



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Accelerated Assessment (AA)

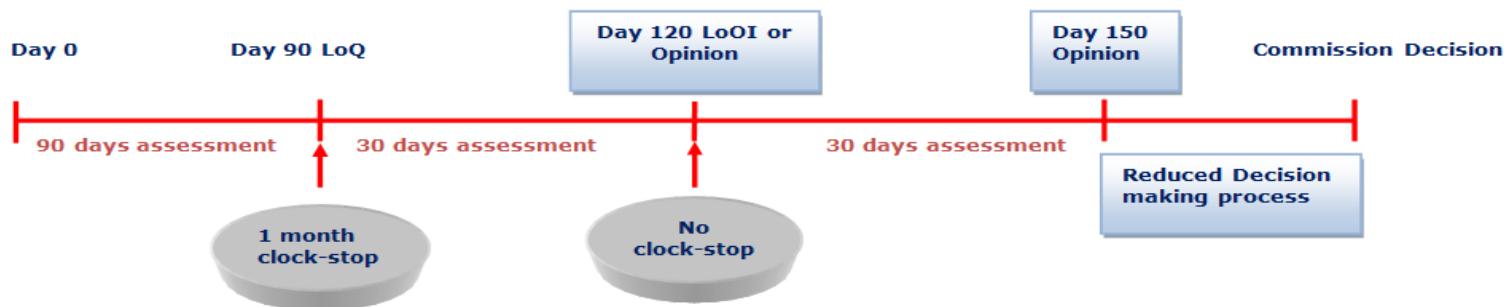
Review of 10 months experience with the new AA process

Industry platform meeting – 3rd July 2017



Better process to facilitate earlier authorisations

- ❖ Under the EU legislation, a medicinal product of major public health interest may be reviewed under an accelerated assessment procedure.
- ❖ In 2016, the procedural framework was optimised with a **new process and revised guidance**. The new time table (used since September 2016) was optimised with the introduction of an additional list questions and the opportunity to reach earlier opinions.





Scope of the revised AA process

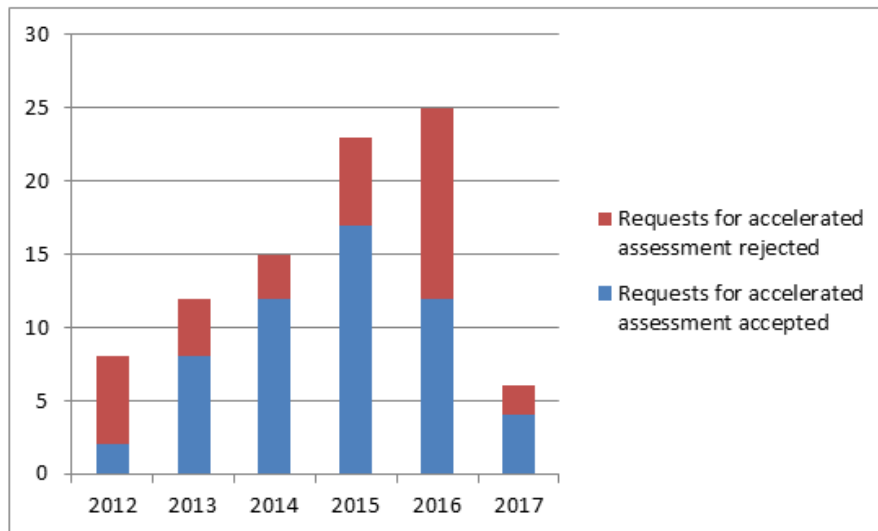
In addition to the optimised time table, the revised tools:

- Provide more detailed guidance how to **justify a request for accelerated assessment** from the point of view of unmet need, public health interest and therapeutic innovation
- **Promote early dialogue** between regulators and applicants
- Promote compliance with **intended submission dates**
- Provide **timetables** to streamline evaluation of **request for accelerated** assessment
- Provide more **transparency in the decisions** for accepting/rejecting/switch



Recent experience – AA request

An increase in requests for accelerated assessment has been observed over the last years, along with a increase of acceptance rate by the Committees.



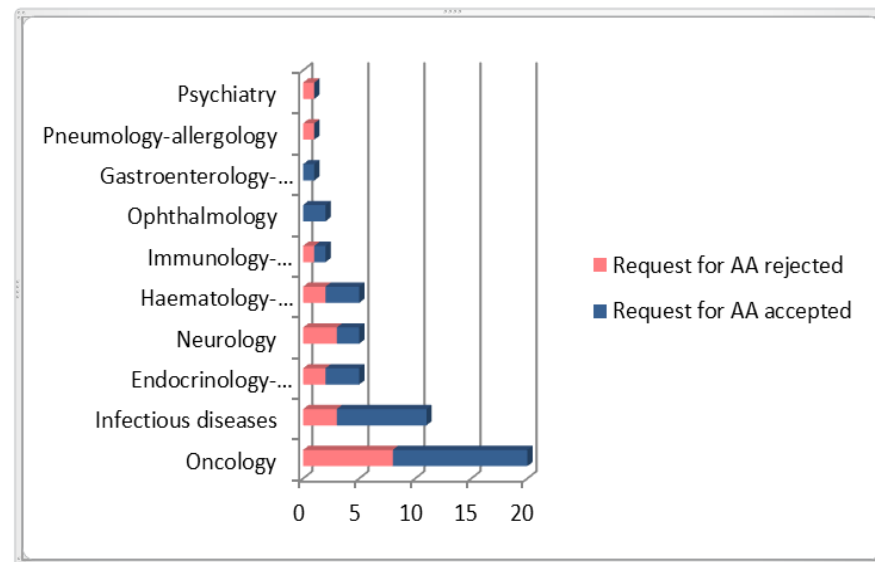
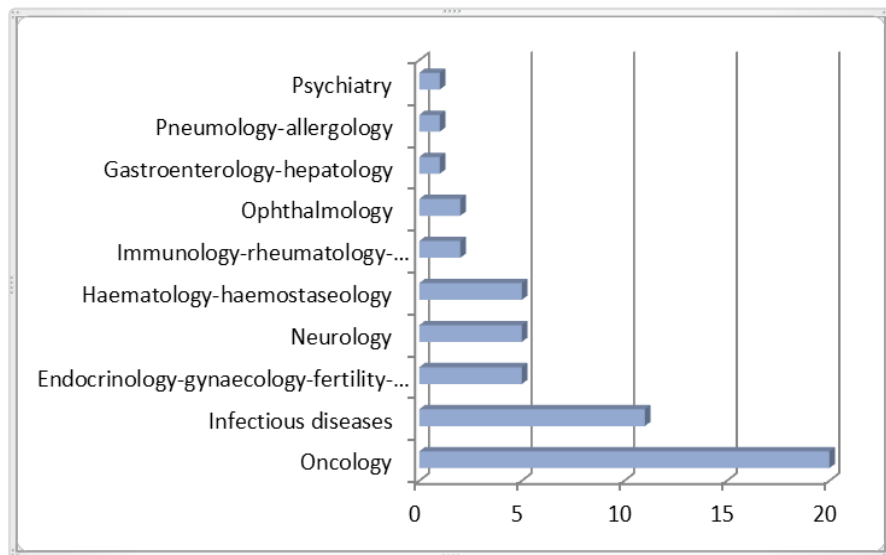
Main reasons for rejection were :

- Unmet medical need not adequately justified or not substantiated by the patient population included in the clinical programme
- Data not sufficient to justify a major public health interest
- No major advantages compared to available treatments
- Dossier not mature enough



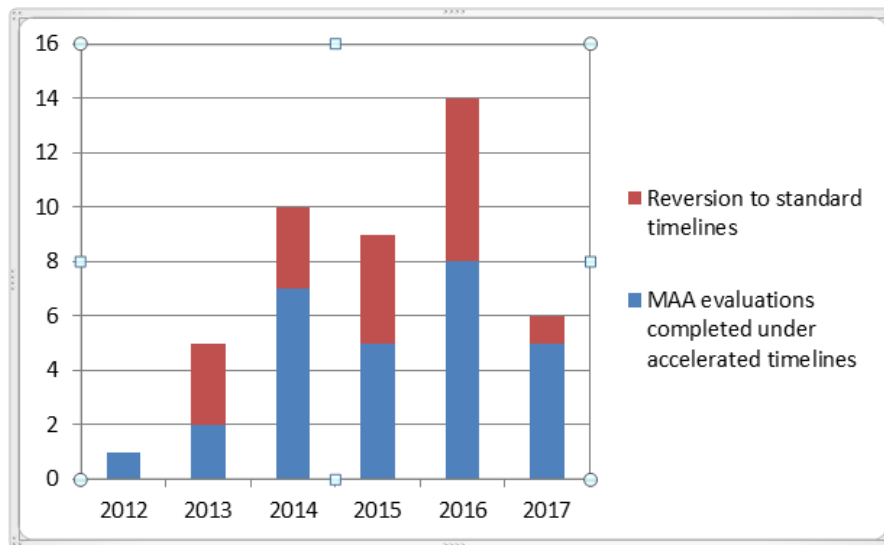
AA requests per therapeutic area

January 2015-June 2017





Medicines recommended for approval under AA



Main reasons for the switch to standard TT:

- **extension of clock stop by applicants**
- **major objections not resolvable under accelerated assessment**

It is expected that the optimised timetable for accelerated assessment reduces the number of applications reverted to standard timetable

*Only one medicine which initially started its evaluation under AA received a negative opinion from the CHMP in 2017.



MAA under new AA process September 2016-June 2017

Product	Indication	Status of submission
Brineura (cerliponase alfa)	Neuronal ceroid lipofuscinosis type 2	finalised
Spinraza (nusinersen)	Spinal Atrophy	finalised
OXERVATE (cenegemin)	Neurotrophic Keratitis	finalised
Vosevi (sofosbuvir / velpatasvir / voxilaprevir)	Chronic hepatitis C virus infection	finalised
Maviret (glecaprevir / pibrentasvir)	Chronic hepatitis C virus infection	finalised
Amglidia (glibenclamide)	Neonatal diabetes	Switched at day 90
Verkazia (ciclosporin)	Severe vernal keratoconjunctivitis (VKC)	ongoing
Letermovir MSD (Ietermovir)	Cytomegalovirus (CMV) reactivation and disease	ongoing
Jorveza (budesonide)	Eosinophilic esophagitis (EoE)	ongoing



Recent experience and key findings with new process

- ❑ 9 applications were submitted for review under AA since Sept 2016
(5 were recommended for approval, 3 ongoing, 1 switched to standard TT)
- ❑ **Vosevi and Maviret are the first 2 medicines for which accelerated assessment has been carried out within 120 days.**
- ❑ Only one application was submitted by an SME and switched at day 90 at the applicant's request (list of questions not resolvable under accelerated assessment).
- ❑ 78% of the applications (7/9) had an orphan designation at the time of submission.
- ❑ All applications had a pre-submission meetings.
- ❑ Over 50% of the applications (5/9) delayed their submissions from the date notified in the letter of intent.
- ❑ One request for AA for an ATMP applications has been agreed.



Recent experience and key findings with new process

- ❑ Very positive feedback from industry on the clarity of the guidance to request AA
- ❑ Very positive feedback from EMA on the quality and timeliness of interactions with applicants
- ❑ Shorter timelines are challenging for assessment teams & require meticulous planning
 - **Applicants' compliance with communicated submission dates is critical for the availability of assessment teams/inspectors.**
 - **Mature dossiers are needed to respond to questions during the short clock-stops.**
- ❑ Early dialogue in terms of pre-submission meetings occurred in all recent applications
- ❑ Increased level of dialogue (EMA/Applicant) during evaluation
- ❑ To date, the new time table has provided an opportunity reduce the number of procedures reverted to standard timelines and **reach opinions even earlier.**



Facilitating approvals for medicines that make a difference to patients' lives

In 2016, more than one third of the medicines containing a new active substance (n=27) was recommended for approval using at least one of EMA's initiatives to facilitate early access to medicines that address unmet medical needs.

➤ 7 new medicines were recommended for marketing authorisation following a review under accelerated assessment; In addition, one medicine which received a positive opinion for use outside the EU also benefited from an accelerated assessment.

➤ 8 medicines received a recommendation for a conditional marketing authorisation.



Overall conclusions with the new AA process

This recent experience reflects only a preliminary review after 10 months and a follow-up will be needed.

Shorter evaluation timelines remain challenging: compliance with planned submission dates, mature dossiers, early dialogue in PSM and increased dialogue during evaluation are key.

The trend seen so far reflects that the new process provides an optimised tool to facilitate earlier authorisations of medicines of major public health interest .



Thank you for your attention

Further information

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