

# The supply of plasma-derived medicinal products in the future of Europe

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# CHESSMEN - Identification of best practices to address medicines shortages

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# Disclosure

- I have no conflict of interest.
- Declaration of interests published at EMA [European experts | European Medicines Agency \(europa.eu\)](#)



# Content

- WP6 Objectives and deliverables
- Mapping of best practices in monitoring, reporting, and managing medicine shortages
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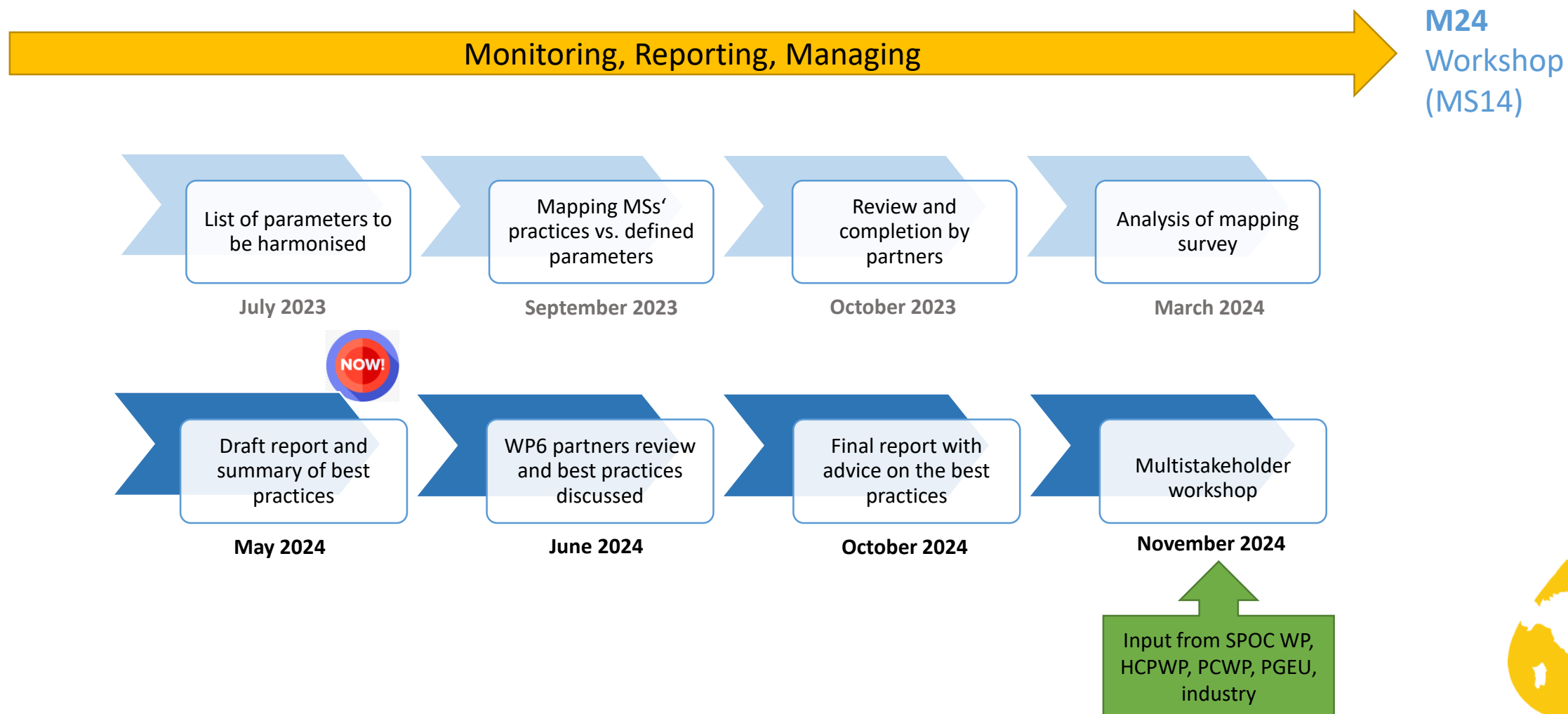


# WP6 Objectives and deliverables

- T6.1 Collection of existing topic-related documents and circulation among WPs → D6.1/MS12 Report
- T6.2 Mapping of best practices in monitoring, reporting, and managing medicine shortages → MS14 Workshop (M24)
- T6.3 Development of comprehensive monitoring, reporting, and managing protocol → D6.2 Report (M30)
- T6.4 National lists of critical medicines and forecasting
  - D6.3: Report on test-case demand forecasting at national level (SUKL) (M27)
  - D6.4: Recommendations for development of National lists of critical medicines (M33)
- T6.5 Design and delivery of Training workshop to the EU national competent authorities → D6.5 Workshop M34



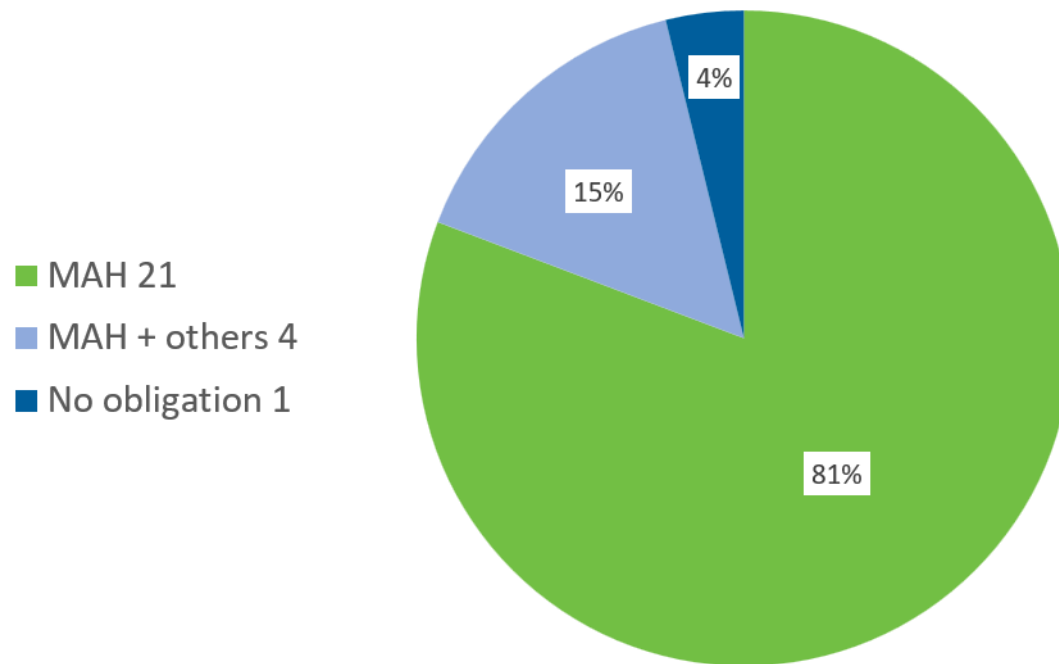
# T6.2 Mapping of best practices in monitoring, reporting, and managing medicine shortages



# **Examples of practices in the reporting medicine shortages (shortage notification) and publication of medicine shortages**



## Legal frame for reporting medicine shortages: Who is obliged to report?



## Reporting medicine shortages: Who is actually reporting?

Who reports	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	S11	S12	S13	S15	S16	S17	S18	S19	S20	S21	S22	S23	S24	S25	S26	S14	
MAH	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
MAH Representatives	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	-	Y	Y	Y	Y	Y
Manufacturers	N	N	N	Y	N	N	N	Y	Y	N	N	Y	N	N	Y	N	N	N	N	N	N	-	Y	N	Y	N	N
Wholesalers	Y	Y	N	Y	Y	Y	N	-	Y	Y	N	Y	Y	Y	Y	N	Y	N	N	Y	N	-	Y	N	Y	N	N
Hospital pharmacies	Y	Y	N	Y	Y	N	N	-	Y	Y	N	Y	Y	Y	Y	Y	Y	N	N	Y	N	-	Y	Y	Y	N	N
Public pharmacies	Y	Y	N	Y	Y	N	N	-	Y	Y	N	Y	Y	Y	Y	Y	Y	N	N	Y	N	-	Y	Y	Y	N	N
Physicians	N	Y	-	N	N	-	-	-	Y	Y	N	Y	N	Y	Y	Y	Y	N	N	Y	N	-	-	N	-	N	N
Patients	Y	Y	-	N	N	-	-	-	Y	Y	N	Y	N	N	Y	Y	Y	N	N	Y	N	-	-	N	-	N	N

### Key:

Y	Yes
N	No
-	No answer



# Published data in the shortage catalogue\*

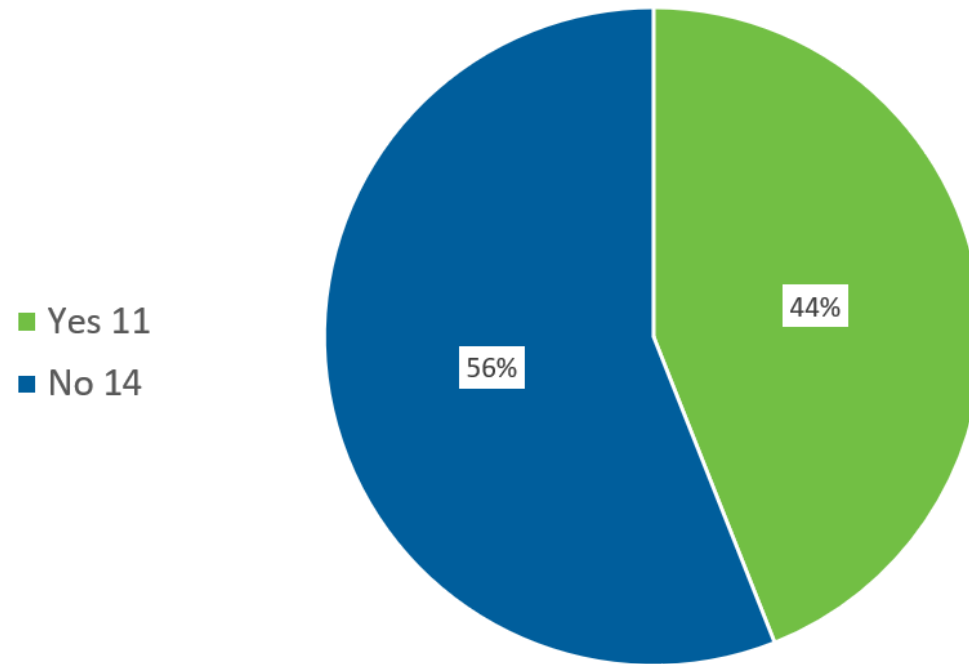
Data point	SE	NO	DE	BE	PT	AT	CZ	FI	FR	HR	DK	EE	ES	HU	IE	IT	GR	LV	LT	RO	SI	BG	CY	LU	NL	PL	26
Product name	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x					22
Strength	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x					22
Pharmaceutical form	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x					22
Active substance/INN	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		x					21
Expected end date of shortage	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x						21
MAH	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		x	x	x						20
Pack size	x	x	x	x	x	x	x	x	x	x		x	x	x		x	x	x	x		x	x					19
Start date of shortage	x	x	x	x	x	x	x	x	x	x		x		x	x	x	x	x			x						17
Root cause of shortage	x	x	x	x	x	x	x			x	x			x	x	x	x			x							14
Availability of alternatives	x	x	x	x	x		x					x	x	x	x	x	x	x	x								13
Date of notification	x	x	x			x		x	x	x	x									x	x	x					12
ATC code	x	x	x	x			x	x			x	x	x	x				x									11
Date of notification update	x	x	x	x	x	x	x	x	x		x				x												10
Expected start date of shortage	x	x	x	x			x	x		x	x		x														9
Information to HCPs	x	x	x		x	x			x						x												7
Alternative medicines listed	x		x		x		x					x							x								6
Shortage status**	x	x		x		x			x																		5
Actual end date of the shortage	x			x	x	x				x																	5
Mitigation measures	x	x			x								x			x											5
<b>Total: 19</b>	<b>19</b>	<b>17</b>	<b>16</b>	<b>15</b>	<b>15</b>	<b>14</b>	<b>14</b>	<b>12</b>	<b>12</b>	<b>12</b>	<b>11</b>	<b>11</b>	<b>11</b>	<b>11</b>	<b>11</b>	<b>11</b>	<b>10</b>	<b>10</b>	<b>9</b>	<b>8</b>	<b>8</b>	<b>5</b>					

\*Analysis of 22 publicly available shortage catalogues performed by JAZMP in January 2024

\*\* e.g. anticipated, ongoing, resolved

## Notification to prescribers:

Do you have in place push notification to prescribers?

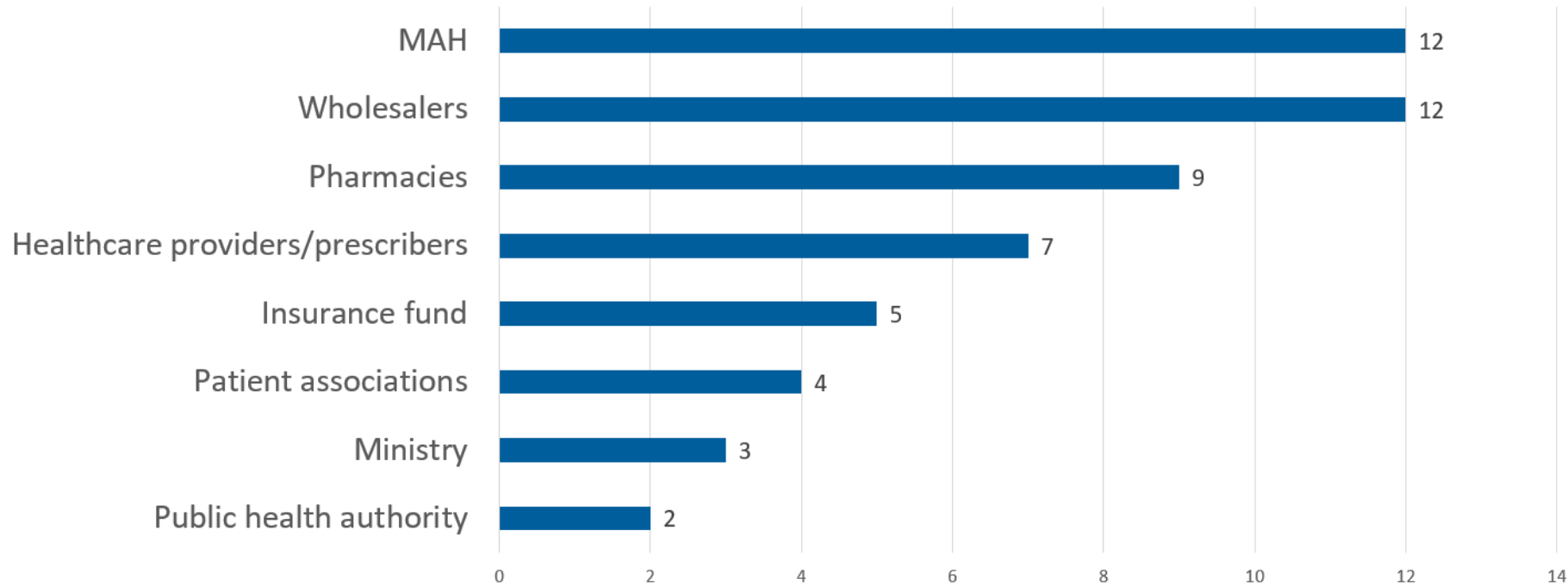


# Examples of practices in managing medicine shortages



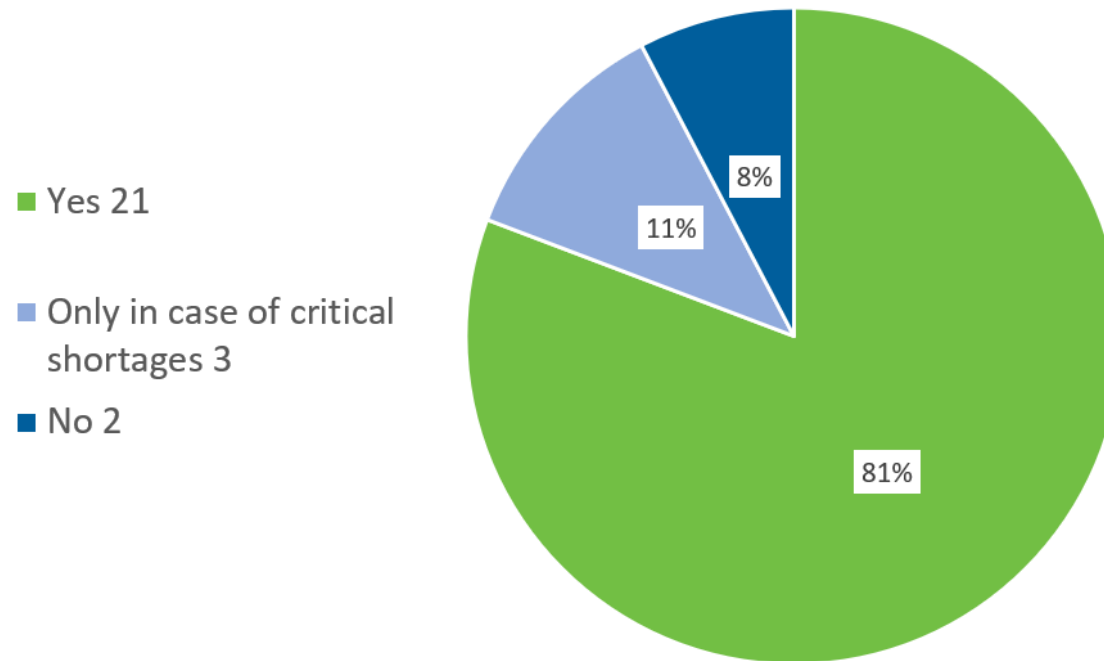
Stakeholder dialog: Do you as NCA take an active role in co-ordination of response to a shortage across the stakeholders? **100% YES**

## Which stakeholder?

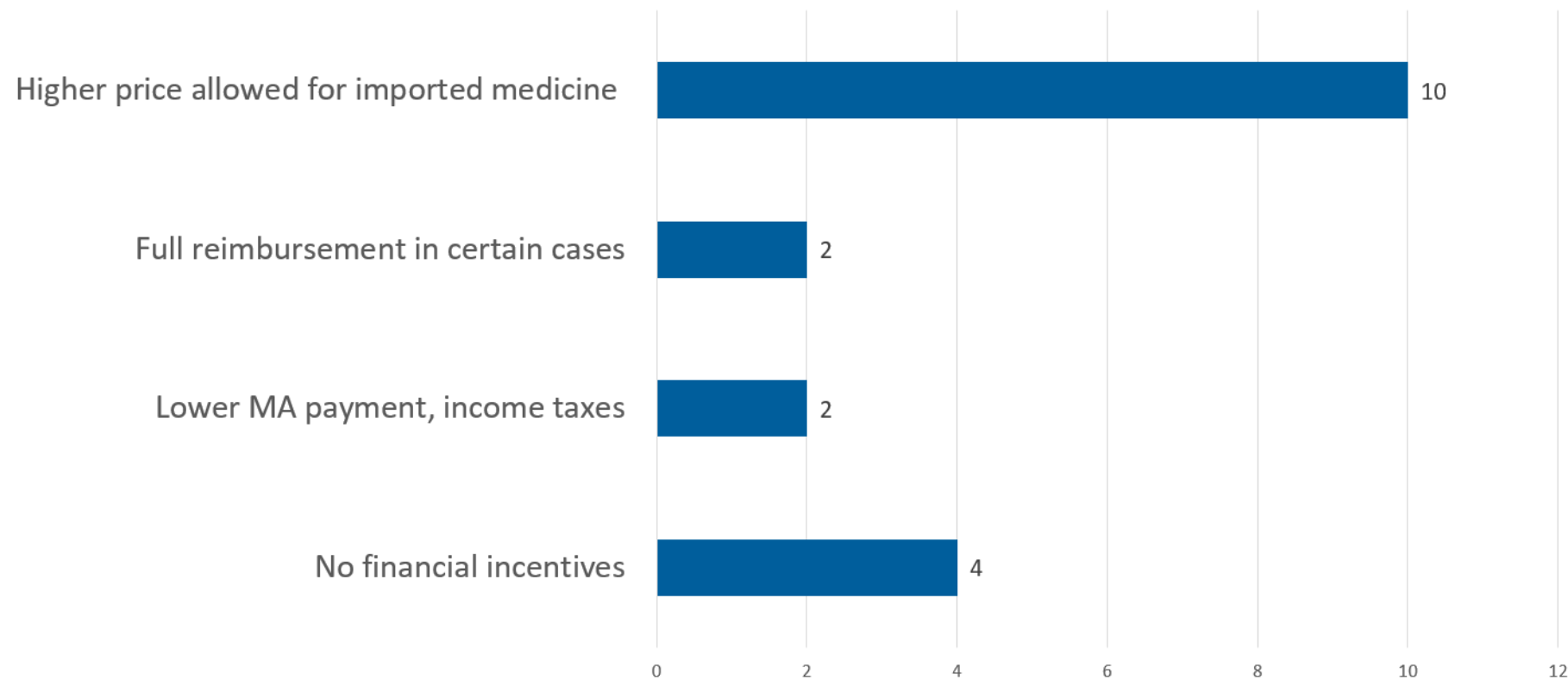


## Stakeholder dialog: Which are the measures that you proactively take?

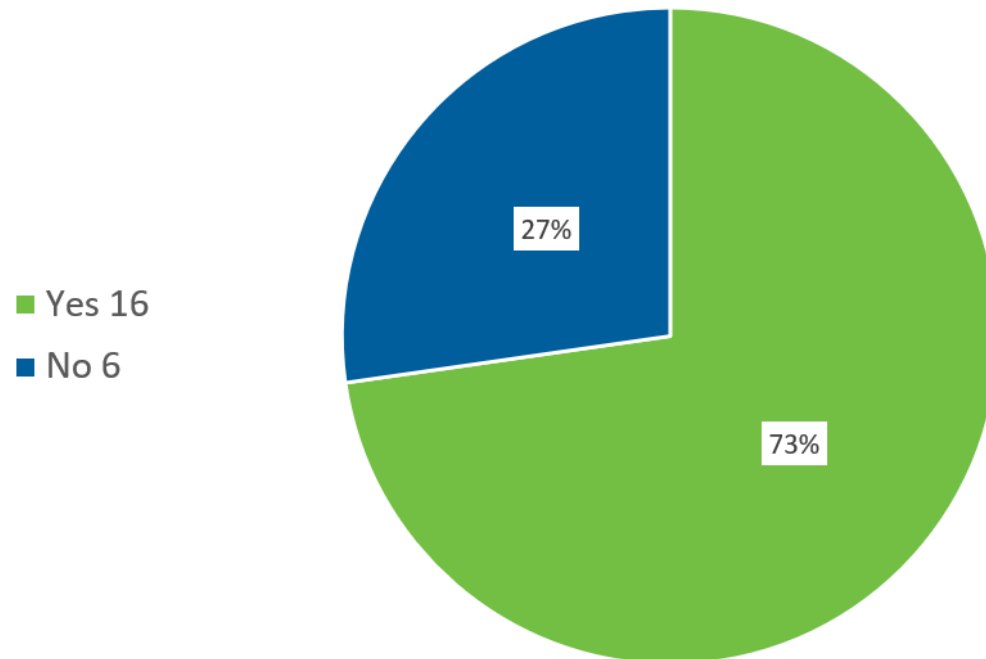
Co-ordination of stakeholders on import of the equivalent or alternative medicinal products (authorised/unauthorised)



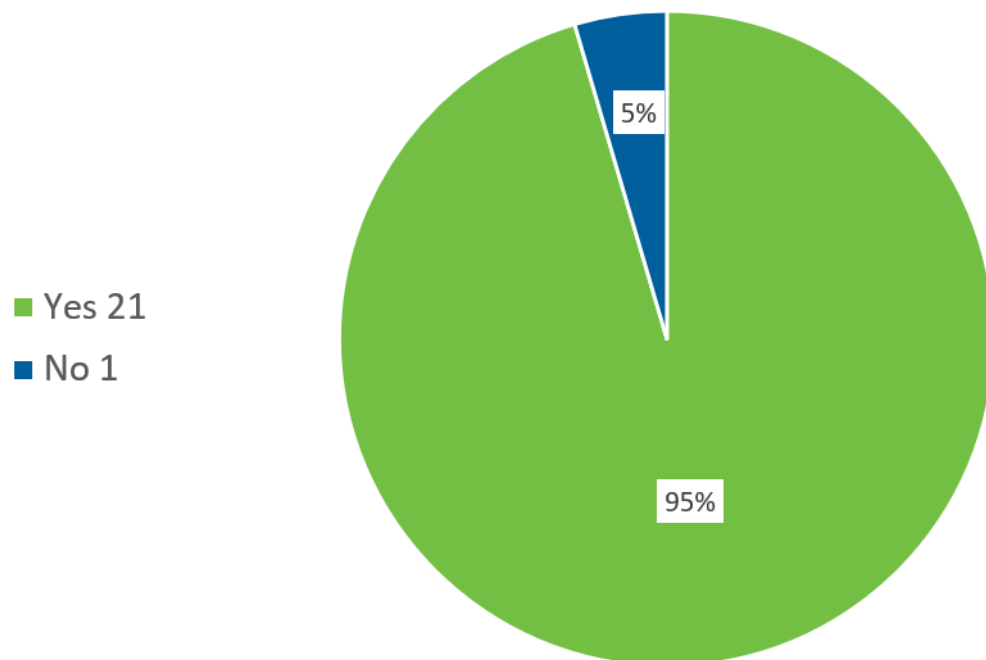
## Financial measures: Which financial incentives do you have in place for imported medicinal products?



**Regulatory measures:** Do you use/have a possibility of fast-track variation regulatory procedures, e.g. to permit MAHs to swiftly source starting materials, reagents, intermediates or active substances from alternative suppliers?

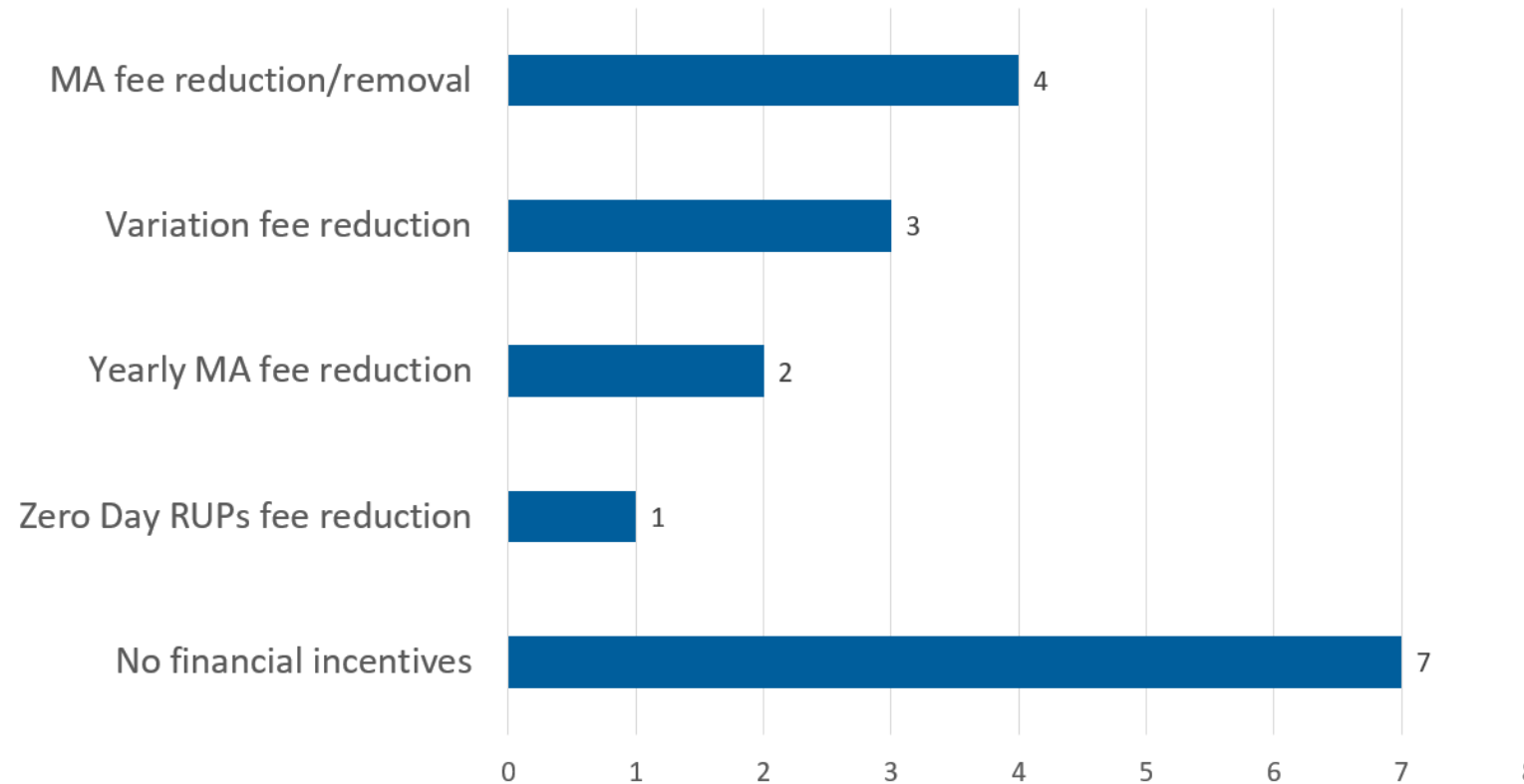


**Regulatory measures:** Do you use/have a possibility of a facilitated granting of national marketing authorisations of medicinal products that are authorised in another EU/EEA Member State, e.g. Day Zero MRP/RUP



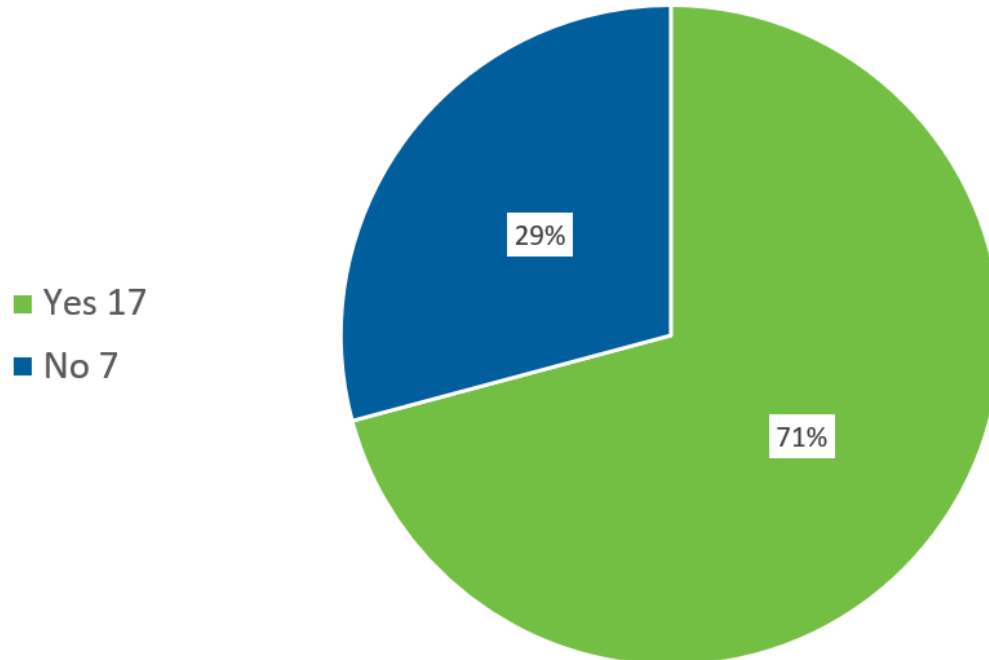


## Financial measures: Which financial incentives do you have in place for regulatory procedures?

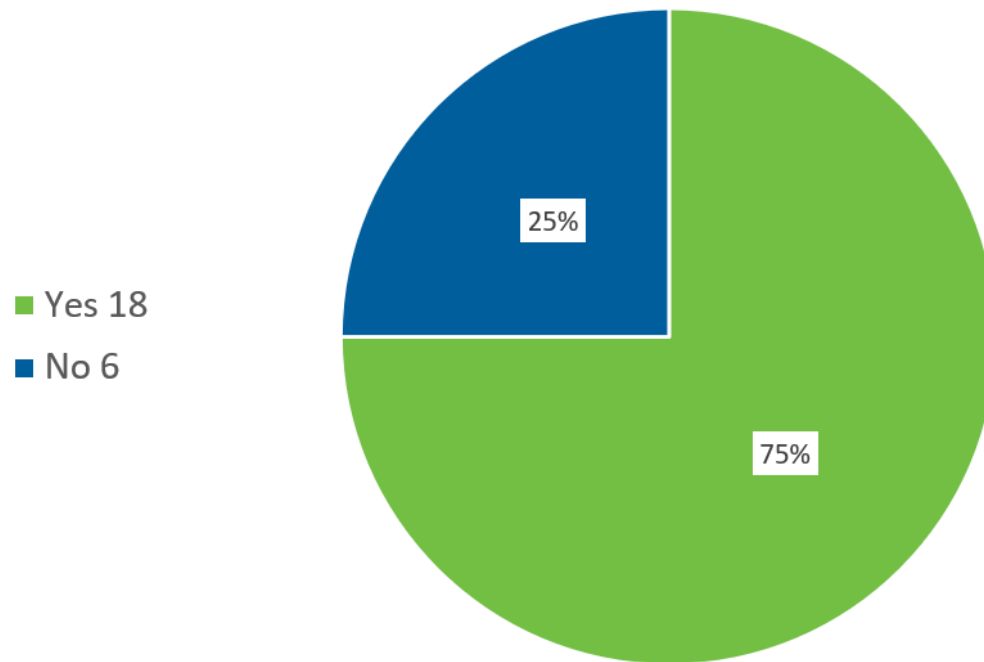


## Stakeholder dialog: Which are the measures that you proactively take?

Co-ordination of stakeholders (e.g. prescribers, advisory board, learned societies ...) on issuing treatment recommendation during shortage of medicinal product

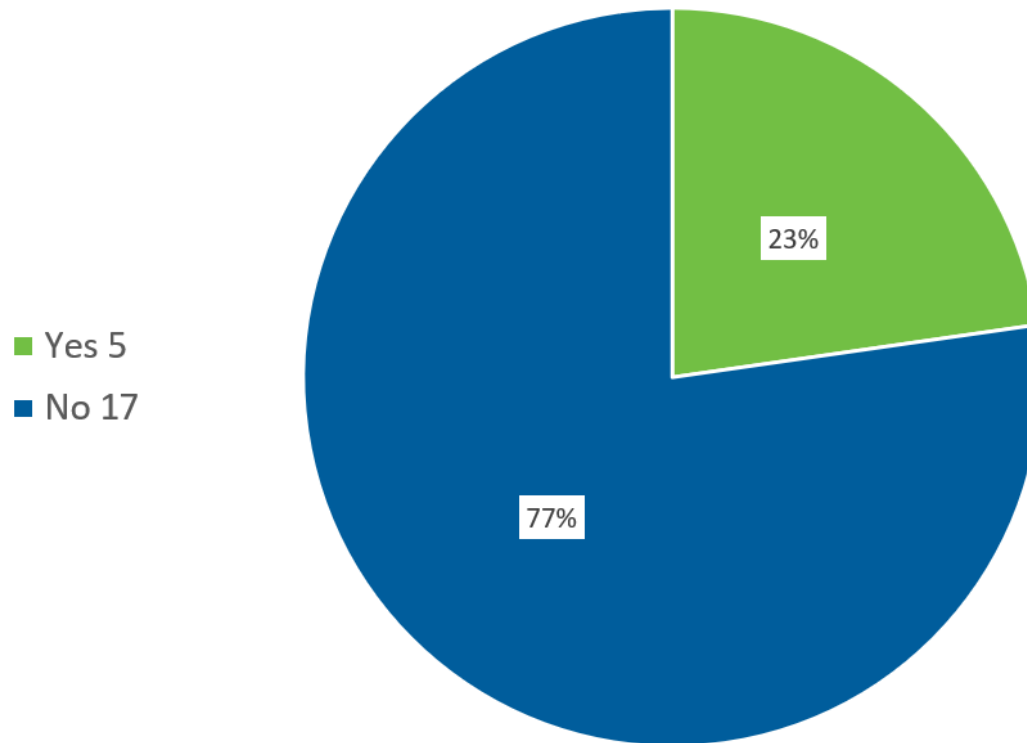


## Widen professional competences of pharmacists: Is generic substitution at the ATC5 allowed?

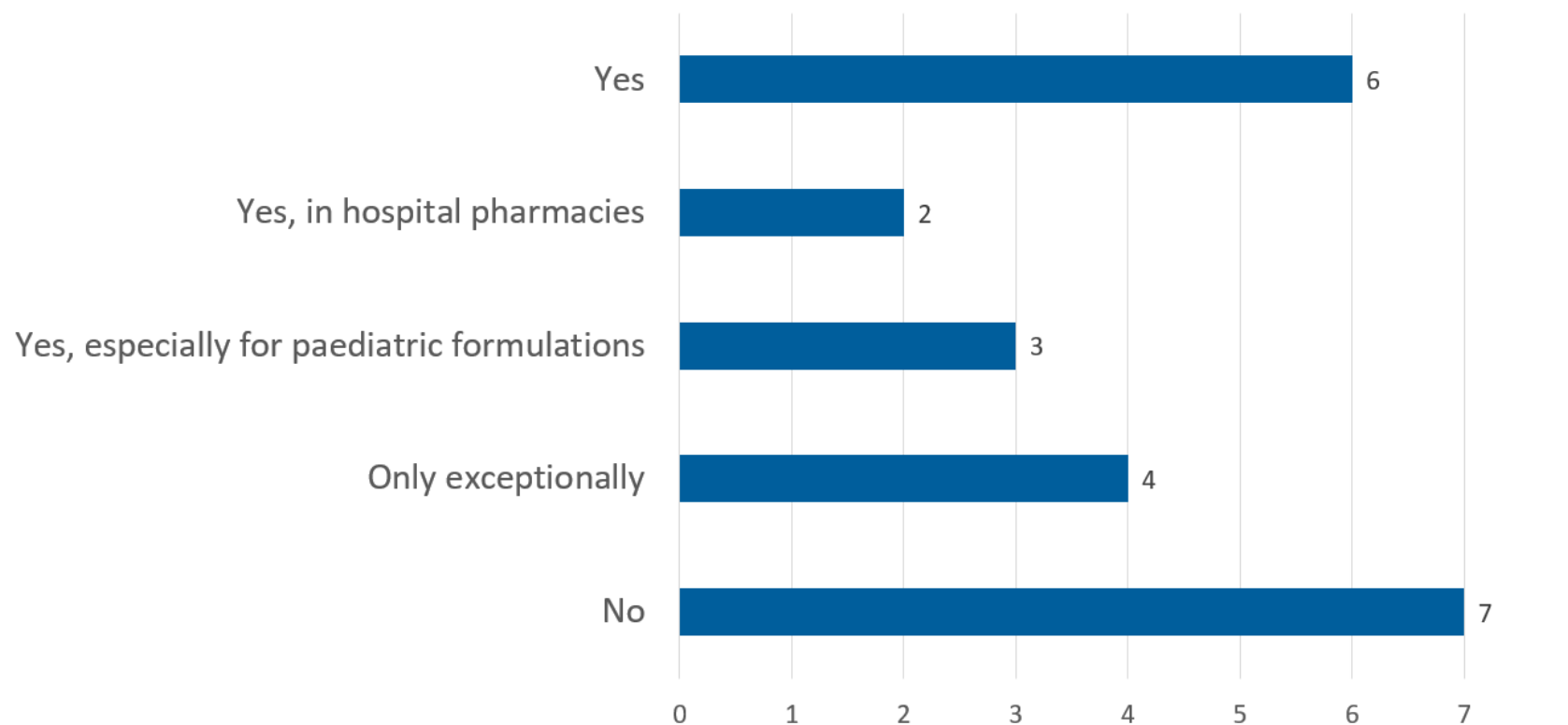


Is therapeutic substitution at the ATC4 allowed? **100% NO**

**Widen professional competences of pharmacists:** Is changing to the same medicine with a different strength when still available, and adjusting therapy posology accordingly allowed?



## Widen professional competences of pharmacists: Do you manage shortages with galenic manufacturing or preparation of magistral medicinal product? Any comments on this measure?



*“Prevention is better than cure,  
but if you must cure, cure quickly.”*

*Winston Churchill*

**Thank you**

