EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Good Pharmacovigilance Practices (EU-GVP)

General update &

GVP Module XVI Revision 3 with new Addenda

Pharmacovigilance Platform Meeting
30 October 2020

Presented by Priya Bahri

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)

Population- or Product-specific Considerations:

- Biologicals
- Vaccines
- Pregnancy & breastfeeding (draft)
- Paediatrics
- Geriatrics

Annex I
Definitions

Annex II
Templates

Annex III
Guidance developed before GVP

Annex IV
International Council for Harmonisation (ICH) guidance

Annex V
Abbreviations

GVP Archive

Links to non-GVP guidance

Priorities for GVP

- At origin implementation of new pharmacovigilance legislation in force since 2012
- Planned as living documents for continued strengthening of pharmacovigilance
- Process simplifications and improvements
- International convergence or harmonisation
- Data-driven regulatory decision-making
- Patient safety in real world healthcare

GVP M VIII Addendum I

- Requirements and recommendations for the submission of information on non-interventional post-authorisation safety studies
- Revision 3 published on 24 June 2020
- Deletion of notification procedure from EMA to Member States following the modification of the search function of the EU PAS Register allowing searches by country
- Addition of Finland and Norway to the list of national competent authorities not requiring progress reports for non-interventional PASS imposed as an obligation
- Editorial amendments

GVP Module XVI on risk minimisation measures and Addenda

- Revision 3 of the Module re-started in October 2019
- PRAC drafting group established with 3 workstreams: educational materials, effectiveness evaluation, pregnancy prevention programmes (PPPs)
- PRAC Interest Group (IG) on Impact of Pharmacovigilance had already started developing guidance on methods for measuring effects of pharmacovigilance activities ('impact guidance') in January 2019
- PRAC endorsed draft GVP Module XVI Rev 3 and new Addendum II on effectiveness evaluation methods in Sep 2020 for Committee consultation, now finalised; EMA legal review ongoing, EC review and Head of Medicines Agencies (EU-POG) agreement thereafter
- Addendum III on PPPs ongoing
- Q1 2021: Launch of public consultation of Module, Addenda II and III planned for about 8-12 weeks

GVP Module XVI – Scope of revision 3

- Additional RMM part of in the benefit-risk life-cycle management
- Educational material 'toolbox' with descriptions of tools - *Workshop with patients and healthcare professionals in Q2 2020 (*" 'educational' is not patronising")
  - Brochures, triptychs, slide decks, leaflets: all to be referred to as guides
  - Patient alert/reminder card: all to be referred to as patient cards; inside/outside/affixed to package
  - Risk awareness form: not an informed consent form, useful to document that a discussion took place
  - Patient diaries: only for the purpose of risk minimisation
  - Demonstration kits: "dummy" devices
- Sections on controlled access and PPP rewritten, and section on DHPC simplified with cross-reference to GVP Module XV
- Expanded section on RMM effectiveness evaluation

GVP Module XVI and new Addendum II – Scope

GVP XVI.B.5 Effectiveness evaluation of RMM

- Principles
- Objectives and approaches to evaluation
- Assessment of effectiveness and regulatory follow-up

GVP XVI Add II – Methods for effectiveness evaluation

- Data sources
- Methodologies
- Reporting results of effectiveness evaluation

GVP M XVI Add II: Principles of RMM effectiveness evaluation

- **Focus on RMM of major patient and public health importance** taking into account the nature, severity and seriousness of the risk, the magnitude of population exposure and the amount of public concern
- **RMM effectiveness should be measured at regular timepoints** to be included in the pharmacovigilance plan of the risk management plan: 12-18 months after initial implementation, within 3 years to potentially add further elements, and within 5 years to assess overall effectiveness (or in time for renewal)
- **Evaluation of intended and unintended outcomes**, as outcomes with a wider impact may occur and unintended consequences may counteract the effectiveness of RMMs, other outcomes of RMM may be investigated where appropriate or upon request **- Monitoring outcomes of risk minimisation is required by legislation**

GVP M XVI Add II: Objectives of effectiveness evaluation

Investigate:

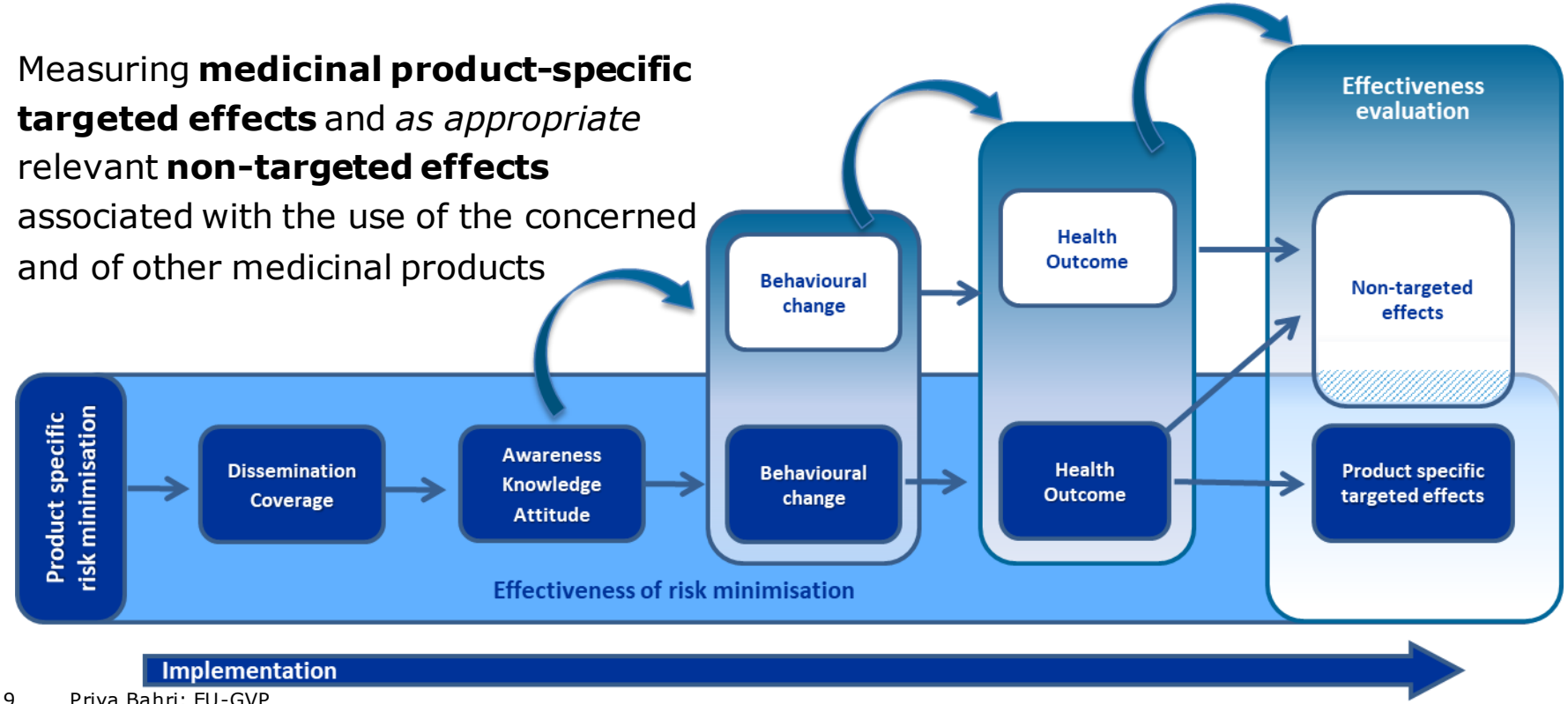
- to what extent the **RMM has been delivered** to the target audience as planned
- if the RMM has led to the intended **knowledge and behavioural changes** in the target audience, or whether other knowledge and behaviour related outcomes have occurred
- to what extent the RMM objectives have been met in terms of **improved population health** within relevant timeframes, or whether **other health outcomes** have occurred

→ Requires different approaches at each step of the implementation process and combination of research methods:

- Qualitative methods
- Non-interventional methods
- Surveys methods *(former XVI.App.I.)*
- Randomised trials

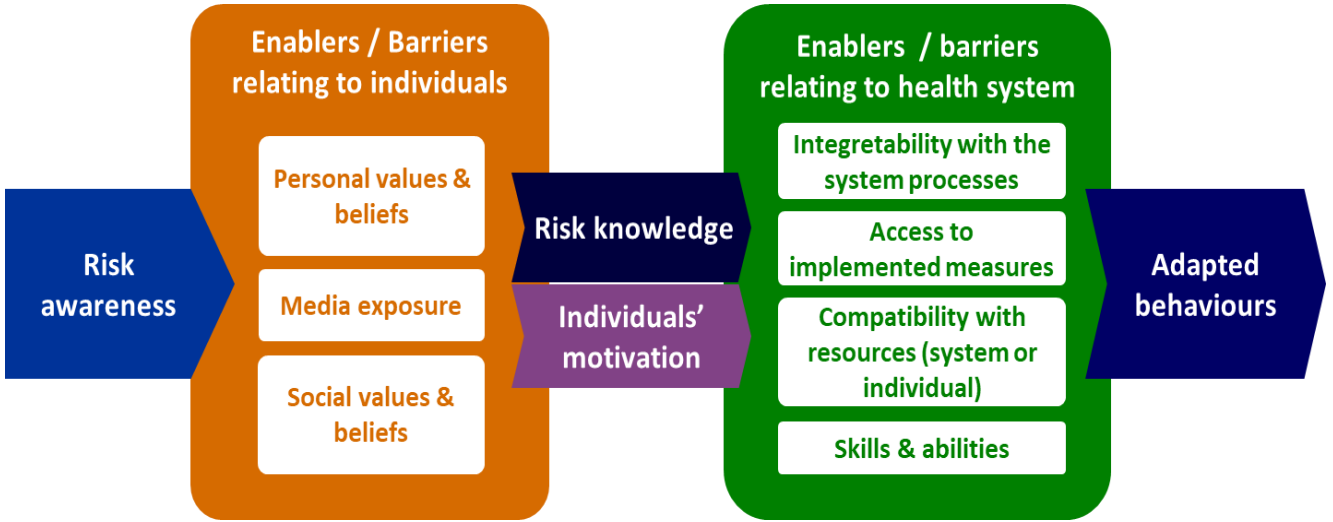
Approaches to effectiveness evaluation

Measuring **medicinal product-specific targeted effects** and *as appropriate* relevant **non-targeted effects** associated with the use of the concerned and of other medicinal products



GVP M XVI Add II:
Effectiveness evaluation objectives – Behavioural changes

Pathway from risk awareness to risk minimising behaviours including enablers and barriers of behavioural change



Any questions?

Please schedule time for comments

Any suggestions for GVP?