EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 691

PHARMACEUTICAL COMMITTEE
21 October 2015

Subject: **Legal and Regulatory news**

Agenda item 1b

➢ New legislation/regulatory texts published

The following regulatory texts have been published since the last meeting of the Pharmaceutical Committee:

- Commission Implementing Decision (EU) 2015/1057 amending Implementing Decision 2012/715/EU establishing a list of third countries having standards of manufacture and supervision of active pharmaceutical ingredients equivalent to those of the EU (Israel and Brazil have been added to the list)
- Notice to Applicants: Guideline on the packaging information of medicinal products for human use (update July 2015)
- Notice to Applicants: Updates of volume 2A (chapter 1 – marketing authorisation), Volume 2B (electronic application forms)
- Commission Report on the use of delegated powers provided by the EU pharmaceutical legislation
- EudraBook – Compendium of EU pharmaceutical legislation: the main body of the legislation in e-book format – free to download from the EU bookshop

Action to be taken:

For information