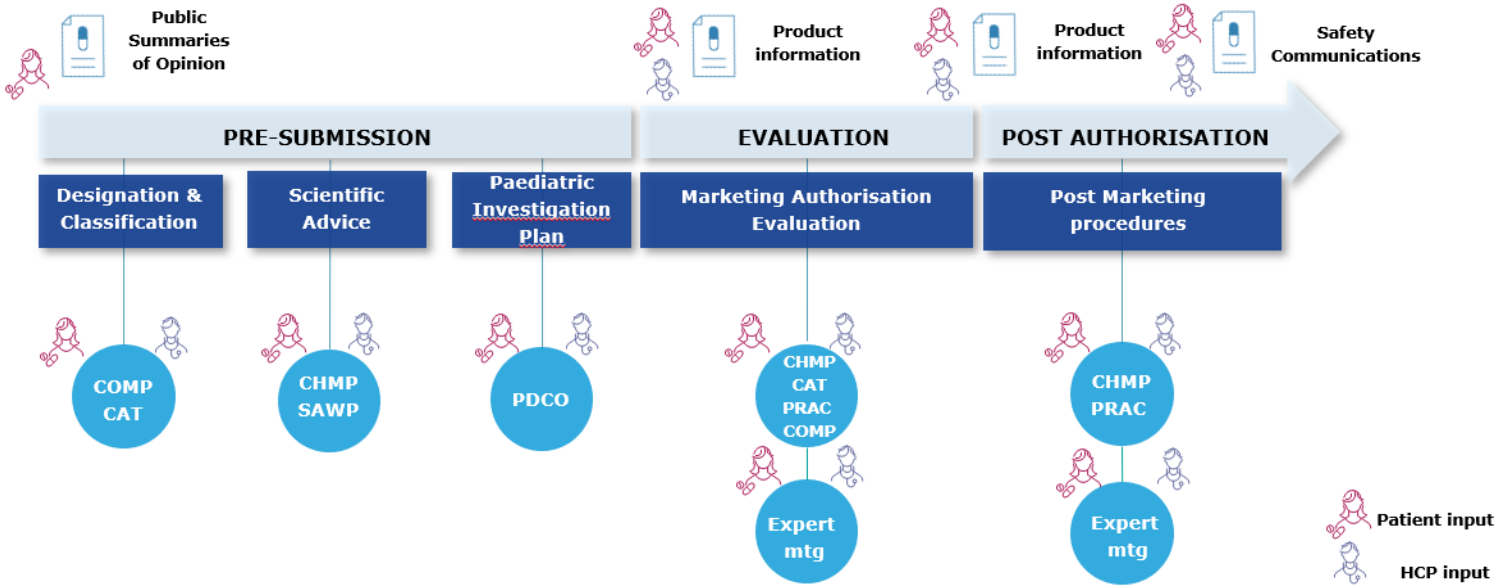
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Activities involving patients/consumers during evaluation phase with CHMP

PCWP plenary

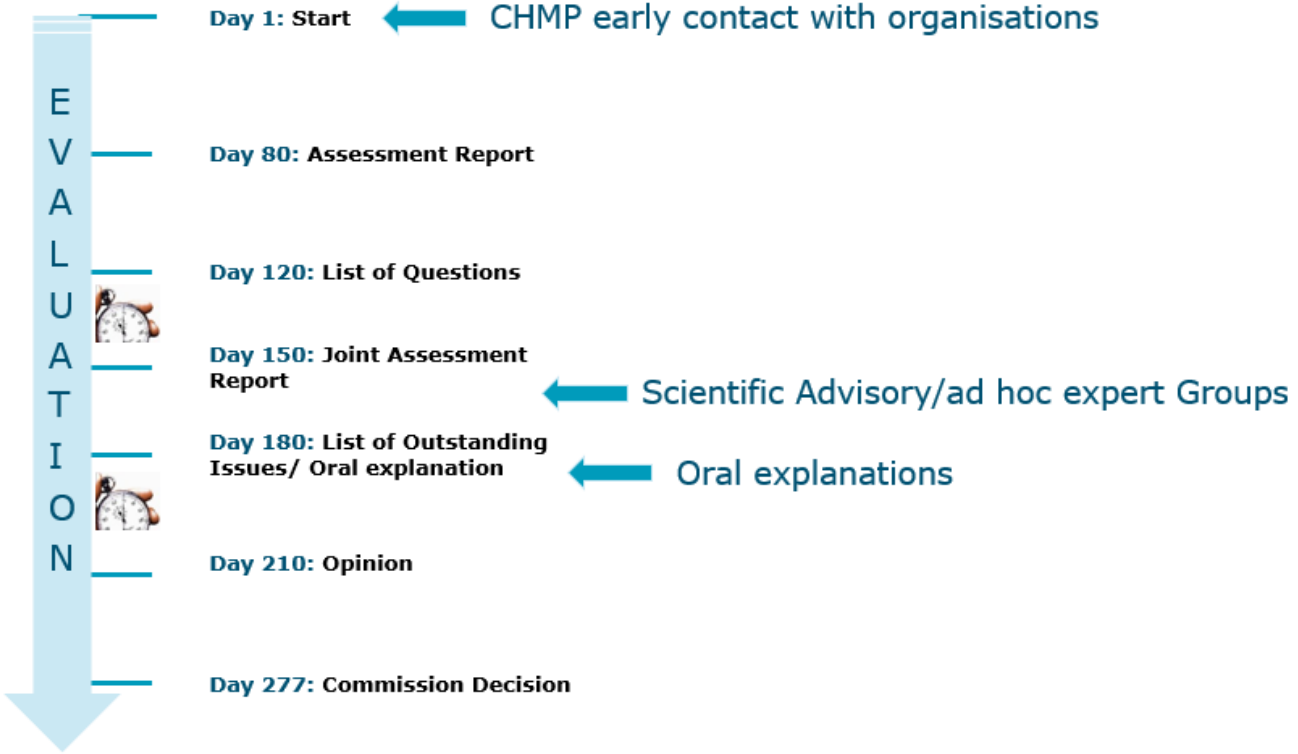
Presented by Maria Mavris on 2 July 2024
Stakeholders and Public Engagement Department

Stakeholder engagement across medicines lifecycle



Activities involving patients/consumers during evaluation phase with CHMP

Timeline for CHMP evaluation



Activities involving patients/consumers during evaluation phase with CHMP

Patient and HCP engagement in product lifecycle

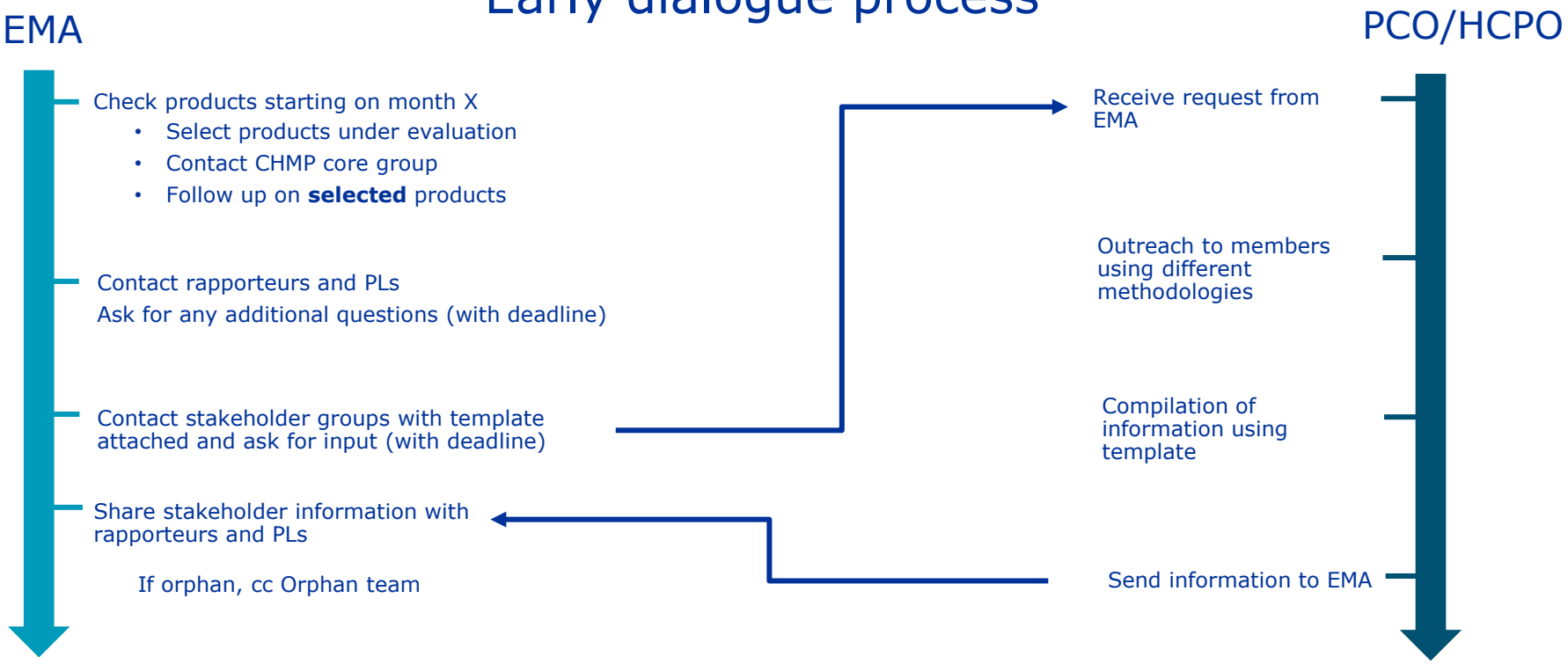
- Early dialogue methodology
- SAGs/AHEGs
- Oral explanations
- Next steps

Activities involving patients/consumers during evaluation phase with CHMP

CHMP early dialogue

Activities involving patients/consumers during evaluation phase with CHMP

Early dialogue process



https://www.ema.europa.eu/en/documents/other/chmp-early-contact-patient-and-healthcare-professional-organisations-process-and-faqs_en.pdf

Activities involving patients/consumers during evaluation phase with CHMP

EMA

How are the medicines selected for early contact?

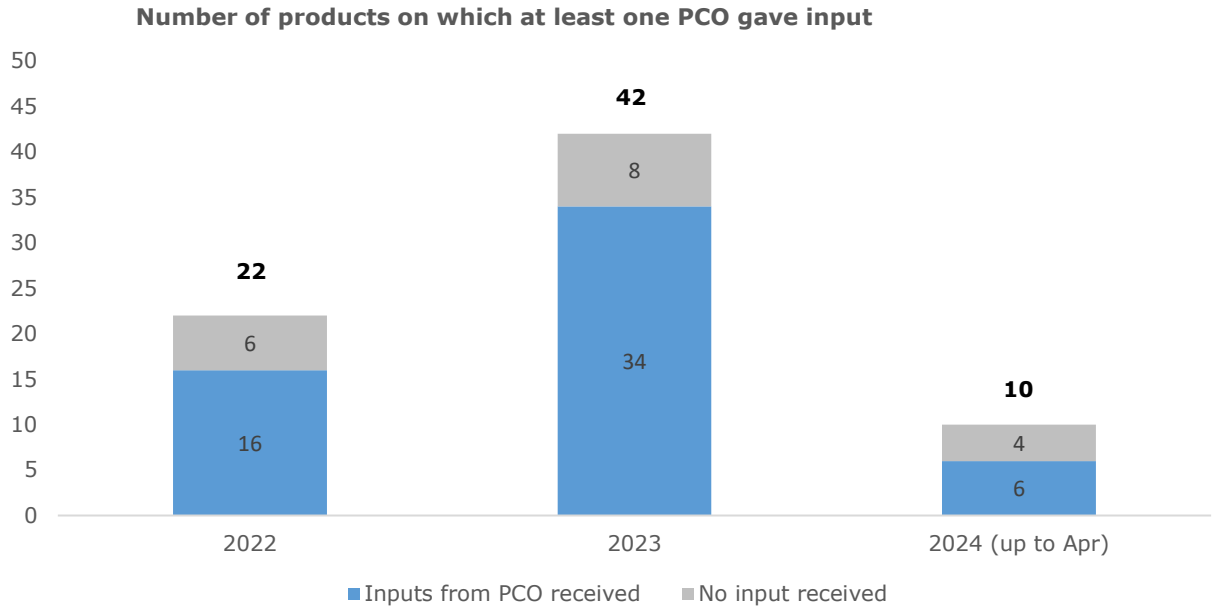
- list of submissions for the month extracted
- consult with the core group at CHMP
- follow up with eligible/relevant patient organisations
- products selected are those that contain a new active substance

PCOs

How do PCOs collect the necessary information?

- Interviews with individuals
- Consulting groups of patients
- Existing information from surveys

Figures to date



Activities involving patients/consumers during evaluation phase with CHMP

Revised input template

PATIENT/CARER EXPERIENCE OF: **indication**
Please include below any aspects that are of particular importance to patients/carers, such as information on: • standard treatments and how acceptable they are, • therapeutic/unmet medical needs, • quality of life, • what benefits would be hoped for in new medicines as well as what level of side effects would be considered acceptable, • considerations for pregnant people/people of child-bearing potential, where applicable. Also mention any aspects about the condition or its treatment that you feel are not well-understood or not sufficiently considered. You may include anything else you feel is important for EMA to know. Please try to keep your main points to 1-2 pages; if necessary, include more details in an appendix.

REMINDER:
Early dialogue does **NOT** aim to collect positions on the medicinal product under assessment

What is done with your input?

- Shared with CHMP (and other relevant EMA committees, working parties and expert groups)
- Shared with applicant (pharmaceutical company) who submitted the marketing authorisation application
- May be shared with another pharmaceutical company for an application with the same indication
  - EMA will endeavour to contact organisations to proactively ask whether the input can be shared and whether modification/adaptation is needed
  - Please keep this in mind when providing input
- Goal is to reflect input in the assessment report that will be made public at the end of the procedure

Discussion on proposal for EPAR

Proposal to consult organisations when European Public Assessment Report (EPAR) is being prepared

What would you prefer to see in the EPAR?

1) Harmonised text:
   - Stating that patient and HCP organisations have been consulted in the context of this evaluation and input has been received
   - This could include the names of the organisations consulted
2) A contextualised summary of the input received that can be reviewed by the organisations prior to finalisation?

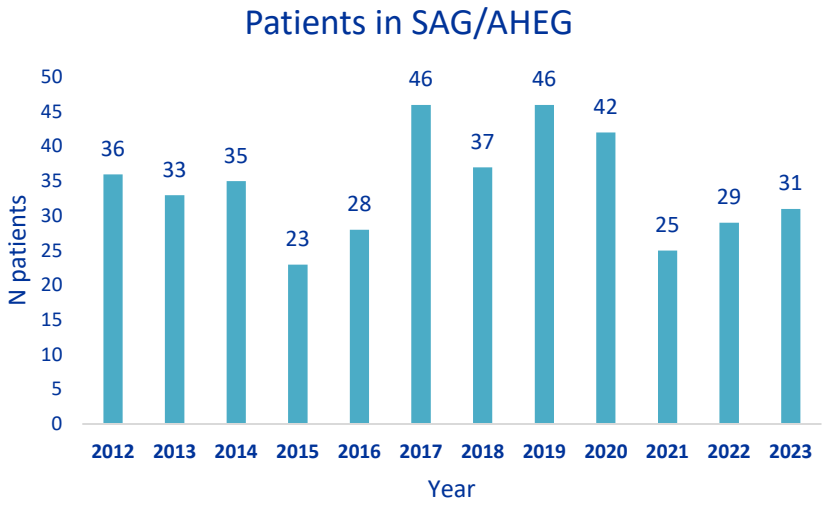
Scientific Advisory/ ad hoc Expert Groups SAGs/AHEGs

Activities involving patients/consumers during evaluation phase with CHMP

SAGs /AHEGs

- Requests received for patients/carers/consumers for SAG/AHEG
- EMA reach out to eligible organisations or existing individual experts

Patients
Identify and contact expert
Process expert – registration and DOI/CV
Once Eudralink arrives – highlight information to read to expert
Organise call to explain meeting – expert role and manage expectations
Support if F2F – send survey at end.



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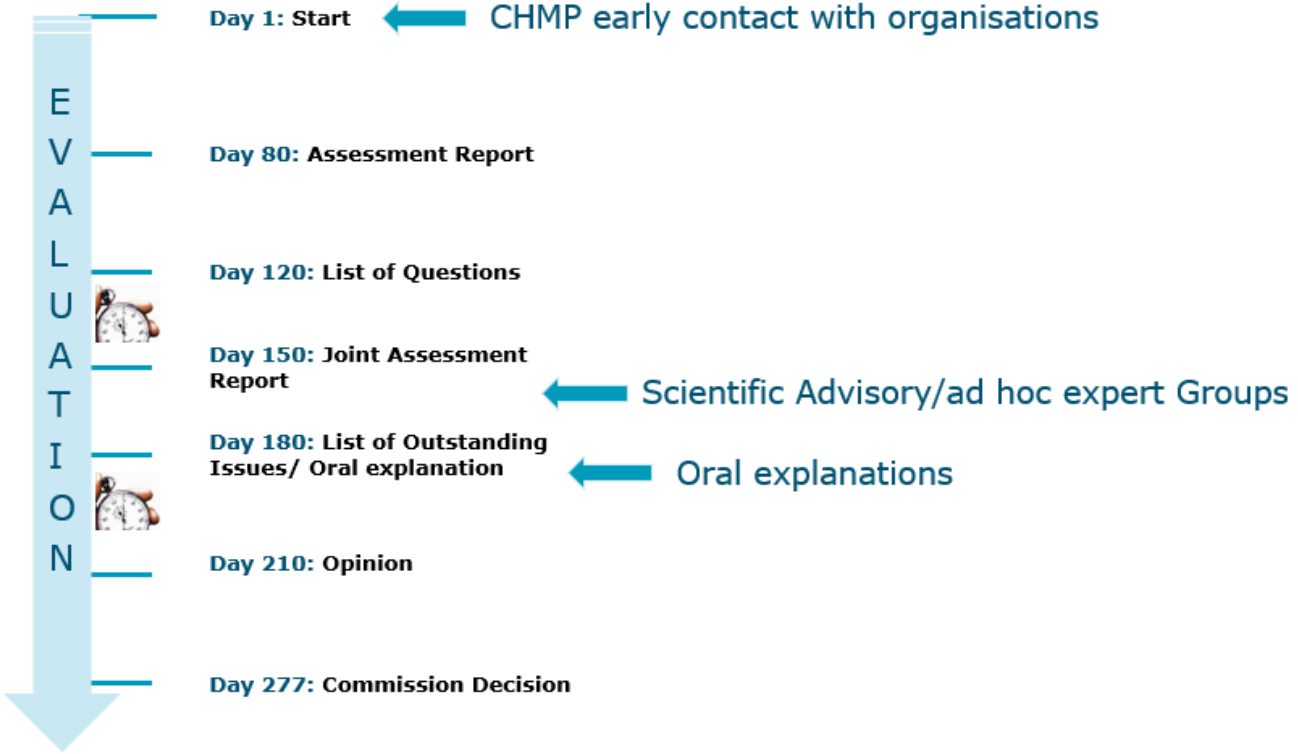
Oral explanations

Timeline for CHMP evaluation



Activities involving patients/consumers during evaluation phase with CHMP

Oral explanations

- Patient involvement piloted in 2014 and now continued as integrated methodology
- EMA exploring systematic way to identify need for patient input
  - Draft CHMP agenda – consultation with CHMP core group
  - Follow up from SAG meetings – involve same patients
  - Consultation of EMA product leads and CHMP rapporteurs

- Numbers of patients involved across years to be compiled and shared.

The evaluation of medicines, step-by-step | European Medicines Agency (europa.eu)

Activities involving patients/consumers during evaluation phase with CHMP

Next steps

Activities involving patients/consumers during evaluation phase with CHMP

Next steps

- Jayne Crowe has replaced Concha Prieto on CHMP core team
- Increased collaboration with Therapeutic teams and Stakeholder Engagement team at EMA on all processes described
- Update and train all PCWP (HCPWP) and eligible organisations on all methodologies

Any questions?

Further information

[Insert relevant information sources or contact details as applicable.]

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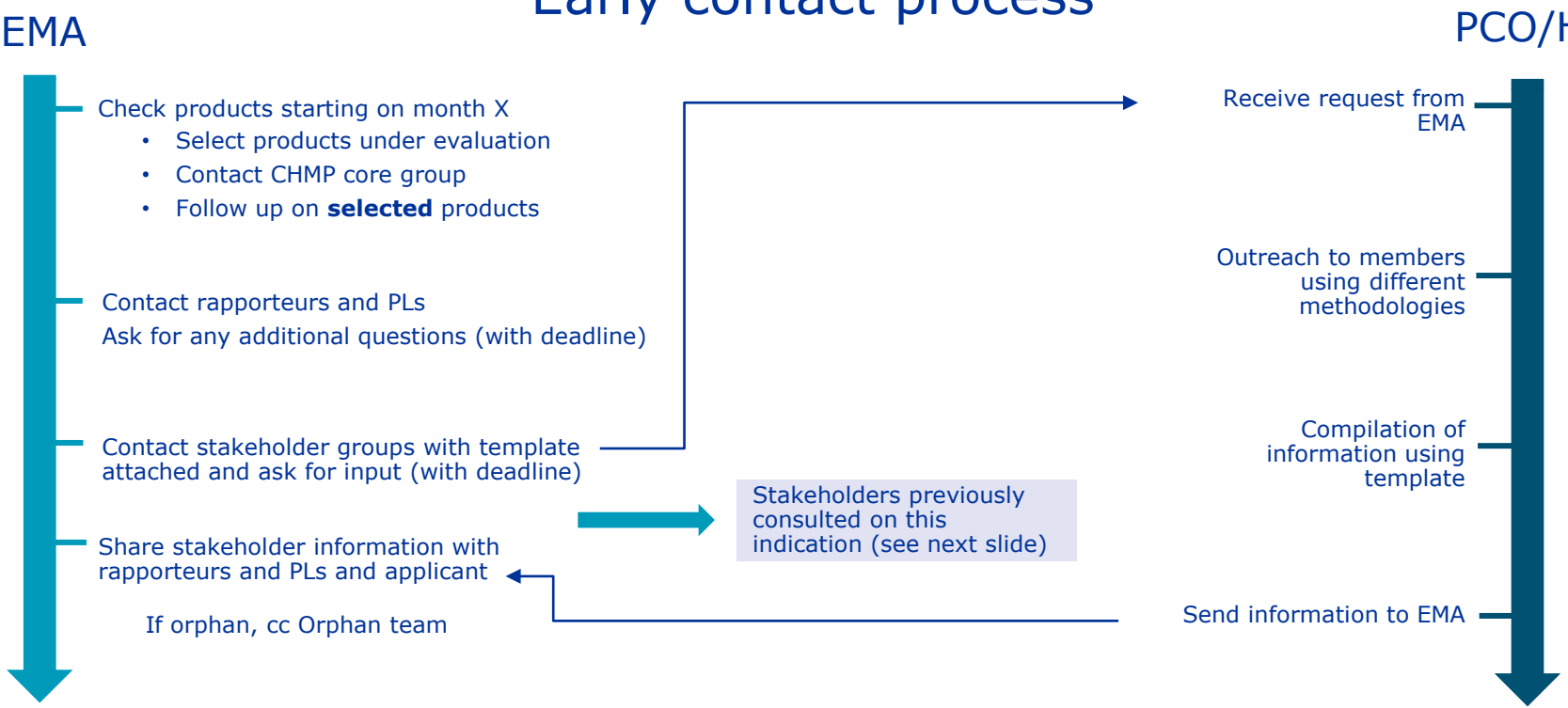
Early contact process



Activities involving patients/consumers during evaluation phase with CHMP

Where previous input exists

Share previous feedback along with new active substance/indication with **stakeholder** organisation

Ask organisation if existing feedback is applicable to new substance/indication

If no: then organisation may complete new feedback form and submit for new substance /indication

If yes: but organisation chooses to complete new feedback form and update for new substance /indication

If yes: but organisation chooses not to update and information is sent as is for previous substance and indication

Input is shared with CHMP, relevant CXMP/WP and applicant