EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on patient involvement in evaluation activities

3rd Industry Platform on the operation of the centralised procedure, 21 April 2016

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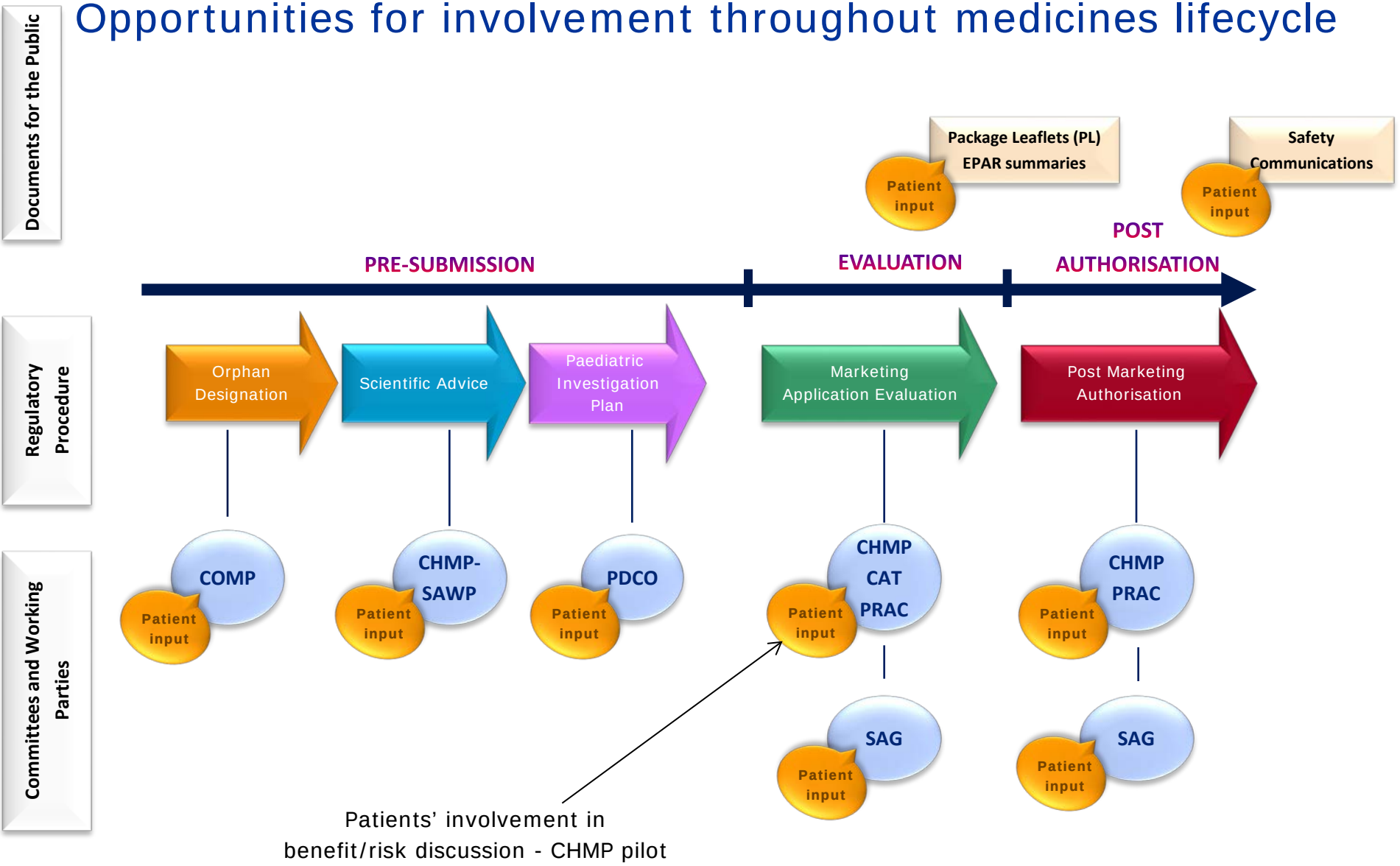
Opportunities for involvement throughout medicines lifecycle



Pilot phase proposal

When should patients be invited to join CHMP?

- During oral explanations where their involvement can bring added value to the benefit/risk discussion
- Decided on a case-by-case basis

How should patients join the discussion?

- Join for Rapps brief, remain for discussion & conclusions and leave once the topic finalised
- Share views and participate in the discussion (including questions to company) but no decision-making (no voting rights)
- If a patient is not able to travel can join via TC
- Consultation may be in writing

Pilot phase proposal

How many patients should be invited?

Two patients or carers would be invited to each identified oral explanation, in addition to a mentor (experienced patient rep - likely a PCWP member) who would support

Declaration of interest and confidentiality

- Every patient will be screened for conflicts of interest, as all experts
- They participate as individuals and do not represent any organisation
- They must adhere to the confidentiality of the documentation and discussions

What support will be provided to the patients?

- Patient “mentor” support
- EMA support; written & personal guidance on the work of the EMA and the CHMP, the issues for discussion, as well as a clear definition of their expected role

Pilot phase proposal

How will the pilot phase be evaluated?

- Questionnaires will be sent to the patients, Rapps and the CHMP working group for feedback on the impact and contribution of the patients.
- An outcome report will be presented at the end of the pilot phase addressing: organisational aspects; lessons learned / areas for improvement; feasibility for full implementation

The aim is to achieve a mutually beneficial exchange of information, whilst increasing transparency and trust in the system.

Progress so far

3 cases:

1. Sept 2014 - **Scenesse** (afamelanotide)- treat patients with erythropoietic protoporphyria (EPP), rare intolerance to light

2. June 2015 - **Intuniv** (guanfacine)- treat attention deficit hyperactivity disorder (ADHD) in children and adolescents

3. Oct 2015 - **Tecfidera** (dimethyl fumarate) - treat multiple sclerosis, referral procedure related to risk management of PML

+ 3 other cases planned (including 2 written consultations)

Outcome so far

- Feedback received from 3 cases is overall positive
- Involvement of patients has been a learning curve and has <u>improved with experience</u>
- The improvement seems to be based on:
  - More focused questions for the patients
  - Tailored support to patients
  - Management of expectations: - patients
    - CHMP

Next steps

Pilot phase should be finalised by end of 2016

- 1st step: analysis of the pilot
- 2nd step: integrate the process in the overall patients engagement at EMA

Thank you for your attention

Further information

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