EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Shortages survey 2015

Shortages Workshop
09 October 2015

Presented by Maria-Jesus Alcaraz on 9 October 2015
Administrator, Compliance and Inspections Department - EMA

Agenda

1. Introduction
2. Data
3. Conclusions

Introduction

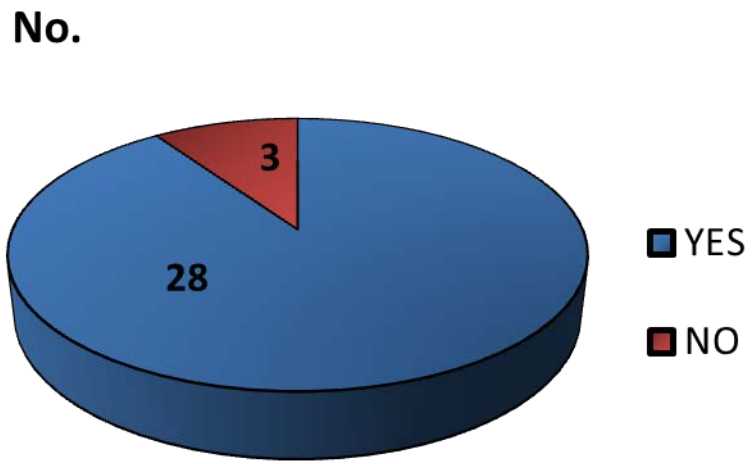
European Medicines Agency (EMA) Virtual Working group on Product Supply Shortages

- Gather information about how EU competent authorities address shortages of medicinal products for human use
- Share initiatives and current knowledge among Member States
- Identify best practices in the management of shortages across the EU

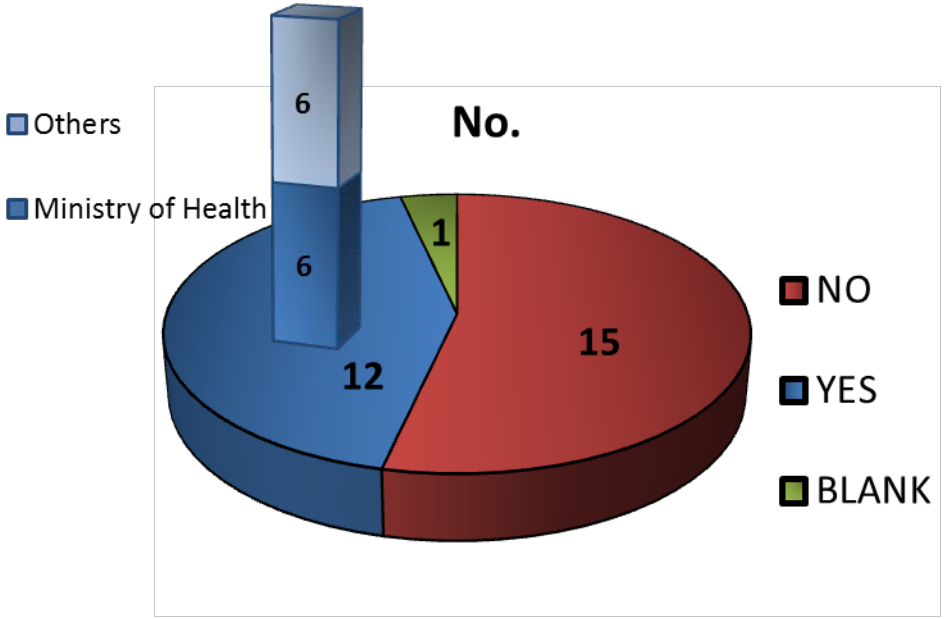
7 Question survey

28 EU Member States + 3 EEA countries

Number of surveys received

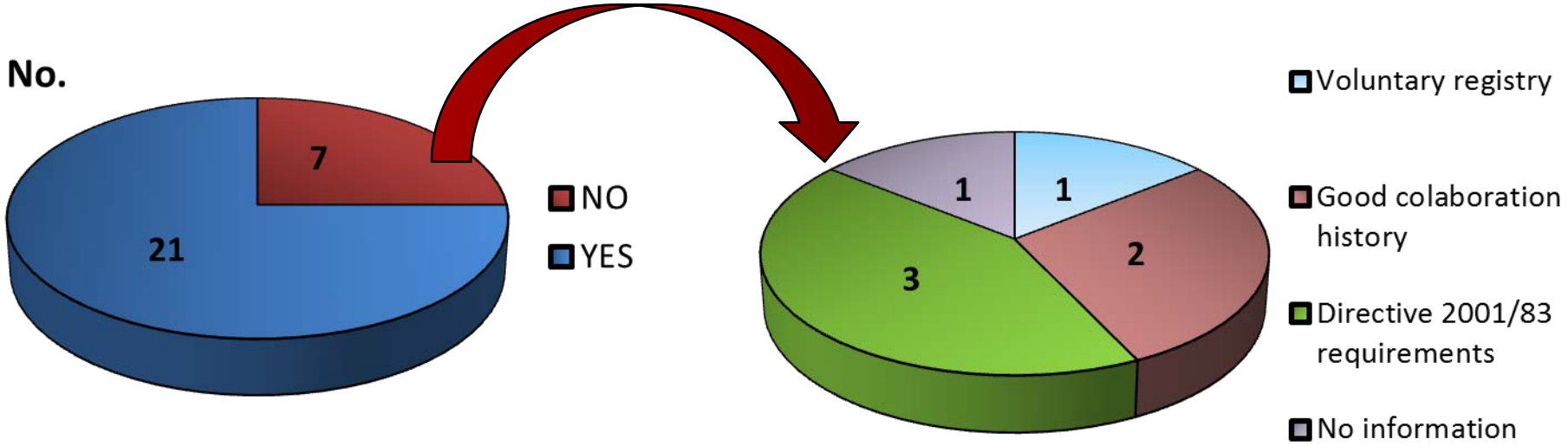


Are there any other Competent Authorities involved?

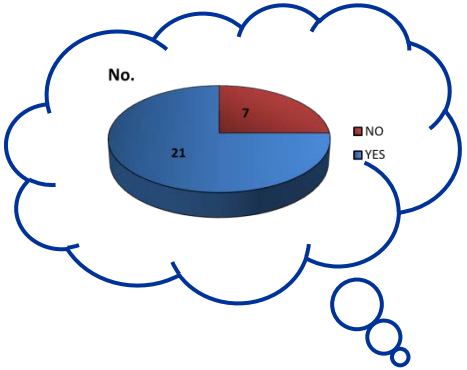


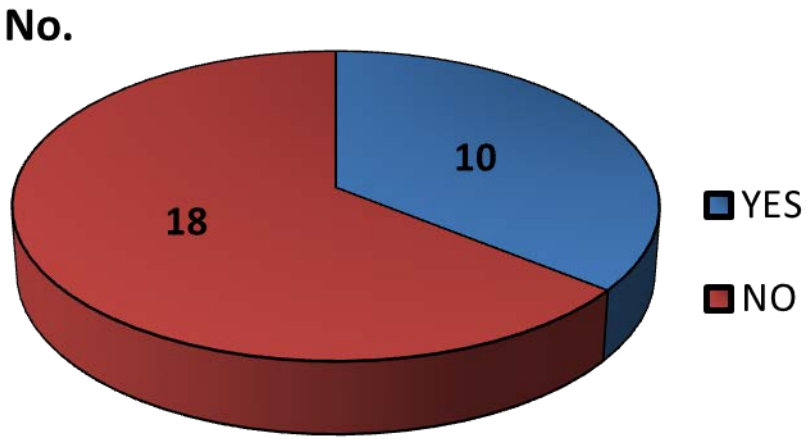
Q1. Is there a requirement in your national legislation for mandatory notification of shortages of medicinal products on your territory?

Q2. If the answer to Q1 is No, do you have alternatives to regulation in dealing with shortages?



Q3. Do you have a definition of what a shortage is in your national legislation / procedures?





Q3. Definition

Non-availability which lasts more than 2 weeks

when MAH cannot deliver a mp to a wholesaler or a pharmacy and it cannot be provided to a patient

Length

Temporary disruption lasting up to 9-12 months

unable to maintain adequate and steady supplies

Adequate supply

All products / clinical impact

No common definition

likely to have an impact on patient care

MAH does not guarantee adequate and continuous supply in order to satisfy the patients' needs

available units of a medicinal product in the pharmaceutical channel below the national consumption needs

Q4(a) Do you require a minimum set of information to be submitted about a shortage?

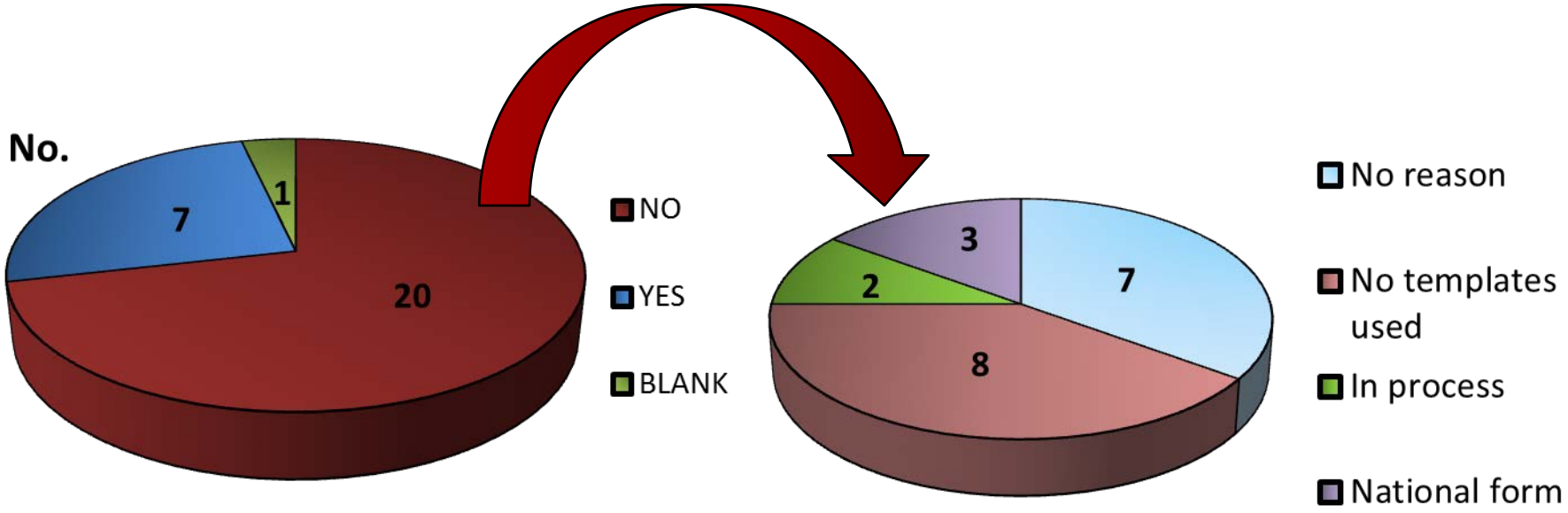
SHORTAGE NOTIFICATION							
Identification of the medicinal product and notifying person and company	Reason/s	Estimated dates of start / end	Stock available (units)	Monthly sales of the affected medicinal product	Alternative treatments	Communication Plan or other mitigation actions	Other information
21	21	21	14 (*)	10 (*)	10	13	2

(*) Some NCAs: data requested in a later stage if needed

Q4(b) Information published about a shortage on your website

INFORMATION PUBLISHED							
Identification of the medicinal product and notifying person and company	Reason/s	Estimated dates of start / end	Stock available (units)	Monthly sales of the affected medicinal product	Alternative treatments	Communication Plan or other mitigation actions	Other information
15	8	13	1	1	9	5	2

Q5. Are you using the templates developed by EMA to assess shortages?



Q6. What analysis do you perform of the shortages that occur in your country?

Q7. Please provide a short summary of the actions you are taking to prevent / solve shortages

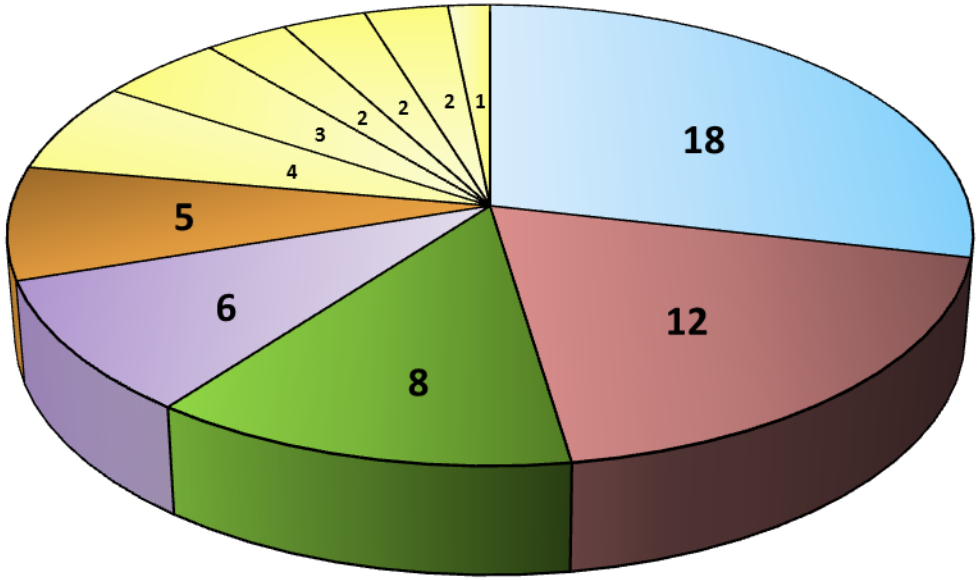
Formal process defined in SOPs

Case by case

No formal analysis

- **Duration**
- **Volume of sales / market share**
- **Strength / pharmaceutical form / administration routes / generics**
- **Other alternatives**
- **Specific population**
- **Specific measures (to prevent / mitigate)**

Q7. Specific measures



- Import from other markets
- Work with MAH/WH
- Export- control
- MA Exceptions / Repackaging
- Increase mf alternatives
- Security stocks (NCAs)
- Information (website) specific recommendations
- Expedited variations
- Periodically reports
- Prevention / mitigation plans
- Gain aditional legal support

Conclusions

In the European Union, shortages are dealt with at national level by the national competent authorities.

No common approach / assessment.

Definition.

Best practices: further development.

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