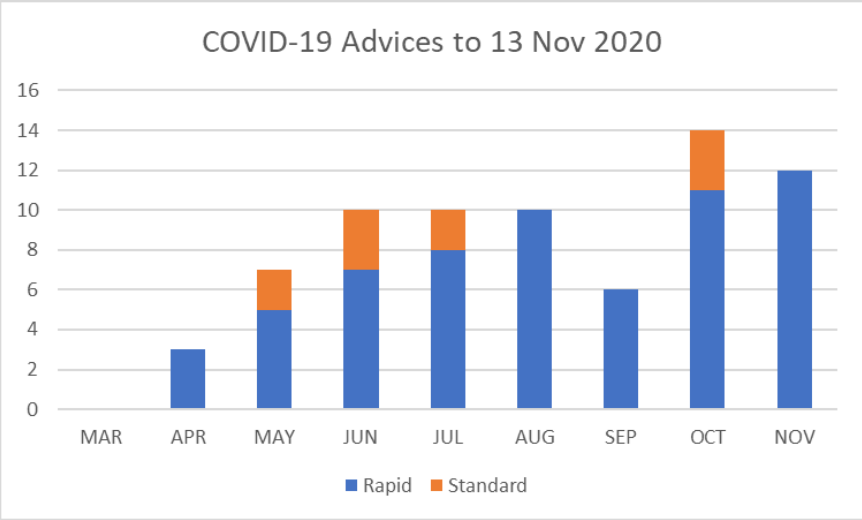
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

First learnings from accelerated scientific advice for COVID-19 medicines

Presented by Efthymios Manolis
Scientific advice Office, EMA

5th industry stakeholder platform for R&D support virtual meeting
16 November 2020

Experience so far (as of 13 Nov 2020)



Focus: Efficient delivery of high-quality advice

What is working well:

- Working party and committees input adapted to the 20 days timeline
- Frequent ETF TCs allow efficient participation of experts
- Validation focus on clarity of questions and the availability of information
- Regulatory or other questions normally considered out of scope and addressed separately included in the advice letter

What is a challenge:

- Resource demanding in terms of coordination and assessment teams
- Dissemination to other Working parties and Committees

Learnings: how should a developer approach rapid scientific advice

- Discuss plans and timelines in advance with EMA
- Focus on completion of information; protocols and reports should be available
- Share with EMA data as they become available, especially regarding status of clinical trials