



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The first experience with the newly launched Parallel Consultation platform



Industry stakeholder platform on research and development support





Outline

Assume familiarity with published documentation

- Scene setting
- What has happened since launch in July?
- General principles
- Patients engagement
- Summary of key messages



Scene setting

Fundamentals and underpinning

- Cooperation supported through Health Technology Network Synergy Paper

**HTA NETWORK REFLECTION PAPER ON
“SYNERGIES BETWEEN REGULATORY AND HTA
ISSUES ON PHARMACEUTICALS”**

ADOPTED BY THE HTA NETWORK, 10 NOVEMBER 2016

- EUnetHTA Workplan Joint Action 3

<http://eunetha.eu/activities/joint-action-3/jointaction31/eunetha-joint-action-3-2016-2020>

- EMA and HMA strategy and workplan

http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000292.jsp&mid=WC0b01ac05800293a4

http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2017/02/WC500221614.pdf



EU-level Advice Landscape

Regulator advice

- CHMP advice
 - HTA observers as option subject to EMA confidentiality undertaking

Parallel consultation

- Regulators and HTAS
- CHMP advice
- HTAS – 2 routes
 - Consolidated
 - Individual

HTA advice

- Consolidated
 - EMA as observers subject to EUnetHTA confidentiality undertaking

Eligibility criteria, Fees and Legal Basis are the same for EMA



Principles in Parallel Consultation

Roles and remits

- Multi-stakeholder procedure - equal partners - adherence

Confidentiality and Conflict of interest (COI)

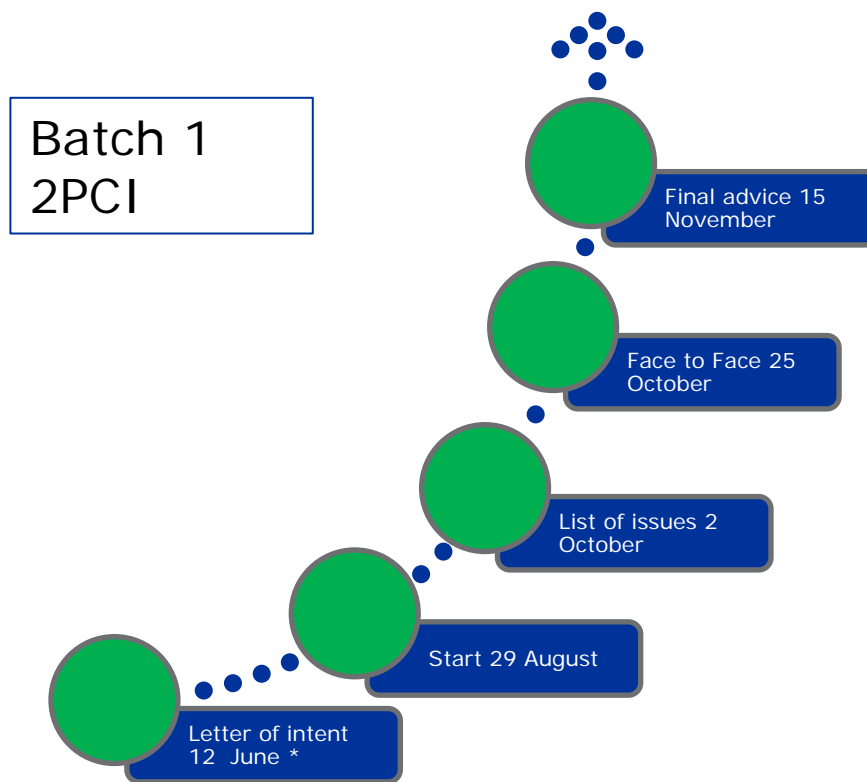
- EMA code of conduct and EMA policy on access to documents, and COI (policy 43, Policy 44)
- An EUnetHTA Declaration of Interest Confidentiality Undertaking Conflict of Interest; Letter of intent; Briefing documents and presentations

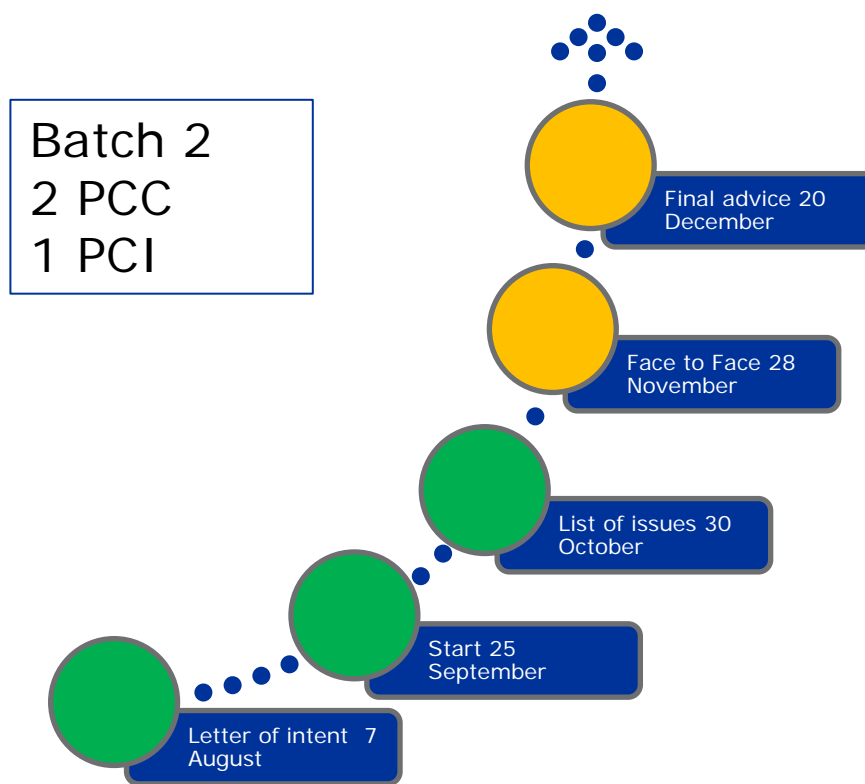
Status of Parallel Consultation outputs -

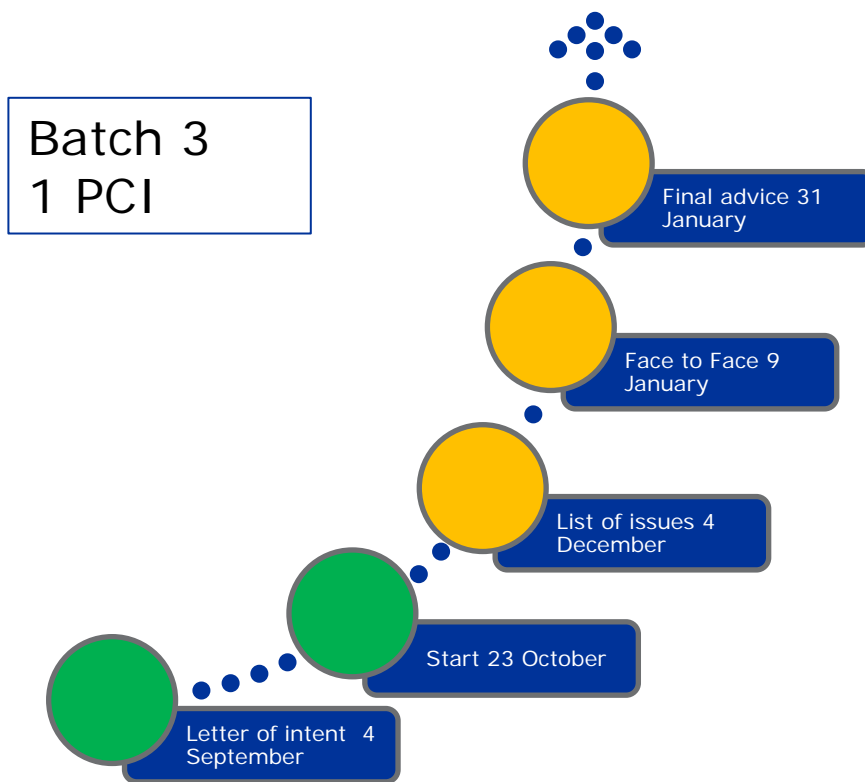
For - EMA : Applicants should justify any deviations from the advice given

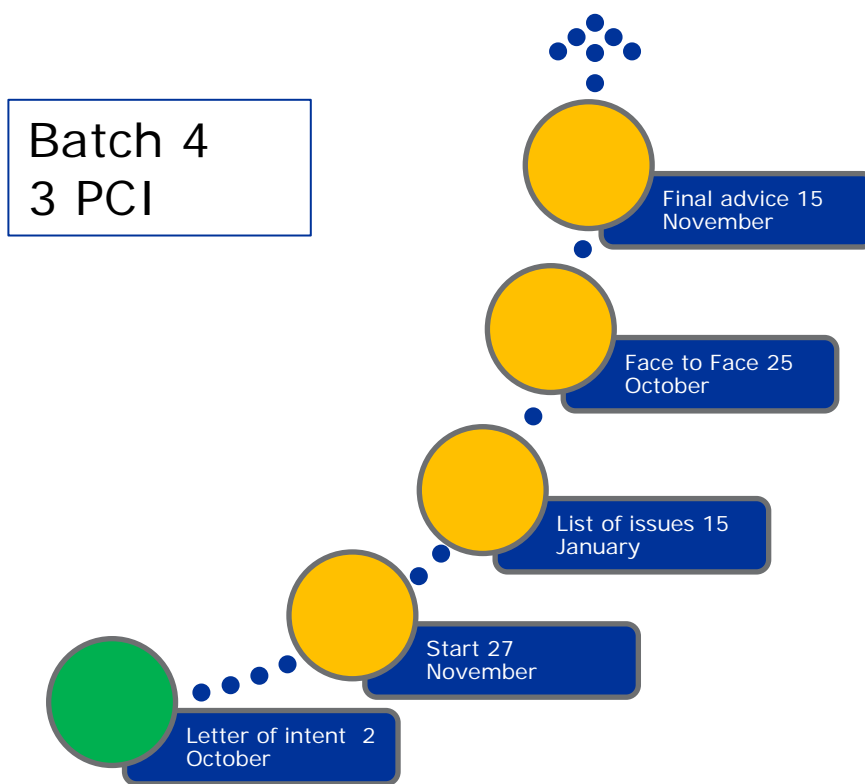


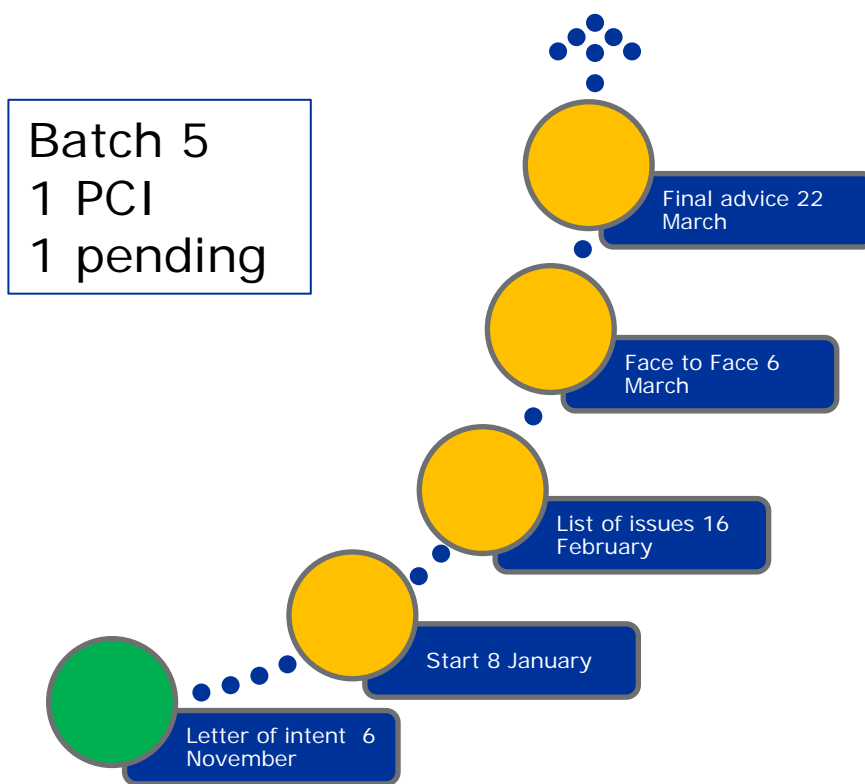
Batches of requests since launch





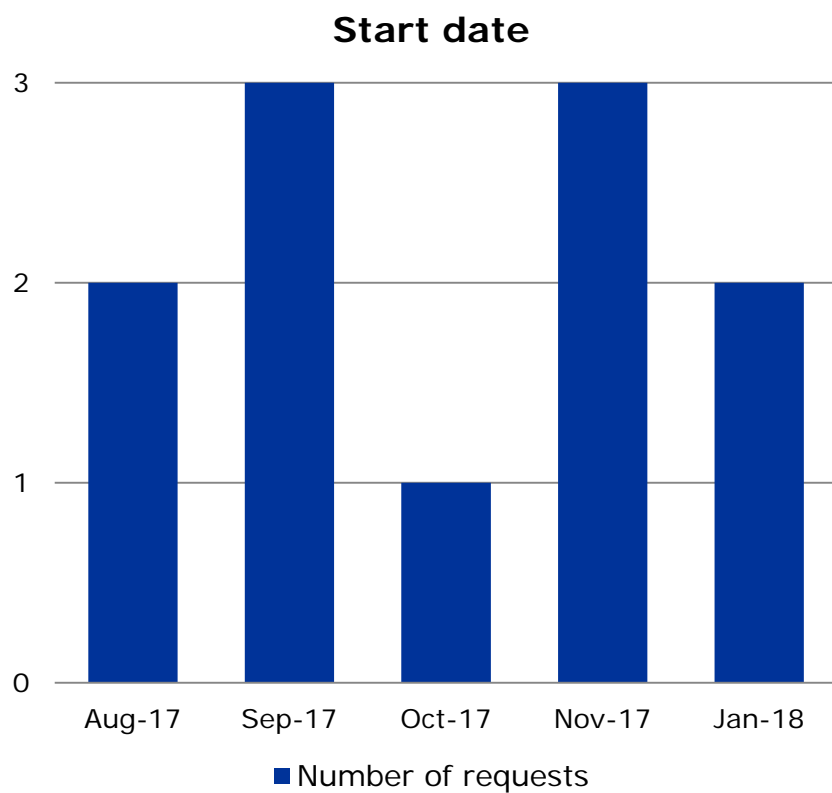






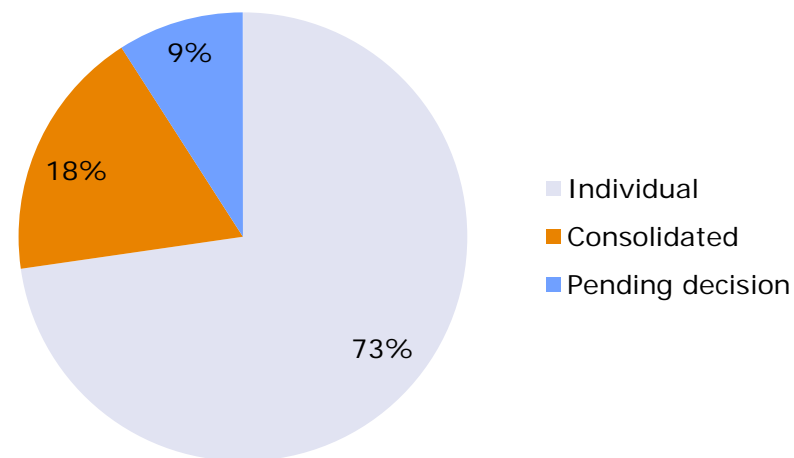


Number of parallel consultations (PC) requests



Total number of PC requests as of 10/11/2017: **11**

- Procedures started: 6
- Procedures finished: 2

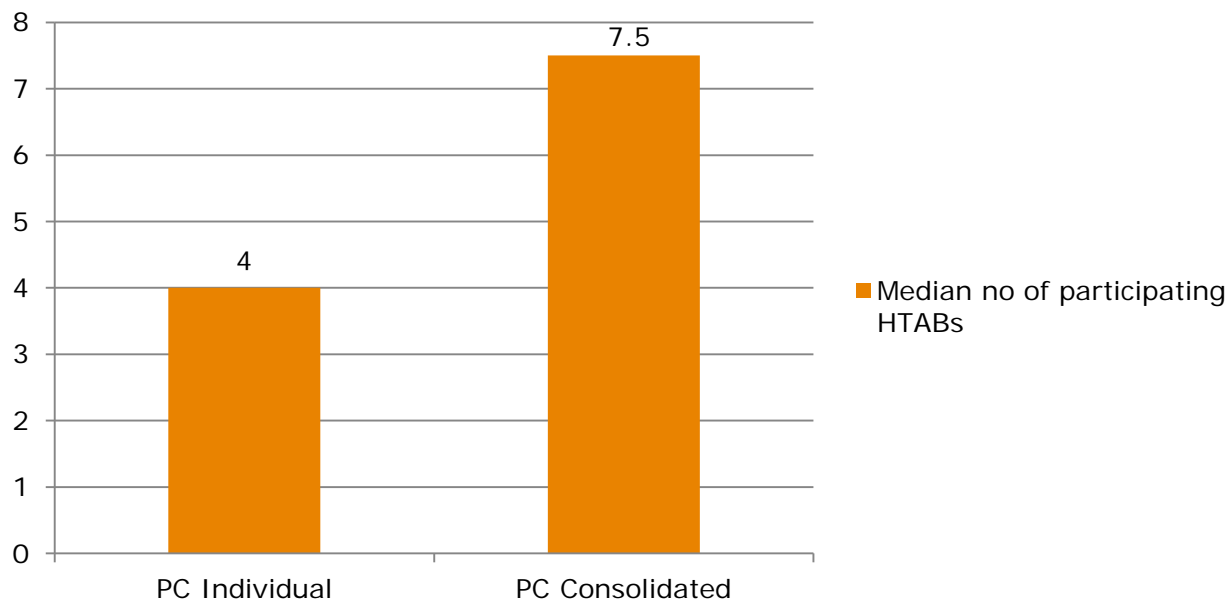




Features of requests

- Mostly oncology indications 6, (dermatology, ophthalmology, metabolic, connective tissue)
- Patient representatives involvement in all 6 started procedures
- SME, Orphan and ATMP appear under-represented.

Median no of participating HTABs





Patient Engagement recognised and integral part of the Agency's work

For Parallel Consultations - Individual patient experts identified

- through patient organisations under the EMA [framework for interaction](#) - EMA - patients – consumers (EMA/637573/2014)
- Capacity-building / training / briefing
- A pool of patients acting as experts in their disease and its management
- Invited to attend all teleconferences and the EMA HTA Applicant meeting;
- Also declare conflicts of interest, managing barriers to participation

Item on EMA-EUnetHTA workplan

EUnetHTA will also comment



Additional Reflections

Excellent communication and interaction with EUnetHTA ED Secretariat

- Monthly administrative TC
- Setting dates, resolving issues, communication plans

Opportunities for closed interactions

- Taken place and good exchanges made on content-
- Adherence to remits

Policy for continuous improvement and streamlining

EUnetHTA – will cover do and don'ts, and forward plans



Summary

Positive collaboration between EMA and EUnetHTA

- New platform, one gateway for all procedures for advice/dialogue
- Centralised HTA recruitment,
- HTA working party for prioritised subset with consolidated HTA advice
- For all parallel advice/early dialogue procedures - Streamlined logistics, greater HTA coordination
- Multi-stakeholder, EMA and EUnetHTA equal partners, working together, benefits patient access and public health
- Respect for roles and remits to facilitate optimised evidence generation for different stakeholders
- Building on successes of PSA and SEED and Interactive focused meetings



Key messages

- Platform for parallel discussion on initial evidence generation for MAA/reimbursement, and post licensing evidence generation
- Launched 03 July 2017- Early experience so far but positive
- More procedures /applications for parallel consultation encouraged -
What are the barriers?

Thank you for your attention

Further information

Contact EMA scientificadvice scientificadvice@ema.europa.eu

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