EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems and products
Medicinal products – authorisations, European Medicines Agency

STAMP 2/010

STAMP Commission Expert Group
6 May 2015

Subject: **Regulatory tools for early access: Accelerated assessment procedure**

Agenda item 3b

Introduction

Article 14 (9) of Regulation (EC) No 726/2004, provides that when an application is submitted for a marketing authorisation in respect of medicinal products for human use which are **of major interest from the point of view of public health** and in particular from the viewpoint of **therapeutic innovation**, the applicant may request an accelerated assessment procedure.

At the first meeting of the STAMP expert group on 27 January 2015, the experience with current use of accelerated assessment procedure was discussed and the group was informed that the CHMP guideline is currently being revised as regards the justification required for a request for accelerated assessment procedure, notably to better clarify the criterion of major public health interest.
The STAMP also discussed the possibility to proactively identify and select a subset of products under development that could be considered for accelerated assessment procedure dedicated mechanisms.

The members of the STAMP are invited to reflect, from the policy perspective, how the accelerated assessment procedure criteria[1] can be used for the proactive identification of potential candidates in this context.

[1] Applications for accelerated assessment must concern medicinal products of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation (Article 14 (9) of Regulation (EC) No 726/2004).