

Risk minimisation measures

PCWP/HCPWP joint virtual meeting, 24 June 2020





Presented by Ulrich Jaeger (EHA), Priya Bahri (EMA) and Núria Semis(EMA)



Objectives of today's discussion

- Risk minimisation is a major area of regulatory activity
- Designing and implementing such measures for effective risk minimisation is challenging
- Regulatory guidance on risk minimisation is available and has been strengthened over time
- A guidance review is ongoing now and EMA wants to involve patient and healthcare professional representatives in this review and obtain their input with a view to strengthen their involvement when developing and reviewing effectiveness of future risk minimisation plans and measures





Structure of today's discussion

- Brief overview on pharmacovigilance guidance
- Overview on the scope of revision regarding risk minimisation measures
- Patients' perspective on risk minimisation
- Healthcare professionals' on risk minimization
- Open discussion on specific topics identified by EMA and patient and healthcare professional representatives
- Discussion outcomes will inform the revised guidance which will be released for public consultation in Q4 2020/Q1 2021



Good pharmacovigilance practices for the European Union (EU-GVP)

- Set of guidelines developed by the EU regulatory network on the practical implementation of legal requirements for pharmacovigilance across the EU for patient and public health protection
- Applies to EU marketing authorisation holders, competent authorities in EU member states and the EMA
- By way of specific agreements with the EU, it also applies in EEA countries (i.e. Norway, Iceland and Liechtenstein)
- Regulatory-scientific content
- Takes into account international standards and guidance
- Developed through internal and external expert dialogue under supervision of the Pharmacovigilance Risk Assessment Committee (PRAC) and public consultation open to all citizens of the EU and parties worldwide
- In force in the EU since 2012, updated regularly and recognised globally

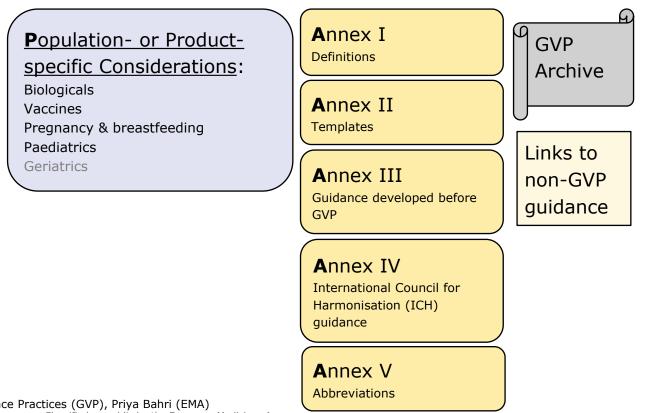




Introductory Cover Note

Modules on processes:

Pharmacovigilance system and its quality management Pharmacovigilance system master file (PSMF) Inspections Audits Risk management plan (RMP) Individual case safety report (ICSR) Periodic safety update report (PSUR) Post-authorisation safety study (PASS) Signal management Additional monitoring Safety communication Risk minimisation measures (RMM)





1.2 Introduction to the Good Vigilance Practices (GVP), Priya Bahri (EMA) Classified as public by the European Medicines Agency



GVP Module XVI – Scope of guidance

- Legal requirements for risk minimisation measures (RMM)
- Current RMM types: product information (routine), educational programmes, controlled access programmes, pregnancy prevention programmes, direct healthcare professional communications (additional)
- Additional RMM types underpinned by an 'additional RMM toolbox'
- Methods for evaluating RMM effectiveness
- Roles and responsibilities of marketing authorisation holders and the EU regulatory network





GVP Module XVI - Purpose of ongoing revision

- Review of terminology for the additional RMM types and tools (i.e. consistency and clarity of terms)
- Description of additional RMM tools
 - Rev2 included list of tools with some descriptions; rev3 draft now includes exhaustive description of guides, checklists, patient cards, risk awareness forms and diaries.
- Review of RMM effectiveness evaluation
 - New addendum
- Pregnancy and pregnancy prevention programmes
 - Changes to come at a later point



Any questions?



Further information

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands **Send us a question** Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

