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Proposal to optimise stakeholder engagement at CHMP

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Background and rationale

Drivers for change

1. **Early expertise identification**
   Build a pool of eligible patients, HCPs and learned-society experts ready for key assessment milestones.
2. **Independent validation**
   Where rapporteur/CHMP expertise on a new condition is limited, validate applicant descriptions with identified external experts.
3. **Structured assessment input**
   Move beyond ad-hoc consultation, so relevant patient and HCP perspectives can better inform selected evaluations.

What the proposal prepares

4. **NPL readiness**
   Prepare CHMP and patients/HCPs to join as members in preparation for the NPL.
5. **Transparency and trust**
   Create clearer consultation points that enhance openness and support robust assessment.
6. **Efficient learning system**
   Pilot stakeholder meetings and future public hearing approaches, capture lessons and standardise criteria/templates.

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Preparing CHMP for civil society membership under new pharma legislation

The NPL foresees that CHMP will have members representing patients and HCP.

Patients and HCP will be invited to attend CHMP meetings ahead of the legislative deadline.

Agreement obtained from CHMP, EMA management, European Commission

A call for expression of interest will be made to all eligible organisations and members of COMP, CAT, PDCO and PRAC (Nov 2026). Selection of members to be made by panel

Patient and HCP attendees would receive training, through EUNTC and mentoring by volunteer CHMP members.

Onboarding to start in January 2027



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