EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

7th Industry Stakeholder Platform

Topic 7: Measures Taken to help the EU regulatory network to cope with increased workload

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Background

- The COVID-19 pandemic had put a considerable amount of pressure on the Network and the Agency (as well as the whole sector)
- Post-pandemic there will be a desire to implement some of the learnings and new approaches from COVID-related products more broadly
- There is an interest from all parties to explore ways to free up resources

3 Areas of focus

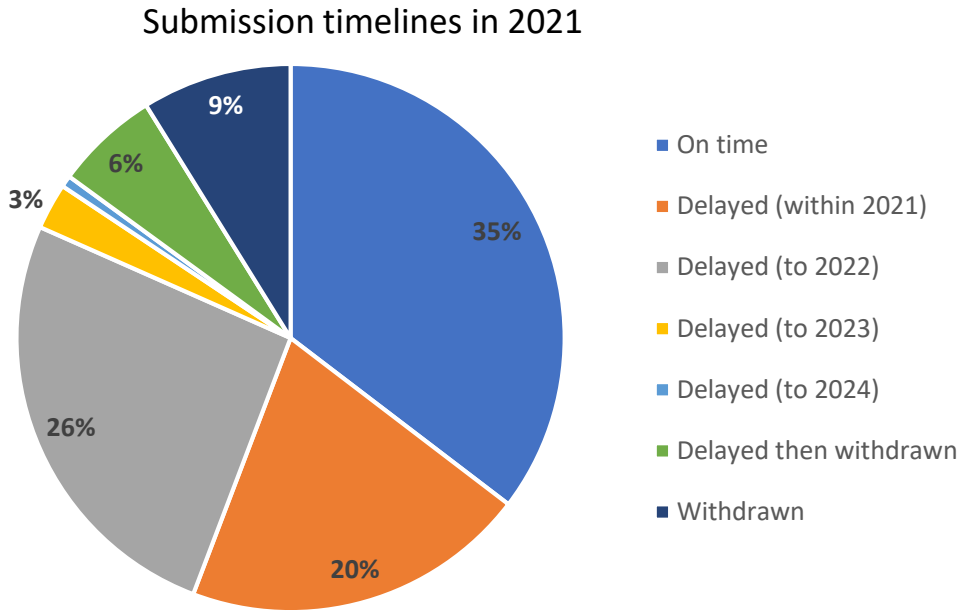
- Better planning
  - Less variability in MAA submission dates
  - More visibility vis-a-vis Type II variation submissions
- Better alignment between documentation submitted and assessment reports
- Clearer Q&A, fewer questions to PLs

Area 1

Better planning

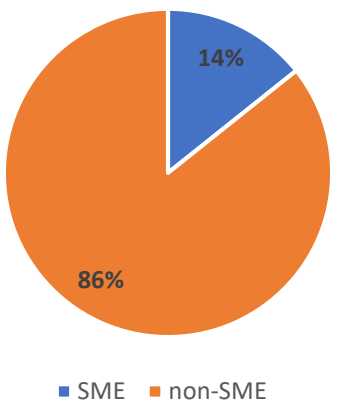
The problem

These data show the actual submissions of initial MAAs in 2021 versus what was projected in Dec 2020

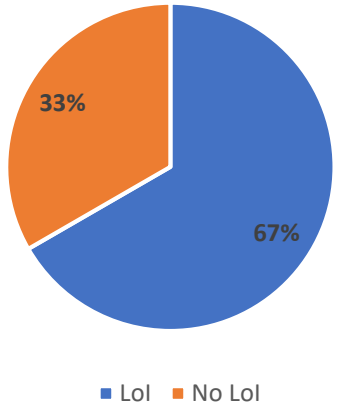


The landscape (delays within 2021)

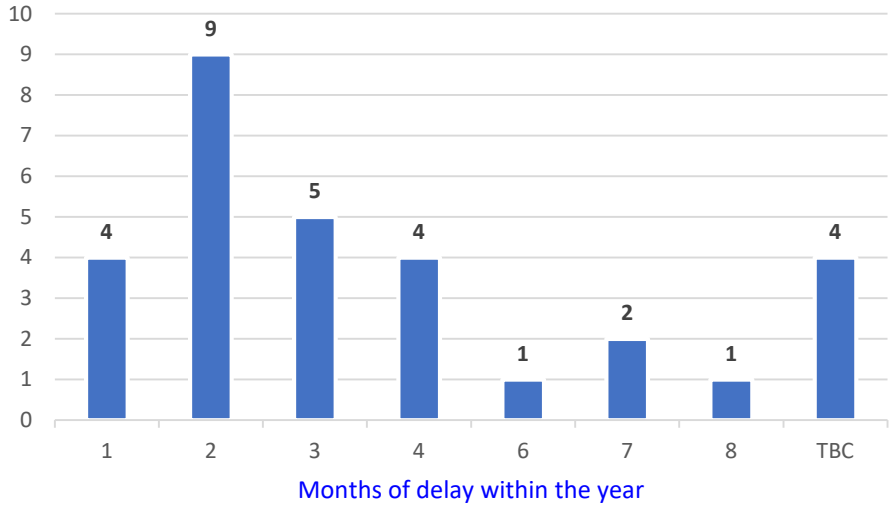
Type of applicant

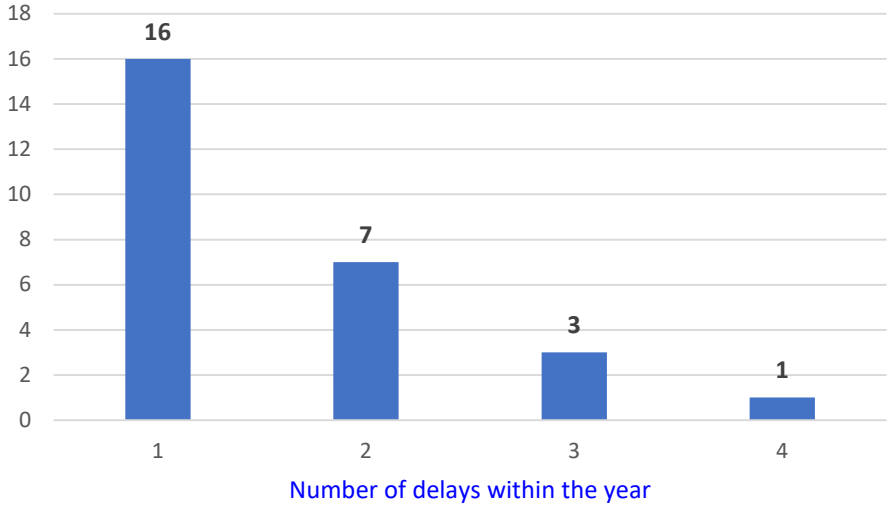


Presence of a Letter of Intent

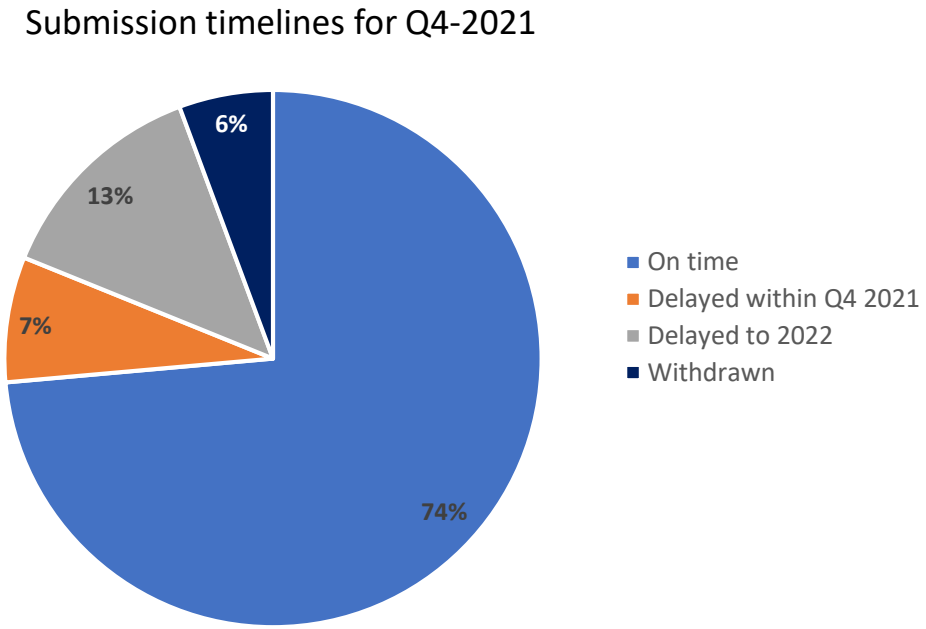


The extent (delays within 2021)

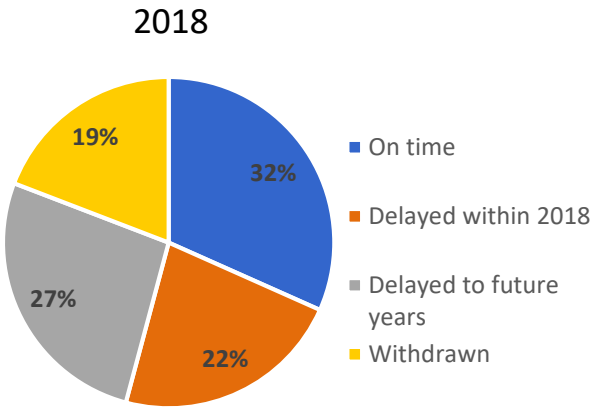


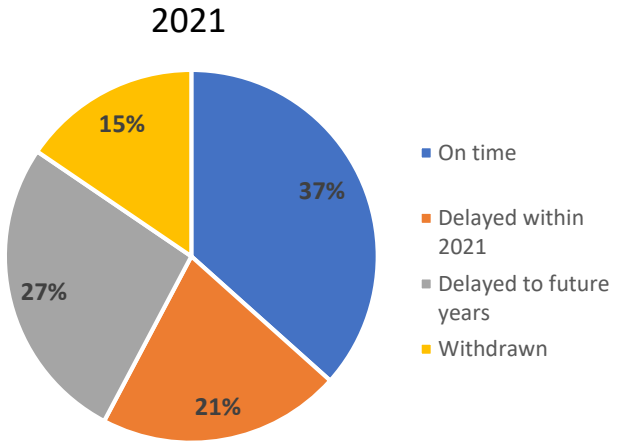


Is the short-term planning better?



Is COVID-19 having an impact?





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

MAAs

- EMA is looking at options to improve planning for initial MAA submissions and Line Extensions
- EMA is considering reducing the time of Rapp appointments closer to the submission data in view of the uncertainties

Variations

- Currently limited visibility of planned submissions, yet they constitute the vast majority of workload
- Workload planning for Rapporteur assessment teams is very difficult
- It would be beneficial for the system if there was some way of projecting the workload in relation to variations (all suggestions welcome)

Area 2

Better alignment between documentation submitted and assessment reports

The problem #1

- A considerable amount of time is spent on consolidating/summarising information into the assessment reports
  - Both on the EMA side but also from the Rapporteur assessment teams
  - Currently the AR template and the information submitted (e.g. M2.5) are not aligned, rendering the exercise more difficult

Possible solutions (for discussion here):

- Update the AR template
- Give better guidance/more granularity for module 2 documents
- Adopt similar approach to FDA with their Assessment Aid

The problem #2

- Complex changes to labelling are often non submitted in the most efficient way
  - Individual submissions instead of grouping
  - Changes to the same section submitted sequentially rather than in parallel or grouped

Possible solutions (for discussion here):

- Encourage dialogue with EMA ahead of submission
- Give better guidance on grouping strategy
- Any other thoughts?

Area 3

Clearer Q&A, fewer questions to PLs

The problem

I would like to ask if it is possible to use the ongoing article 61(3) notification as a base file during the linguistic review for the type II procedures
[Big Pharma RA Manager]

I have received the start of procedure letter for the type II variation - I wanted to clarify if the MAH will see the CHMP Assessment Report at day 60 or will we have access to an earlier version to understand if there is a possibility of an RSI earlier in the procedure.
[Big Pharma RA Manager]

Can I double check with the Agency that overall the below documents in support of the CMA renewal and conversion to full approval is acceptable?
[Medium Pharma RA Director]

Would you mind reminding me (for my records only) who the (co)rapporteurs and PRAC (co)rapporteurs are for Product X, please?
[Small consultant Director]

Product X has not been marketed for more than 2 years, manufacturer informed us that just two or tree batches was issued during 5 years and it might be withdrawn on XX. Should we still submit PSUR?
[SME RA Manager]

Since the variation XX was rejected, should we consider that the approved version of the RMP is the previous version, i.e. vX.Y dated DD MM YY?
[SME, RA Director]

As requested in the initial PRAC PASS protocol AR, dated XXX, Company re-submitted the draft PASS protocol on XXX taking in to consideration the PRAC comments. Would it be possible to confirm that this was received as well as the timetable for re-assessment?
[SME RA Director]

The ask

- What would help companies to access the available information on the EMA website?
- Is there a better structure of information that could be considered?
- How can we encourage individuals to *do their own research* instead of asking the PL as the first step?

Any questions?

Further information

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