Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION

Making Medicines Affordable

Identification and Traceability of Biological Products
EGA Views

London, EMA, 25 May 2012

Suzette Kox

Senior Director Scientific Affairs

Experience to Date

- **Biosimilar medicines marketed since end 2006**
  - Somatropin, Epoetins, Filgrastims
- **Estimation: up to 100 million patient-exposure days of experience (regulated markets)**
- **Experience of ADR reporting with batch number/name very limited compared to vaccines/plasma derived products' industry**

Reporting Batch number and Name

- **Not a new requirement**
- **New: Art. 102 to be implemented by Member States**
  - all **appropriate measures to be taken** to identify clearly any biological medicinal **product prescribed, dispensed, or sold** in their territory which is the subject of a suspected adverse reaction report

Patient Report in General Irrespective of the Product

- **Industry concern: lack or delay of follow-up of suspected adverse reaction reports by NCAs**
  - Potential impact on signal detection, evaluation, RMPs etc.
- **Feedback as received from individual MSs:**
  - 'We have no resources for FU'
  - 'We only FU events of interest'
  - 'We do FU on request of the MAH, but only when medically justified and when there is resource'
  - 'We only FU according to our SOPs'
  - 'If we do FU and if we get information it will be send to you according to the normal routing – so if you hear nothing we either did not FU or did not get a reaction'

Follow up “events which can be signs of immunogenicity”

- Follow up “events which can be signs of immunogenicity” like allergic reactions for example
- MAH will start immunogenicity testing asap to avoid other interventions causing a reaction
- MS will forward to MAH in timelines ranging from 1 week to 2 months
- MS will not initiate testing because they are not alerted on the RMPs
- MS will not issue confidential patient or reporter details – so a potential test is not performed

Comments on Business Process Map (Appendix VI) GVP Module VI

- If report incomplete, an initial case is not validated
- We believe it should be validated also without the batchnumber - otherwise if for whatever reason the batchnumber is not available, the case will never get into the PV database

Required Information Available

- In the EU every medicinal product has a unique approved name (invented name/brand name)
- **Detachable (tear-off) syringe labels**
  - required from EMA to ensure traceability down to the level of batch No used by the patient
  - mentioned in RMPs
- **Batch No stated for all EU countries on the outer carton and the cartridge/syringe label (as required by the QRD Templates)**

Extent of Issue of Identifiability? Next Steps

- Get an overview of implementation of MSs of Article 102
- Proportion of identifiable biological products ? (EV Data Warehouse)
- Role of ISO Identification of Medicinal Products (IDMP) standards
- Unique identifier (Falsified Medicines Directive) for medicines at high risk of falsification (e.g. high priced medicines)
- E-health initiatives by MSs (e-forms, e-patient records etc.)
- Impact of black symbol, statements in SmPCs and PILs
- NCAs awareness campaigns in relation to the requirements for reporting of ADRs related to biological medicinal products
- Education of HCPs and patients on naming

Last but not Least: INN

- **Biosimilars should continue to share the same INN as the reference product (active substance is a known biological substance)**
- **PRCA with Eprex was ultimately tracked down to different batches of the same originator product**
  - example of the need for complete records down to batch number
  - nothing to do with the INN

Conclusion

- Same PV requirements should continue to consistently apply to all biologicals at national level
- All stakeholders must ensure tracking and traceability of safety findings

Thank you