EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6th Meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines

Interactions with patients across the product lifecycle

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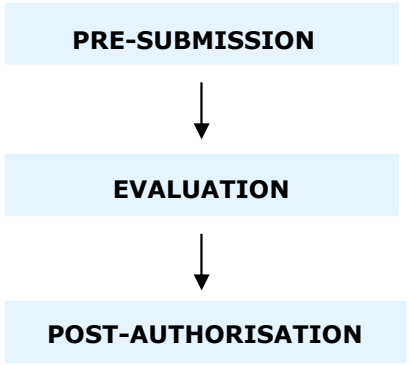
Patient involvement

Patients are involved at various timepoints along medicines' lifecycle:

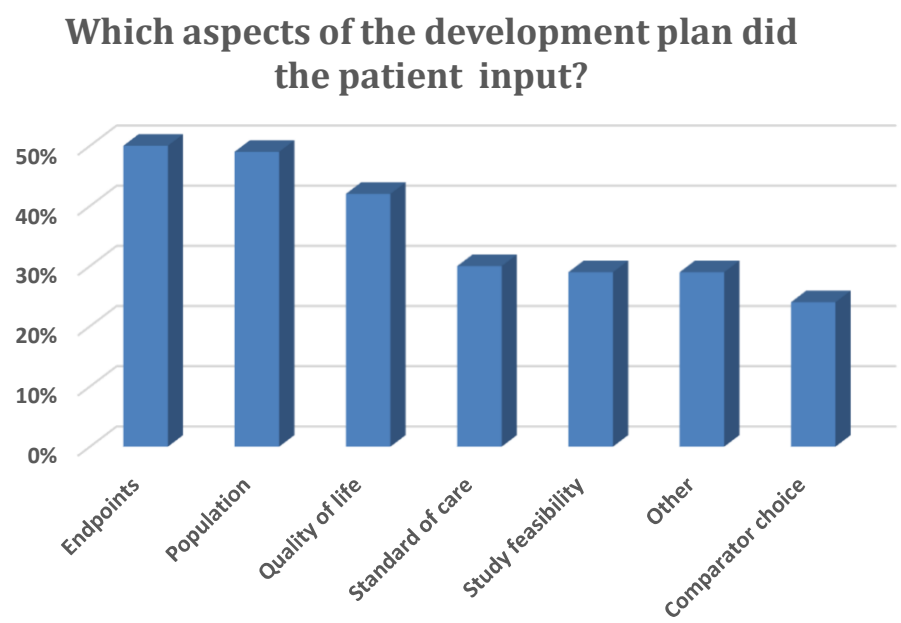
1. Scientific advice procedures
2. Scientific Advisory Group (SAG) / Ad-hoc expert meetings
3. Committee plenaries; oral explanations
4. Written consultation
5. Public hearing / multi-stakeholder meeting
6. Review of documents
7. Early dialogue (new pilot)



1. Scientific advice procedures

- Invited to contribute to scientific advice when questions of clinical nature & more suitable for patient contribution
- Participation either F2F (discussion meeting) or in writing
- Patients contribute aspects such as quality of life, unmet medical needs, proposed endpoints, trial feasibility, etc
- To assess impact questionnaires sent to gather feedback from patients and scientific officers

Scientific advice; impact / value



3 year survey; ≈ 300 Scientific Advice procedures:

- 79% of patients agreed with the proposed development plans
- 53% of patients comments resulted in further discussion
- 20% of patients input resulted in a modification of the final advice

2. SAG / Ad-hoc expert meetings

- Patients/consumers/carers invited to all SAG/ad-hoc expert meetings
- Once a SAG/ad-hoc expert meeting is convened by committee, EMA reaches out to find patients through its network of eligible patient/consumer organisations and database of individual patients
- Patients contribute to the benefit / risk discussion based on their experience as a patient / carer
- Input, together with other experts, contributes to overall assessment

3. Oral explanations

- Since end of pilot in 2017, patients invited on case by case basis to oral explanations
- Often after SAG meeting (same patients)
- Also can participate in plenaries if no OE

4. Written consultation

- Committees can request input in writing from patients at any time; survey / questionnaire.

5. Public hearings; listening to all stakeholders

- Convened by PRAC - within certain safety referral procedures
- Broadcast live
- All public invited to express views - on pre-defined questions
- Allows PRAC to listen & take account of all stakeholder perspectives - contributes to RMMs

Proposals taken into account
- Restricted use
- Education materials - Communication campaign
- Labelling/packaging
- Encourage further research

6. Review of documents

Patients review all documents intended for lay audience:

- Orphan summaries
- Package leaflets
- Medicine overviews
- Safety communications (including COVID safety summaries)
- Herbal summaries

7. Early dialogue with patient organisations (new pilot)

- Patient input often comes at late stage of evaluation, (e.g. SAG, oral explanation)
- New pilot allows for early contact with patient organisations at start of orphan MAA
- Patients invited to share aspects such as quality of life, unmet needs and hopes for new treatment so Rapporteurs well-aware of all aspects from the beginning.
- Template 'letter' (guidance on expected input), 2-3 week deadline
- Facilitates further interactions as the procedure progresses, as needed.
- Questionnaire sent to Rapporteurs and organisations for feedback
- Pilot to last one year (may be extended) - if successful will be extended to all new MAAs

Who do we involve?

European umbrella patient/consumer organisations
(system of eligibility)

EMA individual patient database
(DOI requirement)

Looking ahead

EMA Regulatory Science Strategy to 2025 & Joint European Medicines Agencies Network strategy to 2025, developed with stakeholders, defines future direction of engagement;

- Expand capacity and network outreach
- Enrich training and support with new tools and content
- Exchange methodologies across decision makers (e.g. HTAs)
- Contribute to multi-stakeholder projects (e.g. IMI)
- Work with patient organisations and researchers testing new methodologies
- Progress patient engagement in a global context (e.g. ICH, CIOMS)

Thank you for your attention

Further information

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