Kooperation zwischen der FDA und der EMEA

Sabine Haubenreisser, PhD
Post-Authorisation of Medicines for Human Use
European Medicines Agency

Murray M. Lumpkin, MD
Acting Deputy Commissioner
United States
Food and Drug Administration

7. DGRA-Jahreskongress
Bonn, Deutschland
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AGENDA

- **Increased Bilateral Cooperation**
- **Information Exchange**
- **Provision of Parallel Scientific Advice**

Increased Bilateral Cooperation

- **Promote and protect public health in the globalized world in which our regulated products are developed, manufactured, authorized, promoted, marketed, and used by practitioners and patients**

- **Integral part of the Critical Path of product development and authorization**

Increased Bilateral Cooperation

- **Increase the efficiency and impact of exchange**
  - **Focus on specific information – routine and ad hoc basis**
  - **Focus of timing of exchange**
  - **Institutionalize the processes**
- **Formal - Develop ways to leverage resources**
- **Informal - Peer sounding boards**

The Pyramid

TOOLS FOR CLOSER BILATERAL COOPERATION

Confidentiality Arrangements

- Commercial confidential
- Pre-decisional
- Investigative – compliance

- NOT Trade Secret

INFORMATION EXCHANGE

Information Exchange

- **Implementation Plan for Medicinal Products for Human Use**
- **Finalized 16 Sept 2004 in San Francisco**
- **Document on both the EMEA and FDA website**

Information Exchange

- **Regular (Routine) Exchange of Specific Information**
- **Ad hoc Exchange of Non-Emergency Information**
- **Provision for the Exchange of Staff between the two Agencies**

Information Exchange: Routine

- Quarterly Exchange of Lists
  - Marketing Authorization Applications
    - Newly submitted
      - New – all
      - Variations – major public health interest
      - Still undergoing review
      - Decisions during that quarter
  - Inspections (GMP/GCP/Pharmacovigilance)
    - Performed during last quarter
    - Likely to be performed during next quarter
  - Guidelines Under Development

Information Exchange: Ad hoc (Non-emergency)

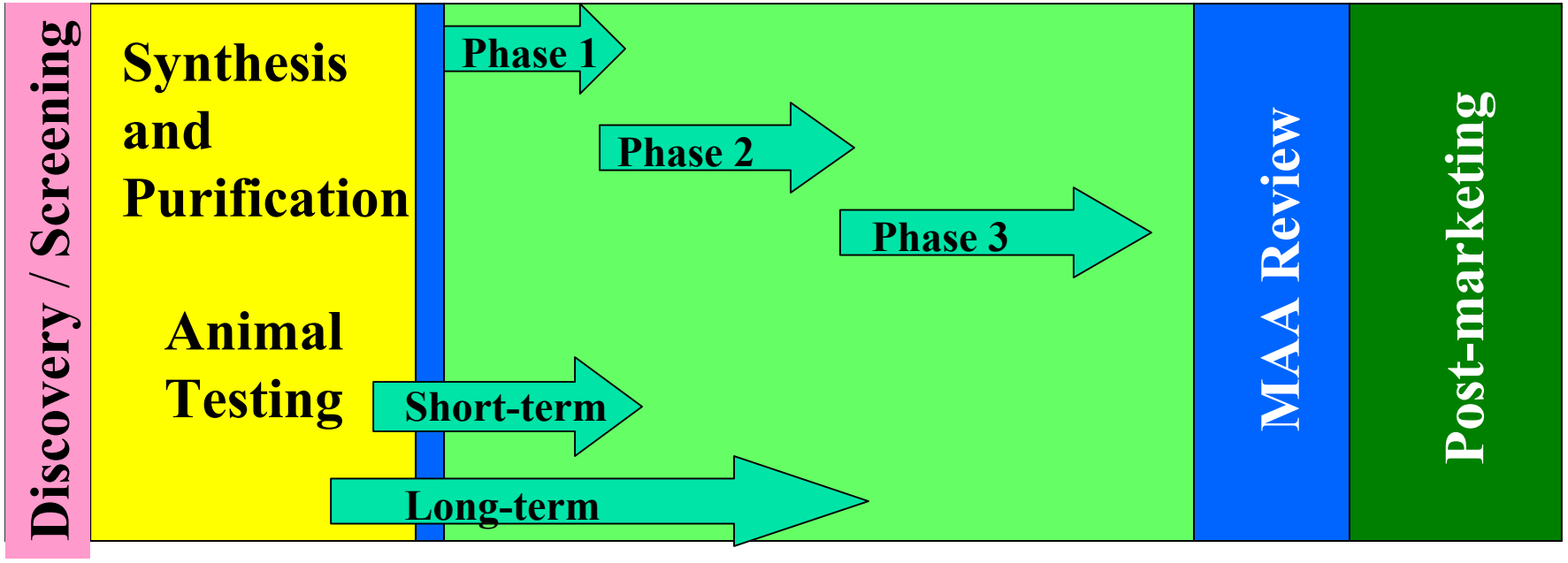
- Provision of Scientific Advice
- Difficulties in evaluation of MAAs
- Pharmacovigilance issues
- Advance notice, before the release of information into the public domain, of significant regulatory sanctions of mutual interest concerning one another's market
- General public health issues (TSEs, Counterterrorism)
- Pilot Benchmarking Exercise – Pre-market review assessments (2 applications)

Information Exchange: Staff Exchanges

- **Already several exchanges have occurred at various levels in the two organizations**

- **Also looking for appropriate opportunities for staff to attend and participate in FDA advisory committee meetings and EMEA CHMP meetings**

NEW DRUG DEVELOPMENT



PARALLEL SCIENTIFIC ADVICE

with the EMEA and FDA

Parallel Scientific Advice

- Agreed Pilot Program for 2005
- "General Principles" Document agreed 17 September 2004 in San Francisco
- Document on both EMEA and FDA websites

http://www.fda.gov

http://www.emea.eu.int

Parallel Scientific Advice

- **Expected Advantages**
  - **Increased dialogue between agencies and sponsor from the beginning of the product life cycle**
  - **Optimize product development by avoiding unnecessary testing replication or unnecessary diverse testing methodologies**

Parallel Scientific Advice

- **Expected Advantages (cont.)**
  - **Allows for additional critical issues to be identified simultaneously by both agencies and shared**
  - **Streamline development and facilitate access: e.g. orphan drugs, products eligible for accelerated review**

Parallel Scientific Advice

- Occurs at request of sponsor – sponsor nominates a product for this procedure
- Focus on specific questions or issues involving the development of a product
- Scope: Important (pediatrics or orphans) or Breakthrough products (US designated "Fast track")
- Initially limited to one such meeting per month
- Single occurrence – not a continuing series on same product

Parallel Scientific Advice

- **"Request for Scientific Advice" letter to Arielle North at EMEA and Michelle Limoli at FDA**
- **Justify why product would benefit**
- **Identify anticipated topic(s), including any specific question(s)**
- **Authorize comprehensive exchange of information between the two agencies, including trade secret information**
- **Request is no guarantee that meeting will be agreed to by Agencies**

Parallel Scientific Advice

- If accepted for this program, sponsor notified by Email
- Pre-meeting between EMEA and FDA – also usual preparations at EMEA and FDA
- Usually scheduled around 60 days after request in the margins of the Scientific Advice Working Party (EMEA)
- Tele- or Videoconferencing

Procedure and Timing

Day 0	Day 30	Day 60	Day 70
Submission of request	EMEA: first expert reports FDA: initial comments	Videoconferences - EMEA/FDA assessors meeting - EMEA/FDA meeting with Sponsor	CHMP final advice FDA final minutes

Parallel Scientific Advice

- Each agency provides independent advice as per usual procedures
- Advice may still differ – not "joint" advice or "combined" advice – "parallel" advice
- Should have a clearer understanding of the agencies' perspectives and the background of any divergence

Parallel Scientific Advice

- **Fees and timelines are unaffected by virtue of this being a parallel scientific advice meeting**

Possible reasons for conflicting advice

- Even among top experts, the way to consensus can be long and winding and sometimes not reached
- Different legal/ regulatory background
- Different priorities: absolute vs. relative benefit/risk assessment or both?
- Different therapeutic practices?
- Concept of ”established” treatment?

Initial experience

- **Up to May 2005 a total of three procedures have been finalised**
  - **Orphan Medicinal product**
  - **Issue on QT prolongation**
  - **Absence of guideline in EU and US**

Initial experience (cont.)

- **Two other procedures were not accepted for logistic/procedural reasons**

Initial Experience (cont.)

- Cautious approach from companies
- Several additional companies have expressed interest in the procedure
- Review after one year to assess experience, value, and determine future course

What has been learnt?

- **Early contact** is of paramount importance:
  - Sponsors intending to pursue this route should notify the agencies as early as possible
  - Agencies will identify experts to be involved and initiate dialogue
- **Best timing** to coincide with EOP-2 or other milestone meeting
- Videoconference best held with participation of the sponsor

VIELEN DANK!