



# Interactions with Rapporteurs (in spe)

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## National ScA

What's in it for “you”?

EMA/CHMP vs. MPA

Complementary

Format similar

Q – your position – our view

In the National Advice

Dialogue always offered

New issues may be raised

Thinking outside the box?

Better suited for early interactions?

## National ScA

What's in it for “me”?

- Learning by doing
- New as well as experienced assessors
- Exchange of ideas
- Finding new answers to old questions

## Joint Advice MPA-TLV

- Initially the idea came from industry
- Objectives:
  - provide parallel Scientific Advice
  - create a better understanding between assessors for methodologies used at MPA and TLV
  - create (an even) better interaction between the two agencies
- Pilot that started September 2009 and was finalized by end of 2010

## How was the pilot organised?

- MPA and TLV assigned participants
- MPA and TLV discussed the questions independently prior to the meeting
- A (short) joint discussion before the meeting
- Meetings took place at the MPA
- MPA and TLV answered respective questions – the different roles of the agencies recognized (important to keep separate) although the process for providing advice is common.
- Industry to provide feed-back after the meeting

## Joint Scientific Advice MPA-TLV

- Twelve joint advices were performed in the pilot
- Most of the requests came from big pharma but small pharma was also represented
- An evaluation of the pilot was performed by the end of 2010

## Has it worked?

- Practical aspects? – absolutely (but it has required some more of planning)
- Met its objectives?
  - provided advice to industry – yes
  - increased understanding of methodologies and the clinical trial setting needed to provide valuable information – yes
  - overall better collaboration between agencies – yes
  - Informative to industry – yes (?)

## Current situation

The agencies have agreed to provide the possibility of joint advices on a regular basis since the beginning of 2011.

Since we decided to offer joint advices on a more regular basis we have received very few requests, fewer than expected from the experience from the pilot. Why?



# Presubmission Meetings

## Objectives

- Social
  - It is about working together
- Exchange Thoughts
  - Strengths and deficiencies of the file
  - “No pre-assessment meeting”
- Practical
  - Issues to be specifically addressed in the overview
  - How to organise, e.g. The Summary of Safety

## Other points of interaction

- During the procedure
  - Clarification meetings (LoQ, draft answers)
  - Debriefing after SAG, CHMP meetings
- Prior to large variations
- New major safety signals

# It is a long-term relationship

Thank You