



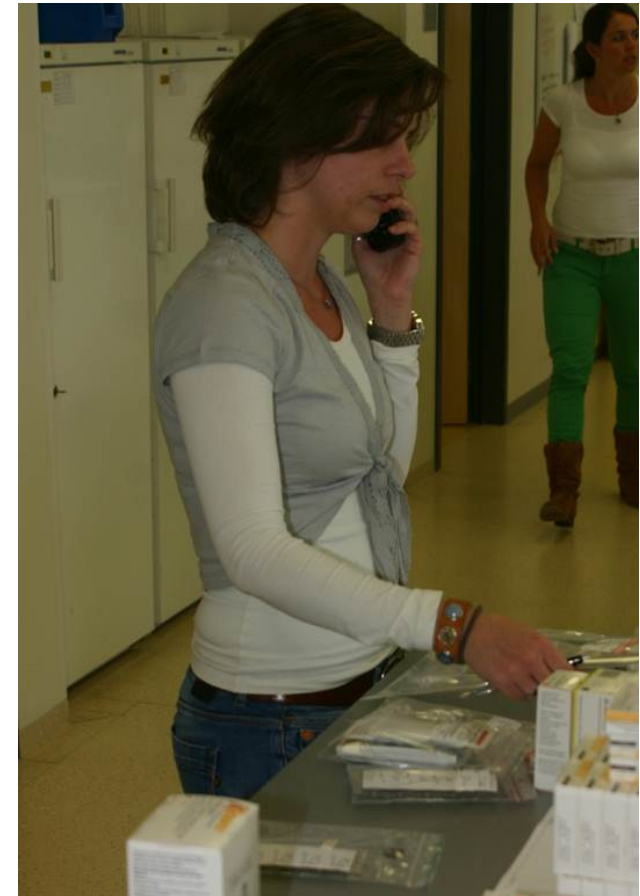
President's Policy Roundtable on Medicines Shortages

18th Congress of the EAHP
13th March 2013



Shortages: a growing problem with patient impacts

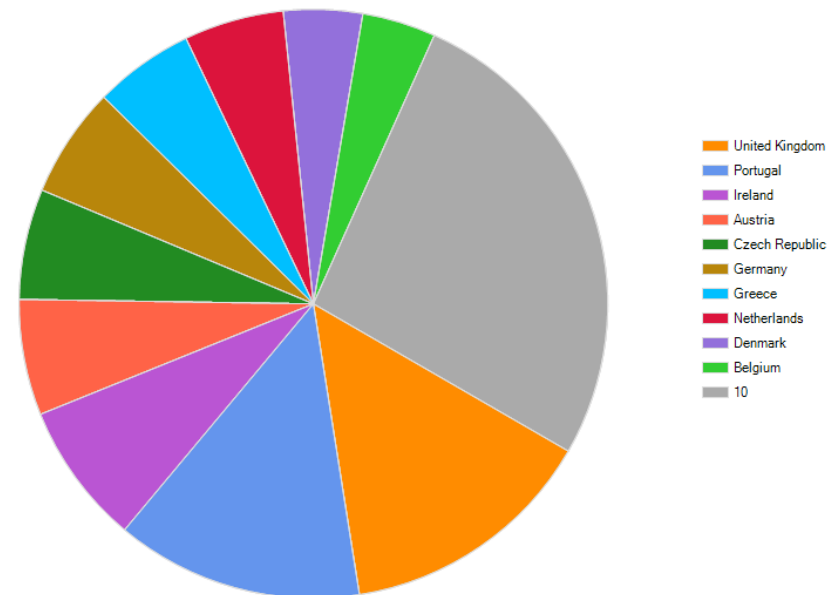
- **Distracts pharmacist from core activities**
- **Places burden on staff and resource**
- **Can increase stress and workload in pharmacy environment with impacts on risk of error**
- **Substitution of medicines in case of shortage of formulary drugs can confuse doctors and nurses with additional risk of error**
- **Can increase health inequalities as medicines are relocated from country to country via parallel trade**



EAHP's 2012 Medicines Shortage surveys

A breakdown of the results

	Response Percent	Response Count
Oncology medicines	70.6%	235
Emergency medicines	43.8%	146
Respiratory medicines	18.9%	63
Cardiovascular medicines	35.1%	117
Hematology medicines	22.2%	74
Urology medicines	11.4%	38
Renal medicines	9.9%	33
Rare Disease medicines	18.6%	62
Pediatric medicines	18.9%	63
Other	32.4%	108
If Other, please describe		132
answered question		333
skipped question		13



Background to the EAHP shortage surveys

- **EAHP's June 2012 General Assembly passed policy on medicines shortages**
- **Gave a mandate for awareness-raising activity by EAHP**
- **Statement presented suggestions for interim solutions (e.g. information sharing)**
- **However a need for evidence gathering was identified in relation to presenting long term robust solutions**
- **Surveys closed in mid-February**
- **Now sharing and analysing the results**

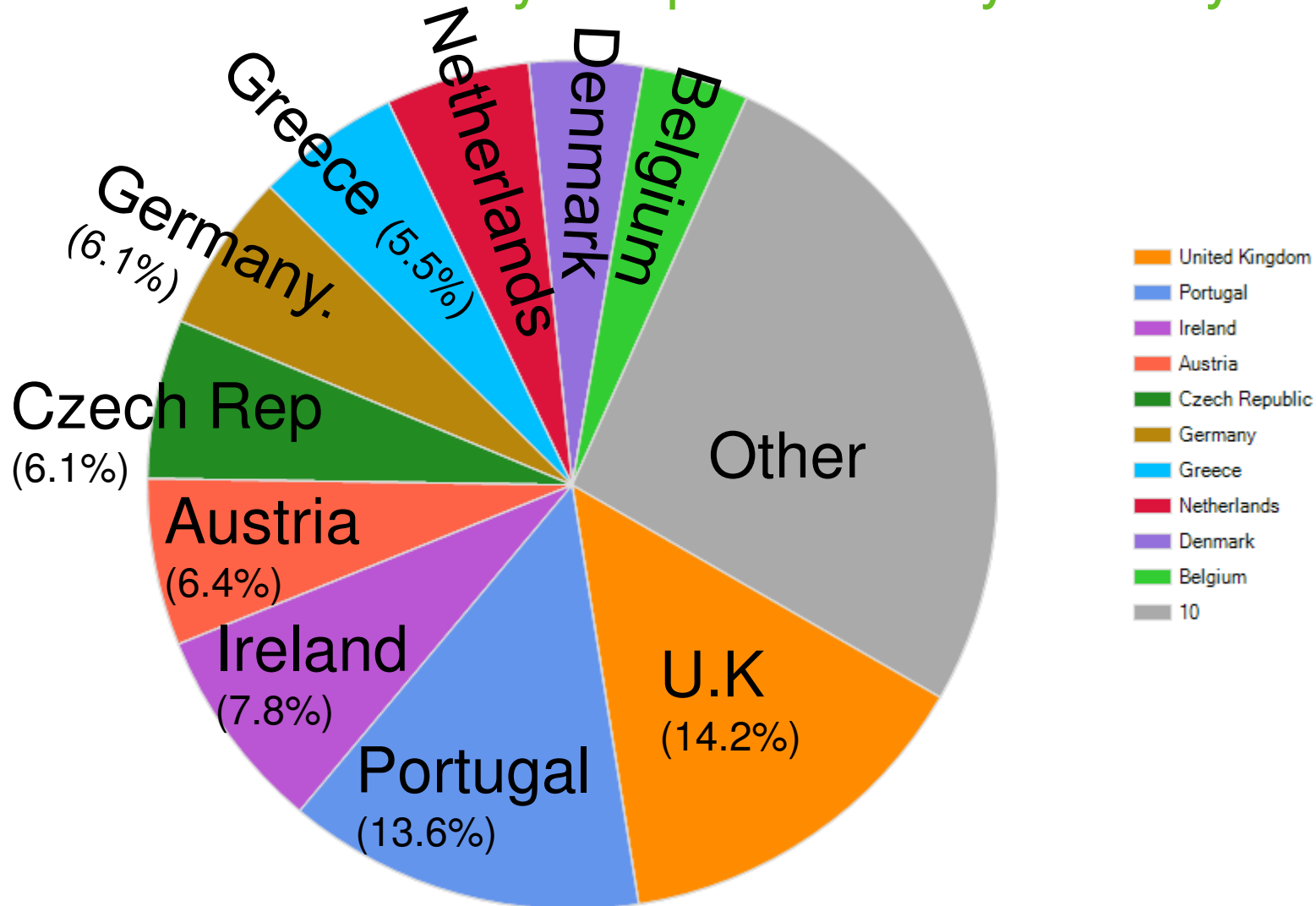


Survey 1: Investigating the prevalence of the problem

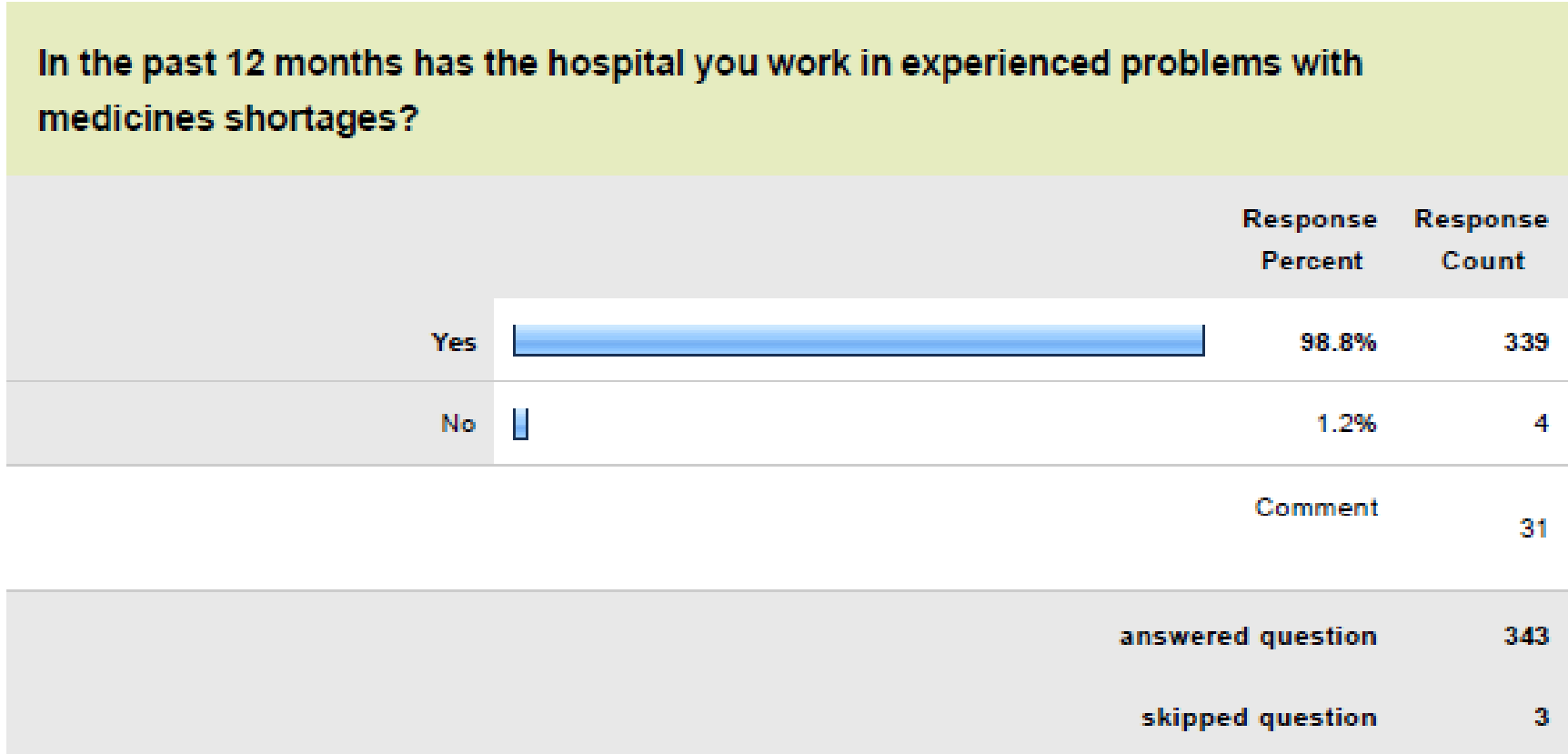
346 hospital pharmacist respondents from 31 countries

- **Austria (22)**
- **Belgium (14)**
- **Bosnia and Herzegovina (5)**
- **Bulgaria (2)**
- **Croatia (4)**
- **Cyprus (1)**
- **Czech Republic (21)**
- **Denmark (15)**
- **Estonia (1)**
- **Finland (14)**
- **FYROM (3)**
- **Germany (21)**
- **Greece (19)**
- **Hungary (8)**
- **Iceland (2)**
- **Ireland (27)**
- **Italy (7)**
- **Lithuania (1)**
- **Netherlands (19)**
- **Norway (14)**
- **Poland (2)**
- **Portugal (47)**
- **Romania (1)**
- **Serbia (7)**
- **Slovakia (2)**
- **Slovenia (7)**
- **Spain (7)**
- **Sweden (1)**
- **Switzerland (2)**
- **Turkey (1)**
- **United Kingdom (49)**




Prevalence survey: respondents by country



Have you experienced shortages in the last year?



How often does your hospital experience the problem?

		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

90% at least monthly

answered question 339

skipped question 7

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

		Response Percent	Response Count
1	Oncology medicines	70.6%	235
2	Emergency medicines	43.8%	146
	Respiratory medicines	18.9%	63
3	Cardiovascular medicines	35.1%	117
4	Hematology medicines	22.2%	74
	Urology medicines	11.4%	38
	Renal medicines	9.9%	33
	Rare Disease medicines	18.6%	62
	Pediatric medicines	18.9%	63
	Other	32.4%	108
	If Other, please describe		132
answered question			333
skipped question			13

Any difference between generic and originator shortages?

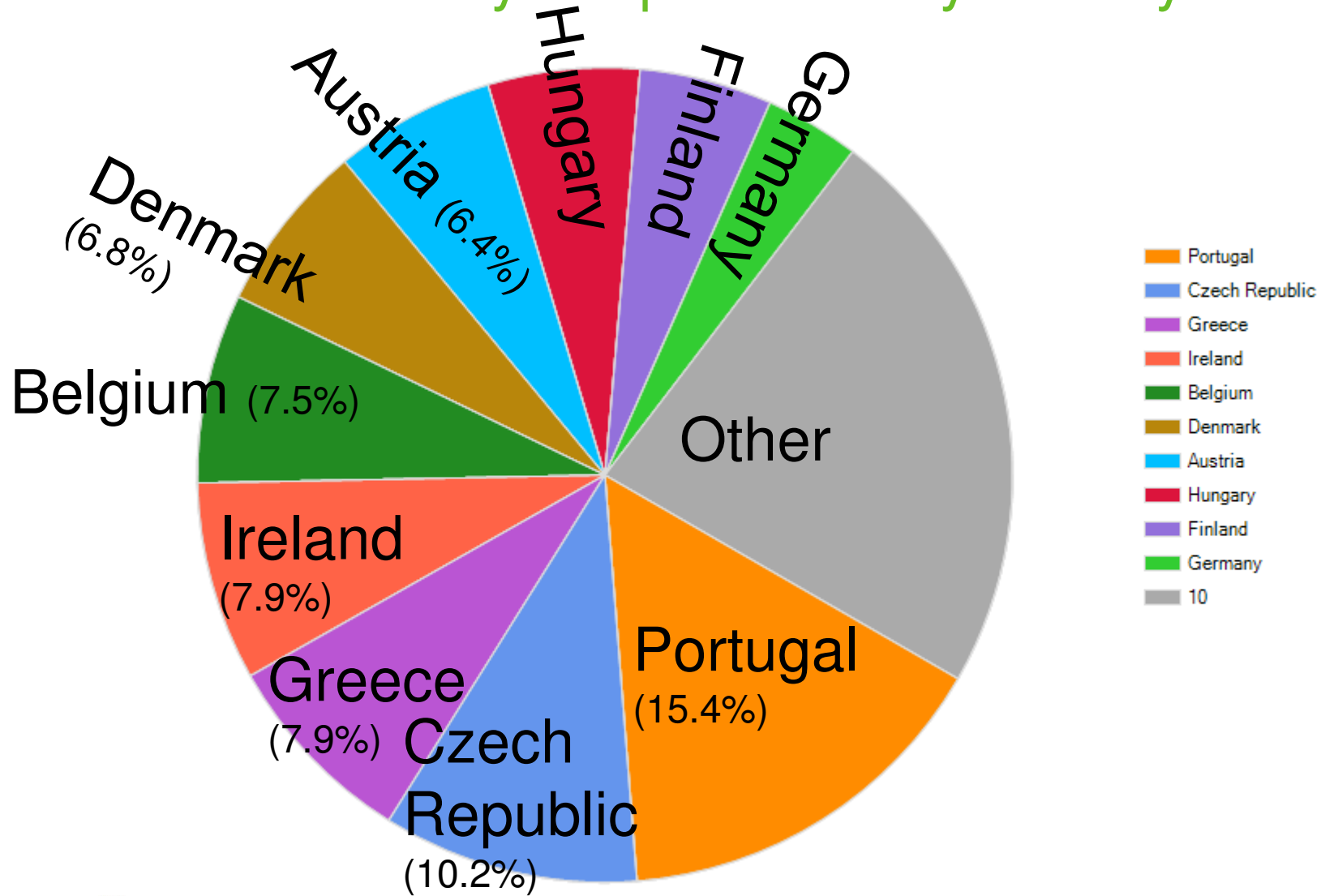
With which kind of medicine is shortage most commonly experienced in your hospital?			
		Response Percent	Response Count
Originator (patented)		42.9%	139
Generic (off-patent)		57.1%	185
answered question			324
skipped question			22

Survey 2: patient impacts and perceived causes




266 hospital pharmacist respondents from 29 countries

- **Austria (17)**
- **Belgium (20)**
- **Bosnia and Herzegovina (5)**
- **Bulgaria (2)**
- **Croatia (5)**
- **Cyprus (1)**
- **Czech Republic (27)**
- **Denmark (18)**
- **Estonia (1)**
- **Finland (14)**
- **France (1)**
- **FYROM (2)**
- **Germany (10)**
- **Greece (21)**
- **Hungary (16)**
- **Ireland (21)**
- **Italy (7)**
- **Lithuania (2)**
- **Netherlands (7)**
- **Norway (2)**
- **Poland (1)**
- **Portugal (41)**
- **Romania (2)**
- **Serbia (6)**
- **Slovakia (1)**
- **Slovenia (8)**
- **Spain (5)**
- **Switzerland (1)**
- **Turkey (1)**
- **United Kingdom (2)**

Prevalence survey: respondents by country





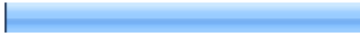


Does the problem of medicines shortage in your hospital have a negative impact on patient care? Please use the comment box to explain your answer and provide illustrative examples. All responses to this survey are treated anonymously

		Response Percent	Response Count
Yes, there have been negative impacts to patient care in the hospital I work in as a result of medicines shortages		50.7%	112
No, the hospital I work in has been able to manage the problem of medicines shortages without patient care being negatively impacted		46.6%	103
The hospital I work in does not regularly experience a problem of medicines shortages		2.7%	6

Comment 56

answered question	221
skipped question	45

In your experience and estimation, what do you consider to be the MOST common root causes of medicines shortages in the hospital you work in?

		Response Percent	Response Count
Manufacturers experiencing shortage problems with raw materials		43.7%	90
Quality-related production difficulties at manufacturing source (e.g. failed batches, GMP failure etc)		43.7%	90
Supply chain vulnerability from only having a single supplier, or small numbers of suppliers, of a product (e.g. global consolidation of manufacturing)		52.4%	108
Supply chain vulnerability from the product only having a small patient market (e.g. not a very profitable product for manufacturers)		29.6%	61
Supply chain vulnerability from a small country only having a small national market (e.g. the cost of entering the market outweighs the benefit to the supplier)		41.7%	86

Please rank the following suggested solutions to the medicines shortage problem that you think would be most useful, with 1 being most useful and 4 being least useful

	1	2	3	4	Rating Average	Rating Count
European wide coordination of response to medicines shortages (e.g. a single European information portal and communication tool about shortages, as coordinated in the USA by the FDA)	30.0% (60)	24.0% (48)	18.5% (37)	27.5% (55)	2.44	200
Stronger legal requirements (and penalties) for Marketing Authorisation Holders to ensure the reliable and sustainable supply of products for which they hold the licence	31.0% (62)	24.5% (49)	33.5% (67)	11.0% (22)	2.25	200
Stronger legal requirements (and penalties) for manufacturers to give due notice of likely supply interruptions, the reason and when they expect the problem to be alleviated	22.0% (44)	32.0% (64)	26.5% (53)	19.5% (39)	2.44	200
New legal responsibilities for medicines regulators to not only verify the safety of products, but also their supply arrangements	17.0% (34)	19.5% (39)	21.5% (43)	42.0% (84)	2.89	200

POINTS FOR DISCUSSION:

Identifying and enacting the solutions



Interim solutions

- **Prescribers to have more awareness, take notice of pharmacist communications, and discuss with pharmacists change in policies**
- **Pharmacists to be vigilant and alert to shortages and share information, including with prescribers**
- **Manufacturers to give adequate notice of problems and expected duration**
- **Information provision and investigation of the problem by national and european regulatory authorities and governments**
- **Awareness raising and solution identifying by representative organisations**

Different types of shortage require different solutions?

TYPE	E.G.	Causation factors	Solutions?	Challenges
Shortages caused by supply issues	“the medicine exists but I can’t get hold of it”	Parallel import	Change EU rules on meds trade?	Fundamental EU principle
		Small markets	Regulation to ensure MA requires supply?	Further burden on industry
Shortages caused by production issues	“the medicine doesn’t exist because its not been produced”	Global consolidation of production (vulnerability)	Medicines regulators to take on supply remit?	FDA experience?
		Pricing squeeze reduces incentive to provide	New approaches for fair prices?	Complexity and difficulty of one approach
Shortages caused by affordability problems	“We can’t afford the medicine or won’t pay the price”	Austerity	HTA & risk-sharing schemes	Still an area of controversy
		Public scrutiny of health budgets	Transparency on benefits outcomes	Overcoming perception issues



POINTS FOR DISCUSSION:

Identifying and enacting the solutions



Areas of consensus?

1. Continue to work together to raise awareness for action (USA model) – include patients – Government issue – power to change situation not wholly with pharmacists
2. Encourage national level databases (Netherlands)
3. Early Warning Systems (USA)
4. Break the question up
 - Parallel import needs investigation
 - Pricing needs investigation (how do we price?)
5. Guarantee of supply maybe not possible – but supply standards (e.g. incentives to give warning, adequate stock of essential medicines)?
6. Clearing system for generics worth exploration