



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## 8th Industry Stakeholder Platform

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**Topic 8:** Predictability on marketing authorisation submissions

27 June 2022

Francesca Day





## Background

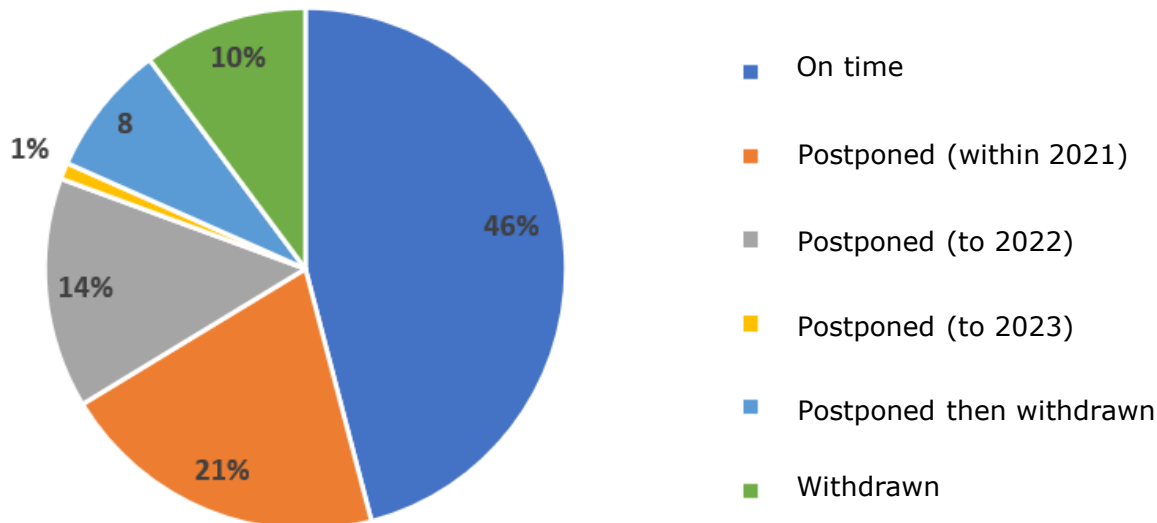
- ❖ At the 7th Industry Platform Meeting on 01 December 2021, data was presented to highlight the very poor predictability of initial MAA submissions.
- ❖ The presentation today aims to update all stakeholders with more recent data.
- ❖ Discussions are occurring at network level regarding options for ensuring better predictability of submissions. EMA would like to work together with industry to find a practicable solution.



# The problem

These data show the actual submissions of initial MAAs in 2021 versus what was projected in Dec 2020. All the submissions had a Letter of Intent.

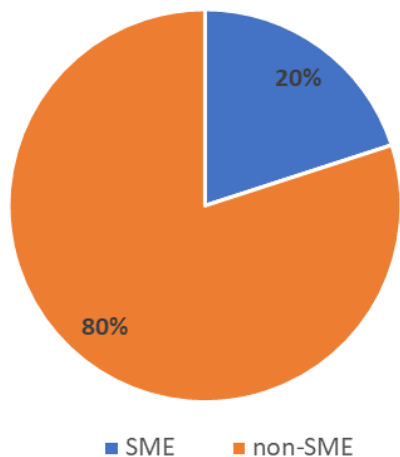
Submission timelines for MAAs with Lol



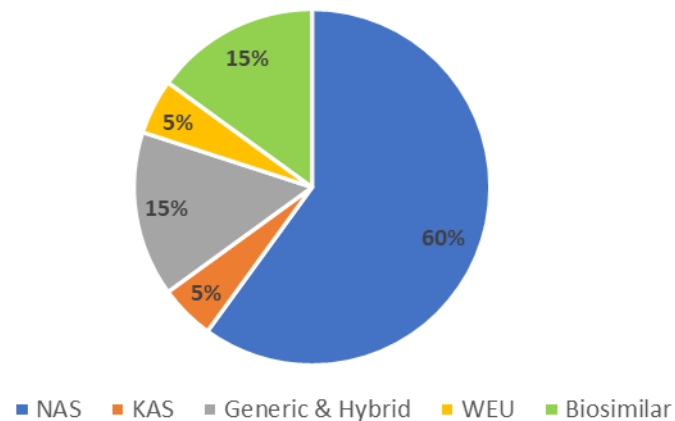


# The landscape (delays within 2021)

Delay within the year: type of applicant

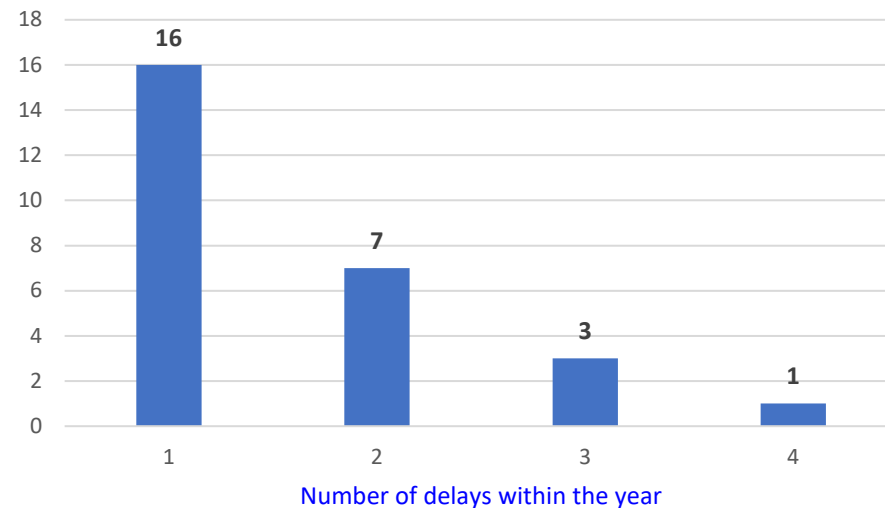
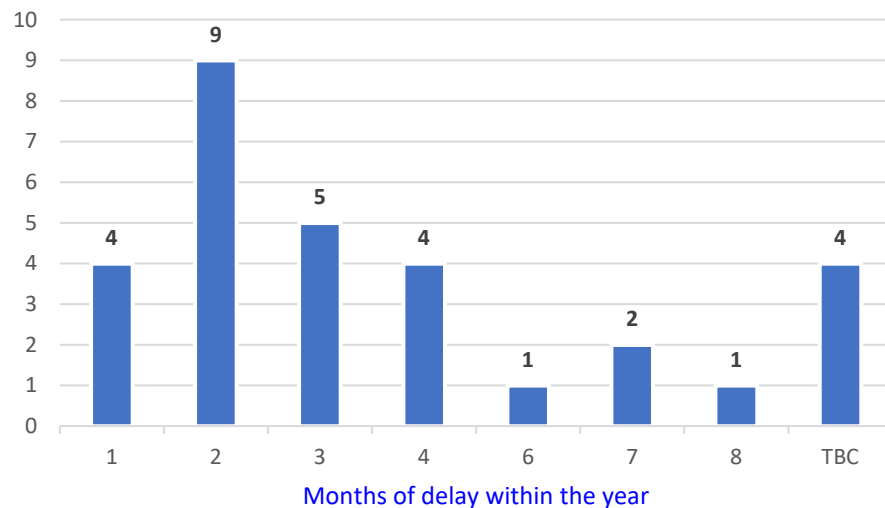


Delay within the year: legal basis



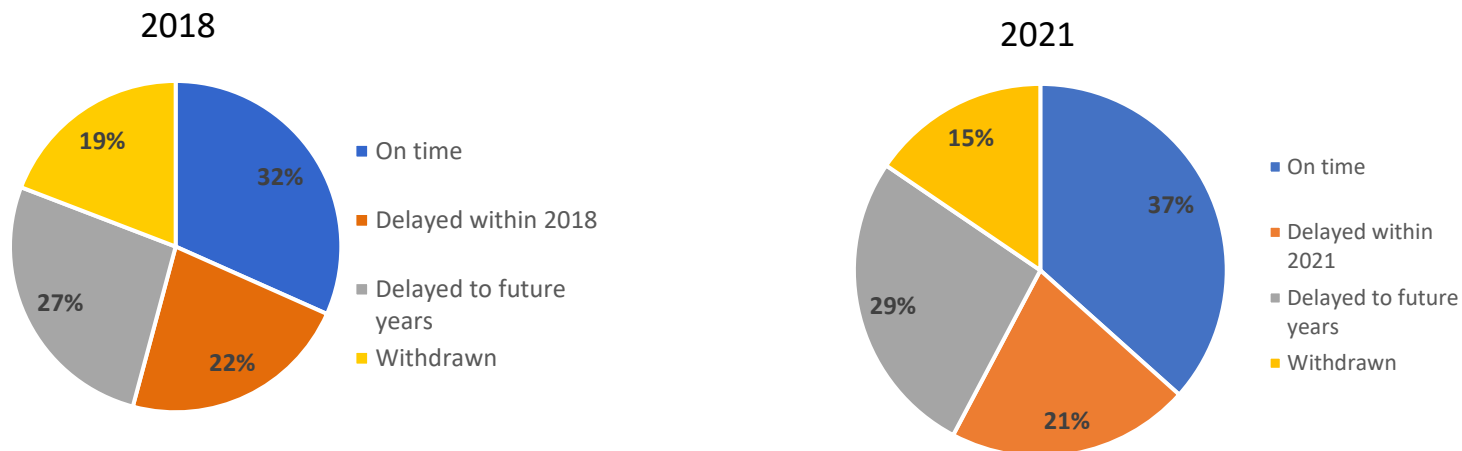


## The extent (delays within 2021)





# Is COVID-19 to blame?

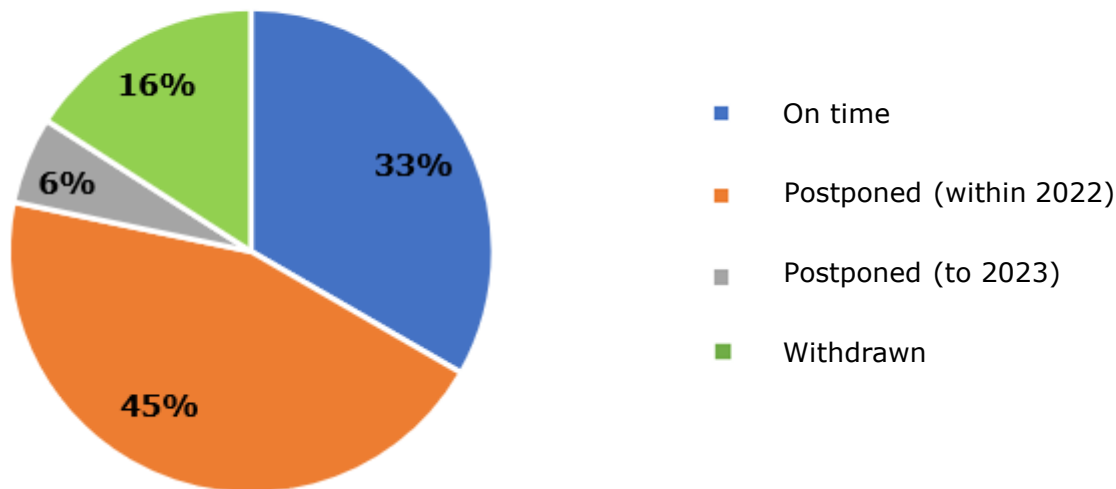




## The landscape for H1 2022

These data show the actual submissions of initial MAAs in H1 2022 versus what was projected in Dec 2021. All the submissions had a Letter of Intent.

Timelines Jan-May-22





## The impact

- ❖ The 1 year forecast in particular is critical for Member States planning and Rapporteur biddings.
- ❖ Rapporteurs are generally assigned at the time of receipt of the Letter of Intent, around 6-7 months prior to submission.
- ❖ Rapporteurs allocate their assessment teams based on the projected submission dates and bid for rapporteurships based on their planned work.
- ❖ Changes to submission dates, especially late changes and/or multiple changes, mean that Rapporteur teams are tied-up and not able to take on other assessments.





## The ask

- ❖ Realistic submission dates in Eligibility Request/Letter of Intent.
- ❖ Inform EMA as early as possible of changes.
- ❖ EMA sends an automatic email, 3 months ahead of the intended submission date, to check whether the company is still on track to submit – please respond to the email asap, in particular if you are not able to make the submission date.



## The future

- ❖ Due to the problems with network capacity, discussions are ongoing to try and find possible solutions to ensure better predictability of iMAAs.
  - Possibility of reducing the time of Rapp appointments closer to the submission date
  - Possibility of utilising slots (as is now the case for DCP/MRP)
  - Not possible to select a new submission date without pre-agreement with the Rapporteurs
  - ...
  
- ❖ EMA would be glad to hear any suggestions from Industry that would help in ensuring better predictability.



# Any questions?

## Further information

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