

EMA experience with the amended Variation Regulation

Statistics on variation procedures and WS

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Assessment of type IA received outside annual update
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- [Type II procedures : 2024 vs 2025](#)

Type IA procedures : 2024 vs 2025



Overall decrease in number of Type IA/IAIN procedures submitted

– 27%

Significant **decrease** of Type IA procedures

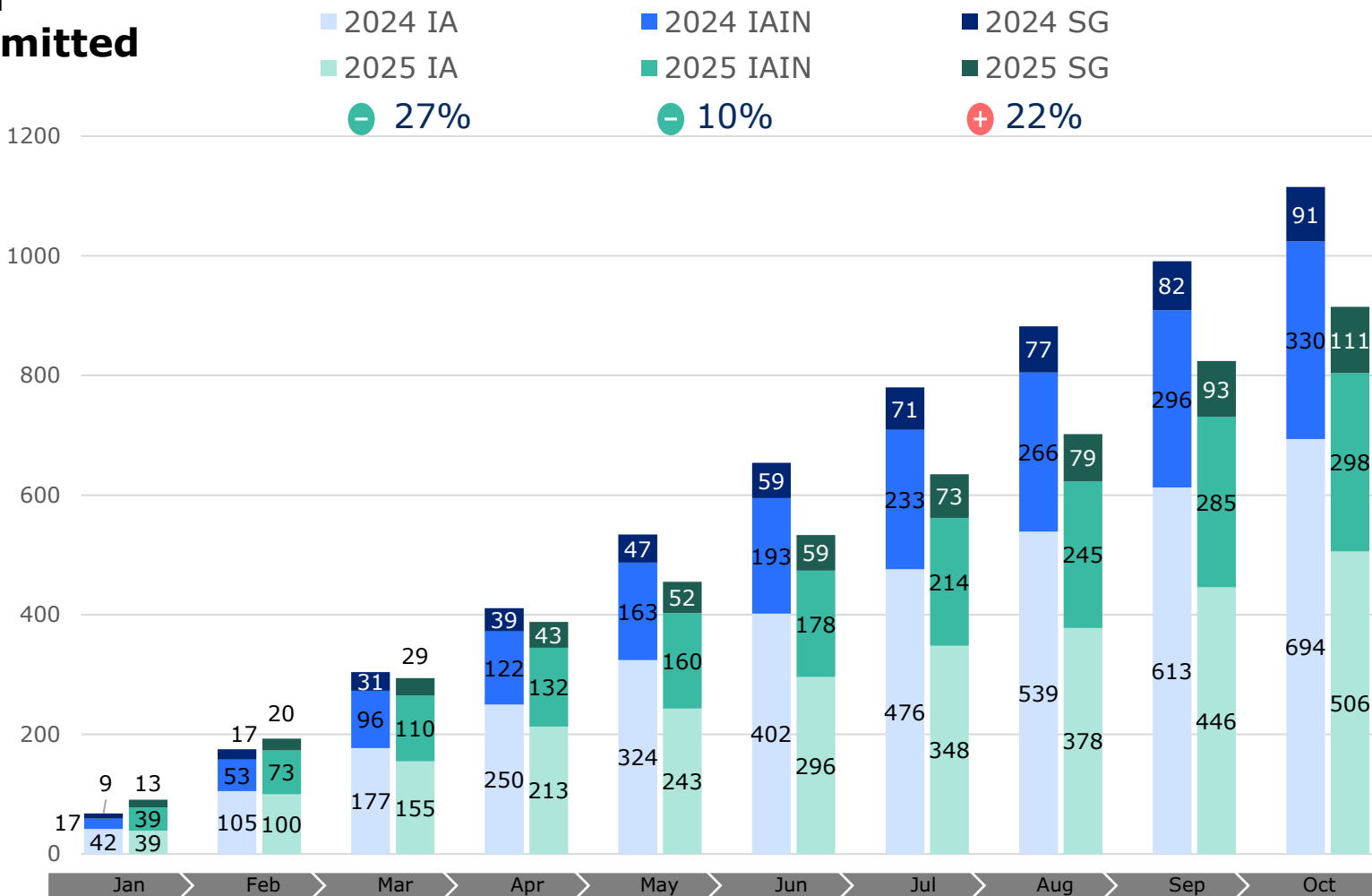
– 10%

Small **decrease** of Type IAIN procedures

+ 22%

Increase of Type IA/IAIN super groupings

2024 vs 2025 Cumulative data

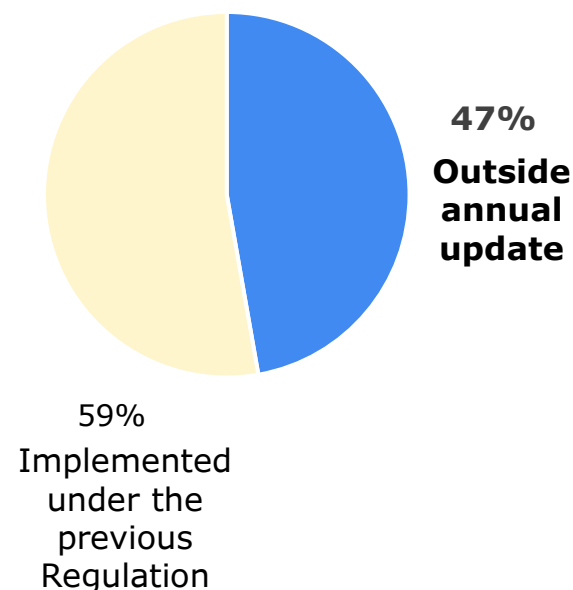


Submissions from 01/01 to 31/10

Analysis of Type IA procedures submitted

47% of Type IA procedures received in 2025 were submitted under the amended Regulation but outside annual update

IA procedures outside annual update for changes implemented under the amended Regulation*	239
IA procedures for changes implemented under the previous Regulation*	267
Total number of IA procedures*	506



Type IA variations implemented as of 2025 must be sent annually, no earlier than 9 months and no later than 12 months after the first implementation date.

Some exception are allowed as per guidance :

These submissions must be **justified** by the MAH

**Data collected from 01/01/2025 to 31/10/2025. Annual update submissions as per the new regulation expected as of 01/10/2025 at the very earliest.*

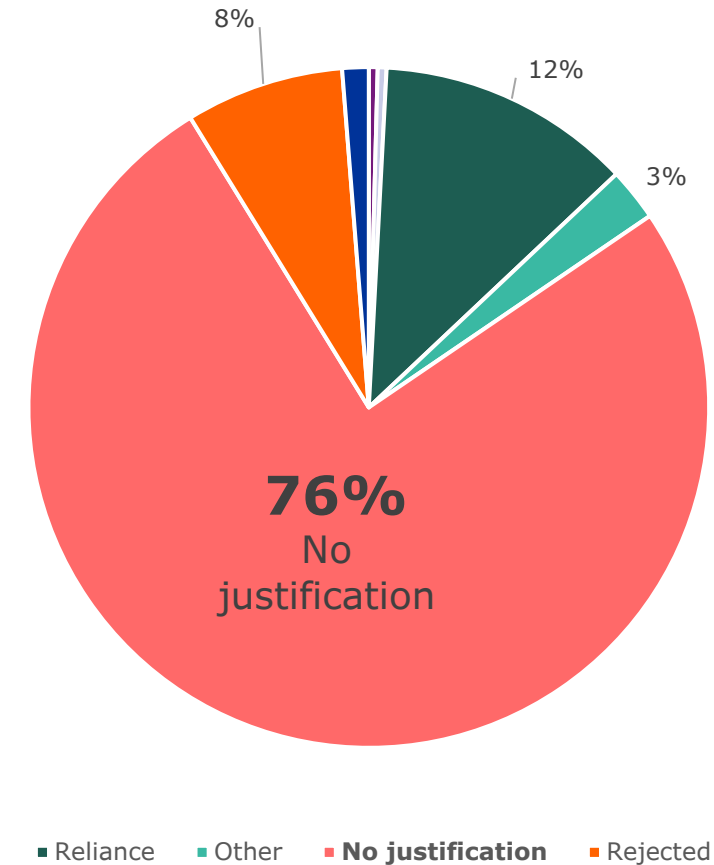
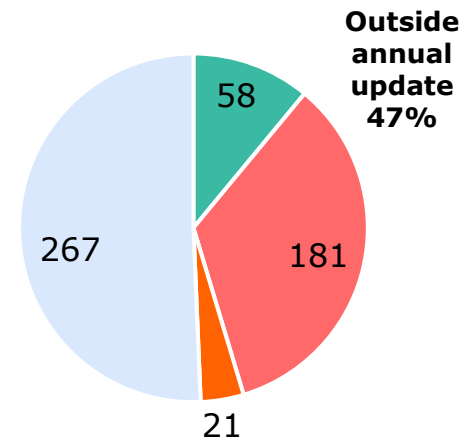
Revised Variation framework

Analysis of type IA received outside annual update

Overall, there was low compliance to the new regulation

76% of Type IA submissions outside annual update lacked justifications from the MAH

Detail of justification	Number of submissions*
Urgent safety restriction	1
Inspection	1
Reliance	29
Other : • To meet a commitment	6
Justification	58
No justification	181
<i>Rejected</i>	<i>18</i>
<i>Withdrawn</i>	<i>3</i>
Total number of submissions outside of annual update	239
Type IA submitted in 2025, implemented under the old regulation	267
Total number of IA submitted in 2025	506



*Submissions from 01/01- 31/10/2025

Conclusions

- General decrease in the number of IA procedures, but not as much as expected (27% decrease on IA, 10% decrease on IAIN and 22% increase in supergroupings).
- Still high number of IA procedures submitted outside the Annual update, the majority of them (76%) with no justification
- No IA has been rejected for this reason, but compliance can be improved.
- MAHs are reminded that Type IAs not requiring immediate notification should be submitted as part of an annual update.
- A justification should always be provided in exceptional individual submissions immediately after implementation as detailed under EMA Q&A.

Type IB procedures and IB WS: 2024 vs 2025



Overall increase in number of Type IB procedures submitted*

+ 9%

Small **increase** of Type IB procedures

+ 175%

Significant **increase** of Type IB worksharing procedures

Total number of IB variations* has increased 14.85%
(2491 in 2024 vs 2876 in 2025)

**Data from 01/01 to 31/10*

2024 vs 2025 Cumulative data

2024 IB

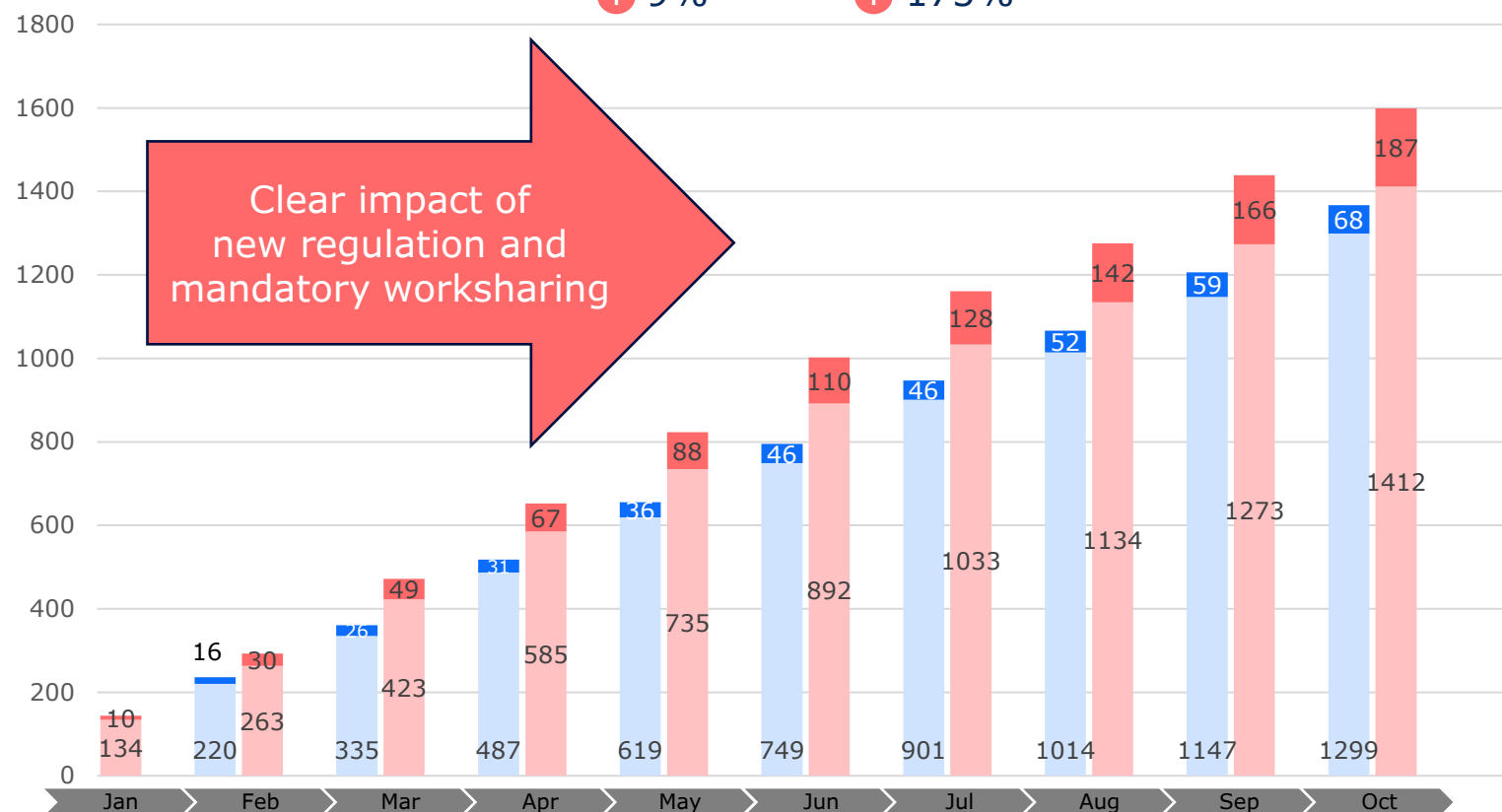
2024 IB WS

2025 IB

2025 IB WS

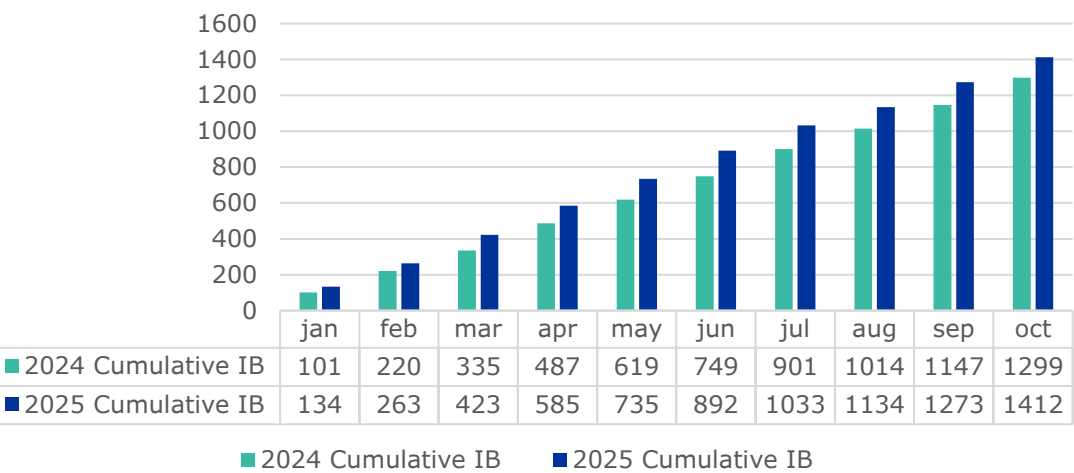
+ 9%

+ 175%

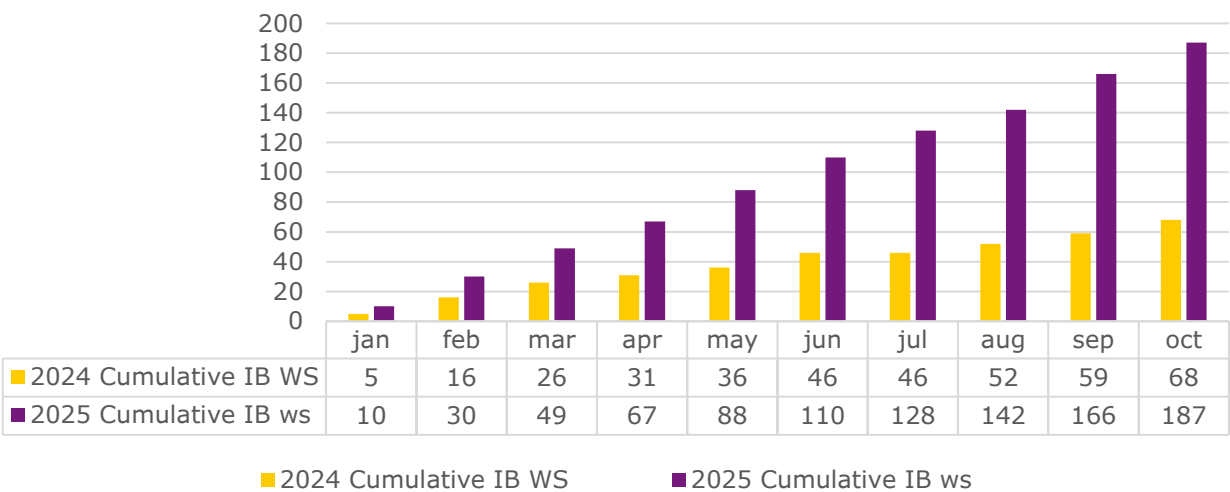


Type IB procedures : 2024 vs 2025

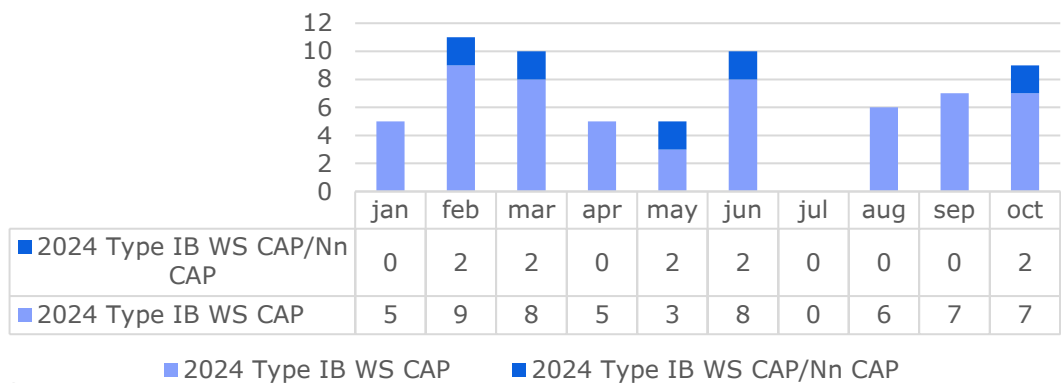
Cumulative overview IB procedures



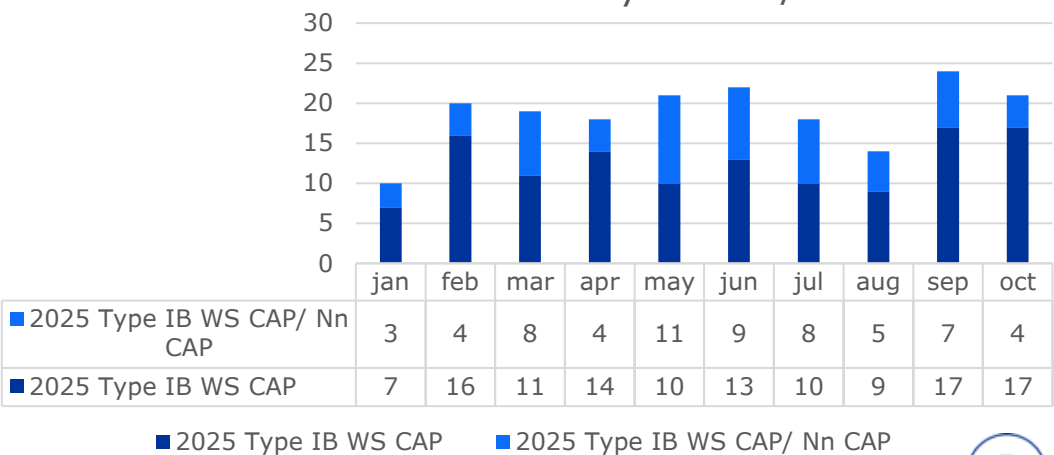
Cumulative overview IB WS procedures



2024 Type IB WS
CAPs only vs CAP/NAP



2025 Type IB WS
CAPs only vs CAP/NAP



Type II procedures and II WS: 2024 vs 2025



Overall small increase in number of Type II procedures submitted

+ 10%

Small **increase** of type II procedures

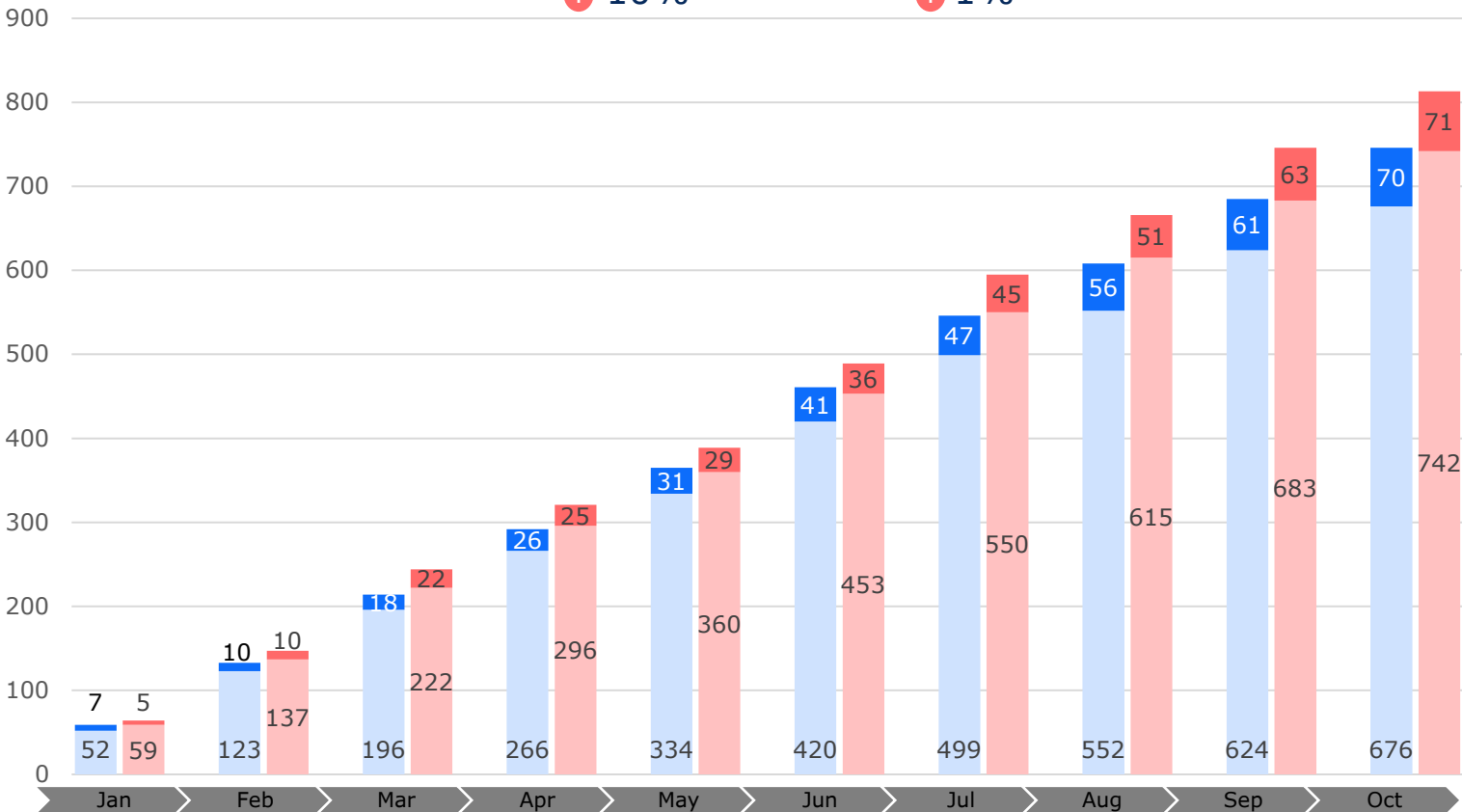
+ 1%

No significant **increase** of type II worksharing procedures

Submissions from 01/01 to 31/10

2024 vs 2025 Cumulative data

2024 II 2024 II WS
2025 II 2025 II WS
+ 10% + 1%



Conclusions

- High increase (175%) in the number of type IB WS procedures.
- No decrease in the number of non-WS procedures as a result, they have still increased 9%.
- High increase in the number of IB variations as a whole (14.85%), maybe due to the New Fee regulation?
- Clear increase in the number of WS including CAPs/NAPs vs 2024
- Different behaviour is observed for type II variations with an increase of 10% in type II procedures, but no meaningful increase on the number of type II WS (1%).



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Thank you

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