EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Report from follow-up meeting with Thalidomide Patients' and Victims' organisations

Patient and Consumer Working Party
13 September 2011

Scientific administrator, Safety and Efficacy of Medicines

Background – Thalidomide initial marketing authorisation evaluation

- Consultation meetings with Patients' and Victims' organisations in May and November 2007
- Input provided on Risk Management Plan and Package leaflet
- Follow-up agreed:
  - PSUR assessment reports to be sent to organisations
  - Future meeting at the EMA to present post-authorisation safety aspects and the updated RMP

Follow-up meeting on 5 September 2011

- Invitation to organisations previously consulted
- Representatives from 1 patients' and 7 thalidomide victims' organisations
- Speakers and participants from:
  - EMA
  - Rapporteur and Co-Rapporteur and assessors
  - Other Member States (NL, UK)

Agenda

- Introduction on the role of the Agency and CHMP and objectives of the meeting
- Update on post-authorisation activities on Thalidomide Celgene
  - Overview of post-authorisation regulatory procedures
  - Overview of PSURs, RMP revisions and reports of events of interest
- Implementation of the Risk Management Plan and Pregnancy Prevention Programme (PPP)
  - Introduction
  - Practical examples of Member States experience (FR, SE, UK)
- New legislation: strengthening pharmacovigilance in the EU
- Closing remarks and follow-up

Objectives of the meeting

- Update on safety aspects and Risk Management Plan (RMP) since the previous consultation
- Information on use of Thalidomide Celgene in the EU
- Practical implementation of RMP for which they provided input
- Provide reassurance on safety aspects of interest
- Agree on future follow-up

Overview of post-authorisation regulatory procedures

- Update on status of product since initial MA
  - 1st launch in the EU on 10 June 2008
  - Launched in 19 Member States
  - 2.5 years of post-marketing experience
  - MA transferred from Pharmion to Celgene

- Variations to the marketing authorisation
  - Changes to quality aspects, pharmacovigilance system or administrative
  - Overview of updates related to safety and efficacy of the medicinal product (including further to request from PSUR assessment)

Overview of PSURs, RMP revisions and reports of events of interest (1)

Presentation of exposure data

- Worldwide exposure summary
- Indication for use and off-label use
  - EU off-label use: approx. 19.5% (PSUR 5 data)
- Patient's age and gender
  - Female of childbearing potential: 3.8% (cumulatively, PSUR 5 data)

Overview of PSURs, RMP revisions and reports of events of interest (2)

Analysis of post-marketing data

- Exposure during pregnancy since launch in EU
  - No pregnancy occurred
  - 3 reports of pregnancy in patient's partner. Outcome of the pregnancy ongoing and additional information requested.
- Thromboembolic events
- Peripheral neuropathy

Overview of PSURs, RMP revisions and reports of events of interest (3)

Risk Management Plan and PPP

- Regular updates since initial MA
- Implemented before launch in all EU countries where marketed
- Effectiveness of RMP and PPP : No pregnancy of patient

Implementation of the Risk Management Plan and Pregnancy Prevention Programme (PPP)

- Presentations on practical experience in France, Sweden, UK
- Outline of controlled distribution systems in place
- Results of survey/questionnaire/audit conducted
- Off-label use and use of unlicensed thalidomide

Outcome of discussions

- RMP and PPP implemented in all countries where launched
- Effectiveness of RMP and PPP : No pregnancy reported
- Off-label use and use of unlicensed thalidomide
  - Close monitoring
  - Under supervision of national competent authorities
  - Conditions of MA and PPP also applied

→ Update and data presented welcomed by organisations

→ Reassurance provided on effectiveness of PPP and monitoring of off-label use

Future follow-up

- EMA will continue sharing future PSUR assessment report and emerging information on events of interest
- Follow-up meeting to be considered after the 5-year renewal of the marketing authorisation