EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The Committee for Advanced Therapies (CAT)

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Committee for Advanced Therapies (CAT)

EMA's scientific committee for the evaluation of advanced therapy medicinal products (ATMPs) established in 2009

- EVALUATION
- CERTIFICATION
- CLASSIFICATION

TASKS DEFINED PER LEGISLATION

- Scientific Advice
- Support to PDCO/COMP/CHMP
- Participation in ITFs
- Interaction with stakeholders
- Publications, Guidelines

CAT procedures

Scientific recommendation on advanced therapy classification									
	2009	2010	2011	2012	2013	2014	2015	2016	Total
Submitted	22	19	12	22	20	28	61	40	224
Adopted	12	27	12	16	23	29	31	65	215

Scientific advice procedure for ATMPs									
	2009	2010	2011	2012	2013	2014	2015	2016	Total
Discussed*	25	30	36	31	36	48	63	34	303
Number of procedures	17	19	21	19	23	33	39	31	202

Jan – June 2016

Advanced Therapeutic Medicinal Products

Initial Evaluation of Marketing Authorisation Applications (MAA) for ATMP									
	2009	2010	2011	2012	2013	2014	2015	2016	Total
Submitted MAAs	3	1	2	3	2	2	1	1	15
Positive draft Opinion	1	0	1[ii]	1[ii]	2	1	1	2	9 Corresponding to 8 ATMPs
Negative draft opinions	1[i]	0	1[ii]	0	0	0	2[*]	0	4
Withdrawals	1	1[i]	0	0	2	0	0	0	4
Ongoing MAAs									2

Jan – June 2016

The PRIority Medicines (PRIME) programme

Medicines eligible for PRIME must address an unmet medical need.

Preliminary data must be available showing the potential to address this need and bring a major therapeutic advantage to patients.

EMA will provide early and enhanced support to optimise the development of eligible medicines, speed up their evaluation and contribute to timely patients' access.

The PRIME programme

FOR PATIENTS

- PRIME is driven by patients' needs.
- It focuses on medicines that **address an unmet medical need**, i.e. offer a major therapeutic advantage over existing treatments, or benefit patients with no current treatment options for their disease.
- It helps to translate research into the development of medicines while meeting regulatory requirements.
- It aims to **bring promising treatments to patients earlier**, without compromising high evaluation standards and patient safety.

FOR MEDICINE DEVELOPERS

- PRIME helps developers of promising new medicines to optimise development plans.
- It fosters early dialogue with EMA to facilitate robust data collection and high quality marketing authorisation applications.
- It speeds up evaluation so that medicines can reach patients earlier.
- It encourages developers to focus resources on medicines likely to make a real difference to patients' lives.

The PRIME programme

Once a candidate medicine has been selected for PRIME, the Agency will:

- appoint a **rapporteur** from the Committee for Medicinal Products for Human Use (CHMP) or from the Committee on Advanced Therapies (CAT) in the case of an advanced therapy to provide continuous support and **help to build knowledge ahead of a marketing-authorisation application;**
- organise a **kick-off meeting** with the CHMP/CAT rapporteur and a multidisciplinary group of experts, so that they provide **guidance on the overall development plan and regulatory strategy;**
- assign a **dedicated contact point;**
- provide **scientific advice at key development milestones**, involving additional stakeholders such as health-technology-assessment bodies, to facilitate quicker access for patients to the new medicine;
- confirm potential for accelerated assessment at the time of an application for marketing authorisation.

July & Sept 2016 – 11 PRIME applications before CAT

Thank you!