EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Generics in the Centralised Procedure

Instrument for Pre-accession Assistance Programme (IPA)
European Medicines Agency, London UK

2 February 2010

Presented by: George Wade
Quality of Medicines Sector : Section Head - Chemicals

An agency of the European Union

EUROPEAN MEDICINES AGENCY

Introduction

- Directive 2001/83/EC as amended -- Definition of a Generic medicinal product, and the EU Reference product.
- First Human Generic Applications received at the Agency in September 2006
- Over three years experience in handling generics
- All of them are generics of of Centrally-Authorised Reference Products

EUROPEAN MEDICINES AGENCY

Introduction

- The majority of Generics in the EU are not authorised by the Centralised Procedure
- They are authorised Nationally, currently through the Mutual Recognition Procedure / DeCentralised Procedure, in the hands of the Member States
- Coordinated by CMDh Committee, not CHMP
- Results in National authorisations in a small number of MS (typically 5)
- CHMP/EMA is involved in these National cases where there is non-recognition or internal disputes – Referral to CHMP for Arbitration – a final binding Opinion

3

EUROPEAN MEDICINES AGENCY

Introduction

- However, Generics may enter the Centralised Procedure for a CHMP Evaluation and a pan-EU authorisation in ALL MS
- There is no possibility of MS divergence with an individual product evaluation
- Coordinated by EMA utilising the CHMP for a Scientific Opinion

4

Eligibility

- Generics of Centrally-Authorised Reference Products have automatic access to CP.

- Generics of Nationally-authorised Reference Products : eligibility to CP is not automatic – must be linked to Interest of patients at Community Level. No experience with these cases yet

5

Steps already taken

- Regular meetings and workshops organised by EGA (EU Generics Association) and EMA

- "EMA Procedural Advice for Users of the Centralised Procedure for Generic/Hybrid Applications" published at the Agency website (July 2008)

http://www.emea.europa.eu/htms/human/gensub/index.htm

6

Steps already taken

- Implementation of legislation
- Development of templates for standardised reports (structure & content)
- Reduced fees for Generics
- Reduced Timetable for assessment

7

Product Name

The CP requirement for ONE Single Product Name, identical in ALL EU Member States may be a problem for generic companies :

<Trade Name> or < Invented Name >
< INN + MAH >

Multiple Applications are possible for commercial purposes – 'selling-on' transferring to other companies, etc.

8

Basic procedure for generics (same as CP in principle)

1st phase

(normal, as for innovative products)

- Potential CHMP Opinion at Day 120
- Inspection request timetable reduced.

2nd phase

- Only if major objections and/or GXP or closed part ASMF issues are raised at Day 120
- Day 180 Opinion

9

Basic Procedure

- Scientific advice, pre-submission and clarification meetings with applicants, as normal
- EMA Team leader in Quality Sector, to coordinate the procedure
- Only one Rapporteur : No CHMP Peer Review
- EMA Peer Review

10

EUROPEAN MEDICINES AGENCY

Problem Areas during Evaluation

Master Files (ASMF) especially the confidential part

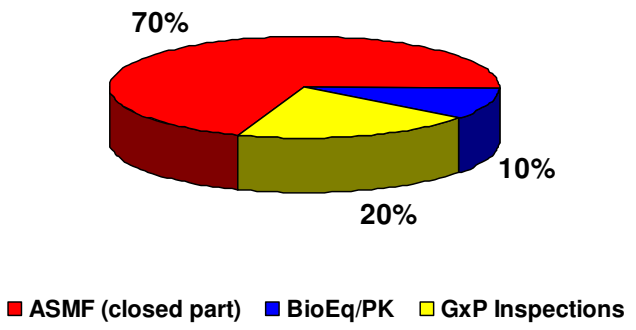
BioEquivalence study design and interpretation

GXP issues, especially GCP problems at the bioequivalence study site.

11

EUROPEAN MEDICINES AGENCY

Type of Questions during Assessment (CHMP List of Questions at Day 120)



12

After the Opinion and Authorisation

- External Communication, exactly as for new products

- Press release /CHMP monthly report
- Summary of Opinion (SmoP)
  - EPAR
  - SPC / PIL/Labelling
  - General Q&A document

13

Post-Authorisation activities

- Generics do not submit large number of Clinical Variations (extension of indications etc.)

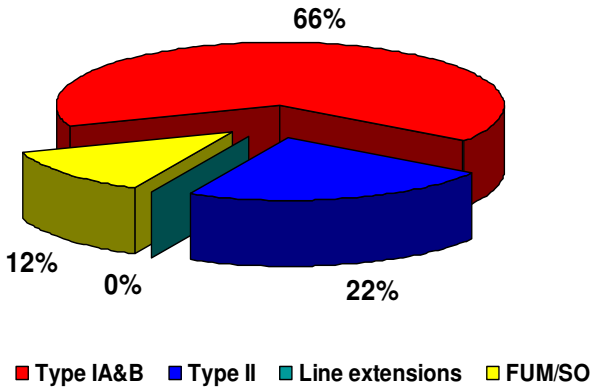
- Generics normally submit large numbers of Quality Variations (Type IA,IB,II)

- In principle, generics are obliged to copy the SPC/PL of the reference product so if this changes, generics must submit 'passive' Variations to keep in line.

14

EUROPEAN MEDICINES AGENCY

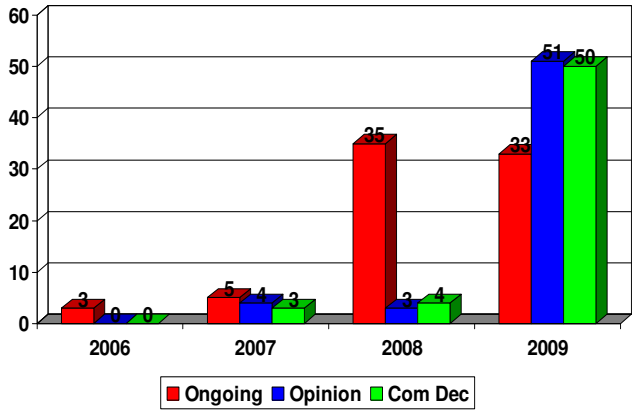
Post Authorisation activities



15

EUROPEAN MEDICINES AGENCY

Generic applications received in the CP (end of year figures)



16

EUROPEAN MEDICINES AGENCY

Challenges for the Future

Improve collaboration between National authorities and EMA

- Must check Consistency of assessment
- Must reduce the risk of divergence between National & Centralised evaluations of the same dossier
- Efficiency of regulatory network

17