liposomal cytarabine [**cancer drug**] was in shortage for several months.” *Hospital Pharmacist, Norway*

“Lorazepam [**for anxiety and epilepsy**] was in shortage for more than two years” *Hospital Pharmacist, Italy*

“Synacthen and Nuvacthen [**diagnostic aids**] have not been available for 9 months. We do not know when they will become available.” *Hospital Pharmacist, Spain*

## Comments include

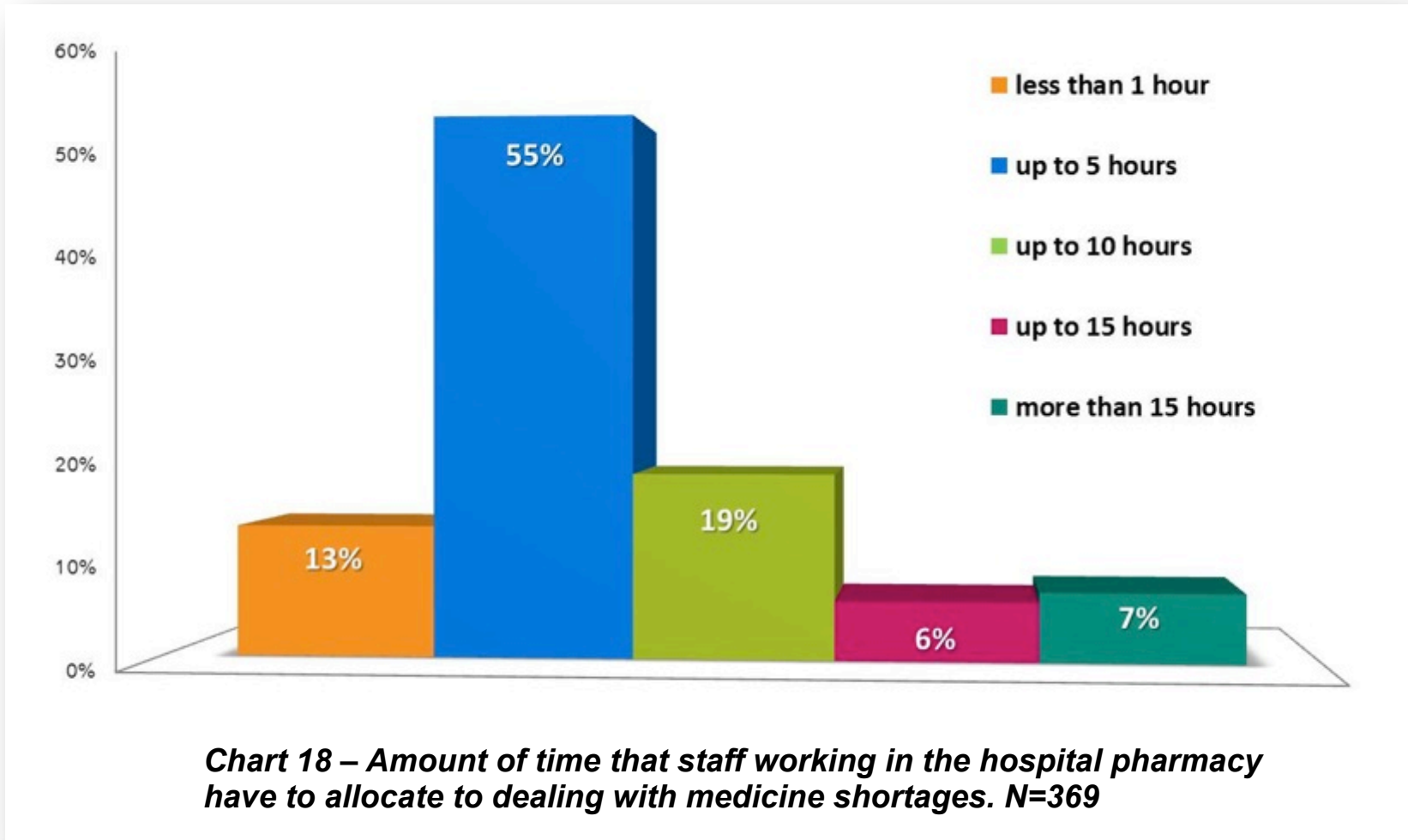
“Rabies vaccine only reserved for patients requiring it after being bitten and not for prevention.”

***Hospital Pharmacist, Switzerland***

“There is insufficient knowledge of near equivalent medicines or medicines with no equivalent alternatives. This leads to therapy at a lower dosage or providing the alternative too late.” **Hospital Pharmacist, Belgium.**

“Alternative therapy might have the same effect but has to be injected more often and is painful for the patients.”  
**Hospital Pharmacist, Norway**

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



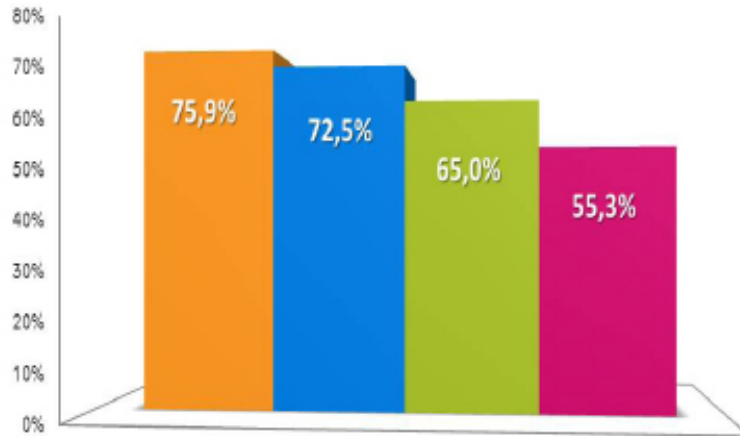
## Comments include

“Accumulation of pharmacist, technician and pharmacy assistant would be 19.25 hours [in an average working week]” ***Hospital Pharmacist, Belgium***

“As a pharmacy department in general **1.5** (full time equivalent) pharmacist work solely on chasing out-of-stock items.” ***Hospital Pharmacist, Malta***

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

# Policy Solutions



- 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

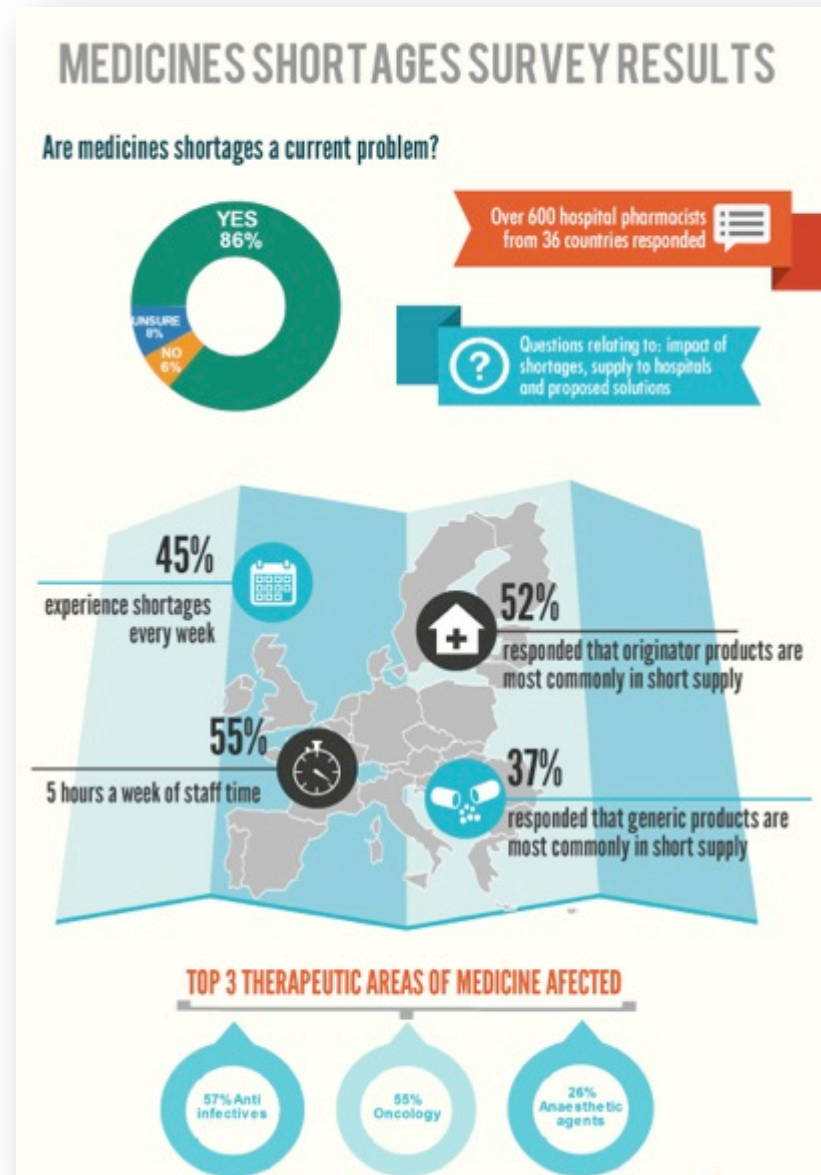
**Chart 24 – Level of support for the proposed solutions/ improvement in dealing with shortages. N=327**

- Experience from the USA (FDASIA 2012) demonstrates that earlier reporting of likely supply disruption enables contingency plans to be made and many difficulties to be alleviated.
- A ‘responsibility gap’ at the EU level must also be overcome



# Conclusion

- 86% of hospital pharmacists report shortages of medicines are a current problem.
- Most commonly affected areas are oncology, antimicrobials and anesthetic agents.
- **EU ACTION REQUIRED!**



## EAHP calls for....

- Improved collection of information about medicines shortages in Europe – **an EU database.**
- Clarification and enforcement of **legal responsibilities for suppliers** to report likely disruptions and problems at an early stages
- **Responsibility to be taken by the European Commission** to tackle this cross border health threat
- **Criteria for a fair distribution** in case of shortages based on patient's needs and not on commercial interests

# Thank you very much for your attention!

