

# **CMDh-IP meeting 15 November 2010**

**AESGP survey on time slots  
(agenda item 2)**

# Objective and results of the AESGP questionnaire

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**Objective:** to find out whether companies are getting slots requested and whether they are using all slots granted

## **Results:**

- 7 companies (including EU affiliates) replied
- *Over period from mid 2009 to mid 2010*, out of 41 slots requested, 15 obtained and 12 used. One not yet used and two cancelled due to change of strategy (procedure type) consecutive to sc. advice given by NCAs to company
- *Over period mid-2010 to mid-2011*: 31 slots requested and 23 granted so far

# AESGP questionnaire – Conclusions

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- Although our ‘n’ is limited, companies use slots granted. However, number slots requests >> number of slots granted.
- Transparency & process improved overall but
  - Still difficult to find out how many slots are open EU wide (as no ‘central’ booking platform).
  - Therapeutic area + interest of the Agency in non-Rx med. also critical to ‘success’ of procedure
- Pre-submission meeting with NCA(s) at latest 6 months before file ready for submission seems more successful in terms of gauging ‘interest’ and discussing ‘time slot’