Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION

Making Medicines Affordable

Industry's perspective on implementation

7th Stakeholders Forum, 2013-09-27

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Agenda

- Educational material
- Requests from referrals
- Pharmacovigilance fees

Educational materials

- **New GVP model creates a high workload …**
- **… but the issue remains on how this should all be handled?**
  - Do it jointly between companies?
    - Difficult to reach agreement.

Educational materials

- **Would it be an option if this is organized by EMA or the NCAs?**
  - DDL in the local language(s).
  - DDL as outcome of a referral → coming from NCAs.
  - Organised by NCA & paid by all MAHs who market the product.

Requests from referrals

- ***Trimetazidine Example***

  - Working group was established;
  - Protocols ready for submission;
  - Remaining question(s):
    - Who owns the data?
    - Which formulation to be used?
    - ...

Requests from referrals

- ***Trimetazidine Example***
  - PK study
  - Drug Utilization Study (DUS)
  - PASS study:
    - Study in Europe: 7 million € + submission costs

Is it worth spending the money on the PASS or will the product be withdrawn from the market?

Requests from referrals

- **Scenarios to consider…**
  - Big generic companies may have resources.
  - Small generic companies will withdraw the product from EU markets.
  - What if all generic companies withdraw the product?

Is that in the patients' interest?

Requests from referrals

- **Scenarios to consider…**
  - Several similar studies being conducted.

    Is it ethical?

    Competition for same patients in the same countries …

  - The innovator company is not always interested in grouping.

Pharmacovigilance fees

- **Welcome:**
  - Dual structure of fees.
  - Fee reduction for lower risk products.
  - Fees charged at national level should not overlap with fees already paid to the EMA.

- **Still a major concern!**
  - Generic MAHs has in average 10-times the product portfolio *vs.* originator MAH.

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Thank you!

Acronyms

- DDL: Dear Doctor Letter
- EMA: European Medicines Agency
- GVP: Guidelines on Good Pharmacovigilance Practices
- HcP: Healthcare professional
- MAH: Marketing Authorisation Holder
- NCA: National Competent Authority
- PASS: Post-Authorisation Safety Study
- PK: Pharmacokinetics