EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Good Pharmacovigilance Practices (EU-GVP) - Update

17th Industry Stakeholder Platform – Operation of EU Pharmacovigilance
7 November 2022

Presented by Priya Bahri

Update

- Thanks for comments, interest, participation and adherence from our industry stakeholders
- Plans and priorities for 2023
- Comments on GVP M XVI ADD III
- Multistakeholder drafting group for Reflection Paper on Digital Support to Risk Minimisation Measures and Their Evaluation
- Feedback from industry stakeholders on potential 2024 priorities

Focus 2023

- EU-GVP
- Impact research
- PRISMA pilot

EU-GVP Work 2023:

Priority 1: first lane – second lane

- **GVP Module XVI Rev 3 on risk minimisation measures (RMM), Addendum II on RMM evaluation and Addendum III on pregnancy prevention programmes**: Finalisation post-public consultation, aiming at publication in 2023 *(for ADD III: Review of timetable in June 2023)*
- **GVP Chapter P III on pregnancy and breastfeeding**: Finalisation of post-consultation, aiming at publication in 2023 *(Review of timetable in June 2023)*
- **GVP Annex I Rev 5 on definitions**: published Rev 4 already includes latest definitions from now applicable clinical trial legislation; previous definitions will be deleted in Rev 5, aiming at publication in 2023
- **Reflection Paper on digital support to RMM and their evaluation**: Development by multi-stakeholder drafting group, aiming at public consultation in 2024

EU-GVP Work 2023:

Priority 2:

- **GVP Module VIII Rev 4 on post-authorisation safety studies**: started in 2022 (draft scope of revision presented to PRAC Sep 2022) and to be released for public consultation 2023 or 2024 – ***Points raised by industry stakeholders?***

Priority 3 :

- **GVP Module V Rev 3 on risk management system**: to be started in 2022/3 and to be released for public consultation (2023 or) 2024 – ***Points raised by industry stakeholders?***

GVP Module XVI on risk minimisation measures and Addendum II on effectiveness evaluation

- Public consultation of Module XVI rev 3 and new Addendum II in 2021
- Comments review and finalisation ongoing
- Comments on Module: 697 comments from 27 stakeholder organisations
- Comments on Addendum II: 73 comments (about 2/3 accepted)

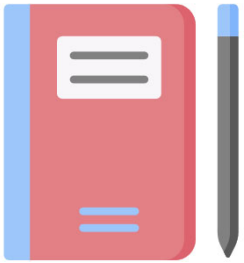
RMM toolkit in draft GVP Module XVI – already practical!

Guides

Checklists

NEW Risk awareness forms

NEW Demonstration kits

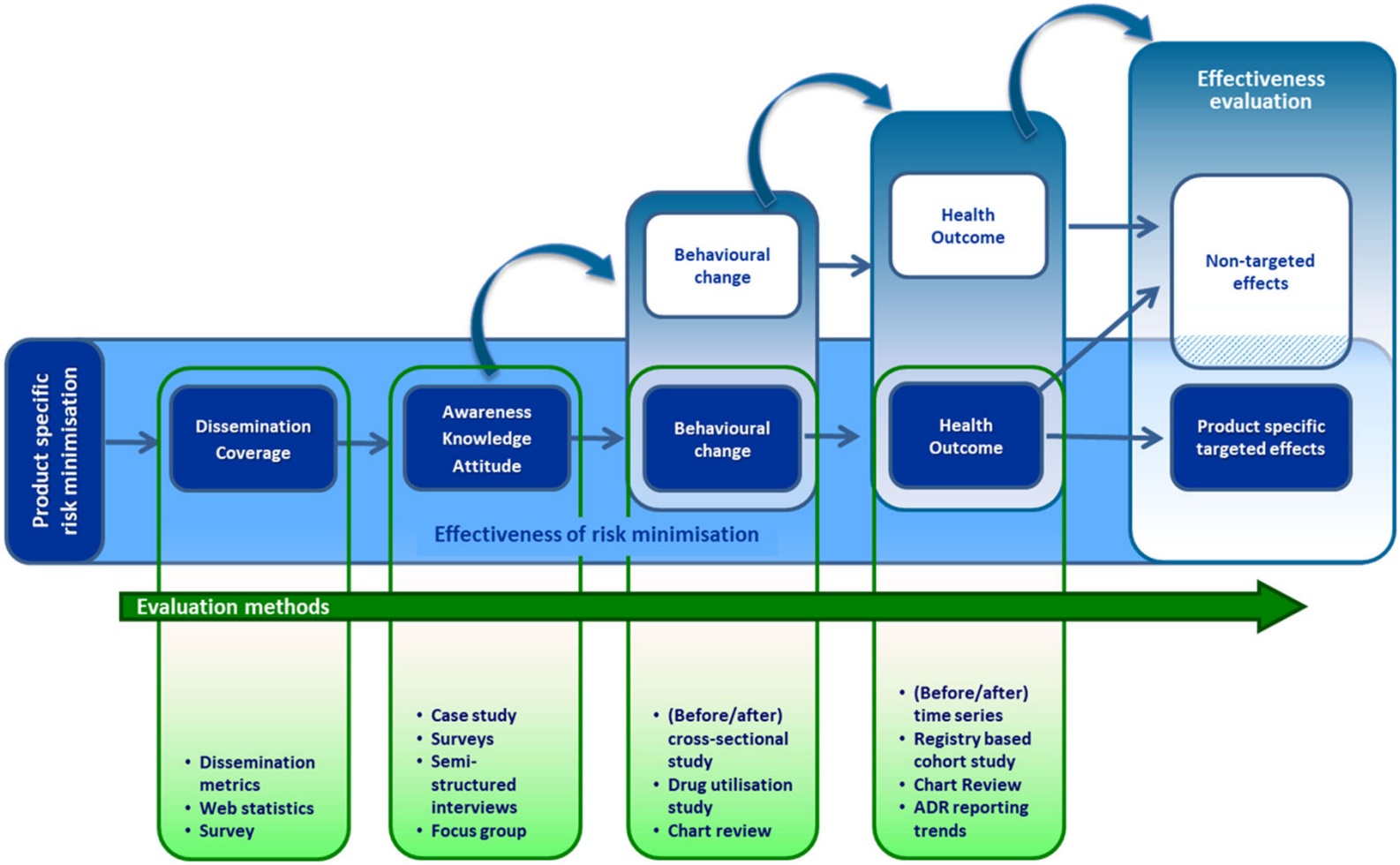


NEW Patient diaries for risk minimisation

Patient cards

Credits for icons: flaticon.com

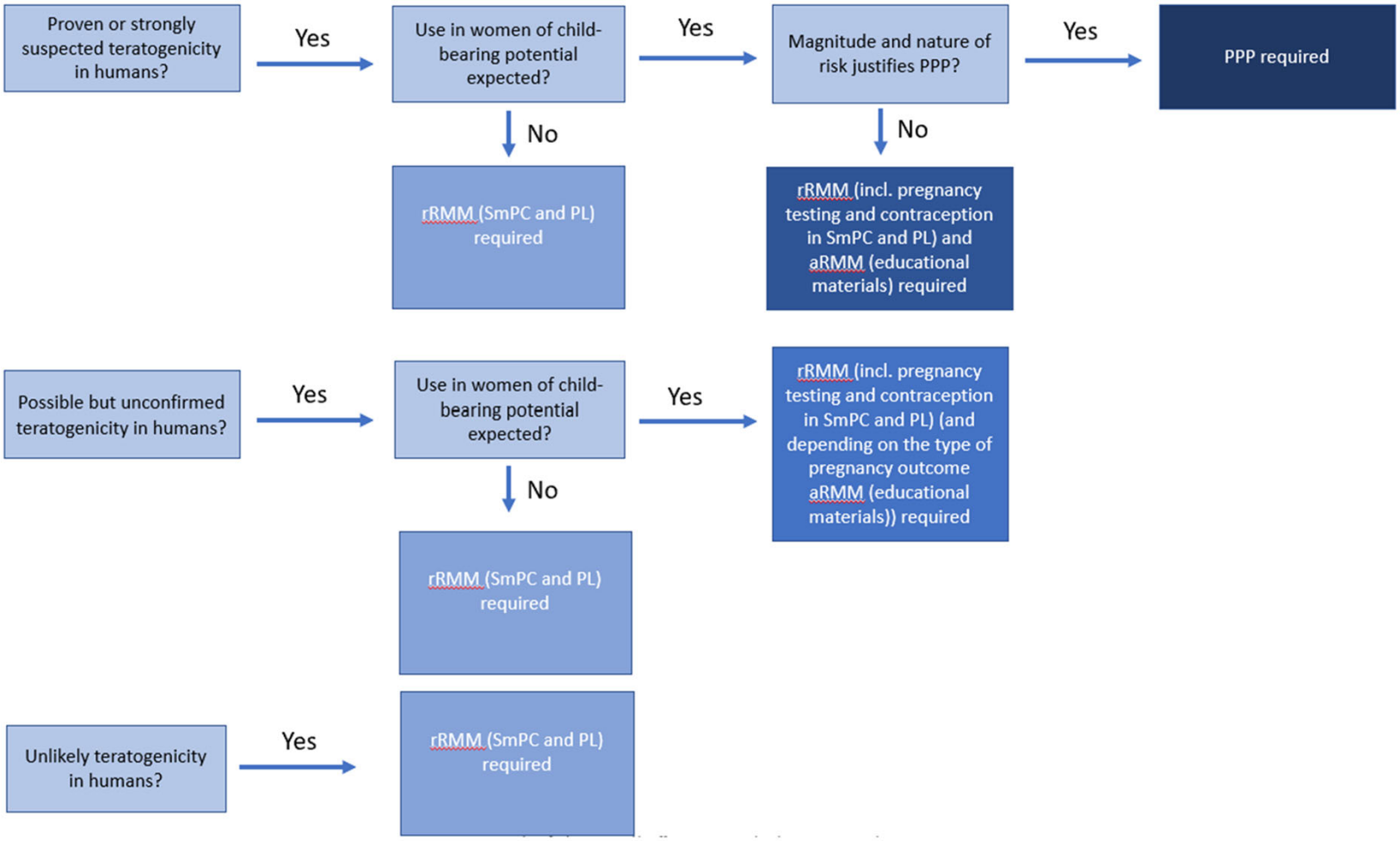
RMM effectiveness evaluation methods in draft GVP M XVI ADD II – already practical!



GVP Module XVI Addendum II on RMM effectiveness evaluation - in the final version:

- Improved structure of methods section (qualitative – quantitative)
- Emphasis on mixed methods approach
- Reference to human factors/usability engineering techniques
- Clarifications

Considerations for requiring 'pregnancy-specific' RMM in draft EU-GVP M XVI ADD III – complex



Public Consultation in 2022 - 33 commenting parties

- Patient organisations: **3**
- Individual patients/citizens: **8** (4 non-EU)
- Healthcare professional organisations: **2**
- Learned societies/research consortia at EU or international level: **3**
- Learned societies at national level: **1**
- Industry organisations at EU level: **3** EFPIA, Medicines for Europe, European CRO Federation
- Industry organisations at national level: **2**
- Individual pharmaceutical companies/consultancies: **8** (4 non-EU)
- National competent authorities: **1**
- Charity: **1** (non-EU)
- Others: **1**

Public consultation – 369 comments

General comments from public consultation: **90**

Section-specific comments from public consultation

- Introduction: **39**
- Criteria: **99**
- Figure: **18**
- PPP: **122**
- Other: **1**

Public consultation – main themes of comments

- Scope
- Impact of PPP on access to treatment / informed choice concept
- Definitions of criteria and evidence thresholds
- Situations of uncertainty

Multistakeholder Drafting Group for Reflection Paper on Digital Support to Risk Minimisation Measures and Their Evaluation

Patient and consumer representatives: **2**

Healthcare professional representatives: **8** presenting the different professions and settings

Industry representatives: **6** (Katharina Bench (Vaccines Europe), Vicky R Edwards (EFPIA), Michael Forstner (Medicines for Europe), Sarah Frise (Vaccines Europe), Randip Kahlon (EFPIA), Klaudija Marijanovic Barac (Medicines for Europe)) – ***Names in the public domain?***

EMA Committee representatives: **8** from PRAC (incl. 2 patient and 2 healthcare professional members) and **2** from CMDh

EMA: Priya Bahri, Monica Buch, Sabine Brosch, Machteld van Egmond, Pedro Pina Ferreira, Thomas Goedecke, Viola Macolic-Sarinic, Marie-Helene Pinheiro, Ana Sempere, Elias Tavares, Thorsten Vetter

Status

Reflection Paper on Digital Support to Risk Minimisation Measures and Their Effectiveness Evaluation

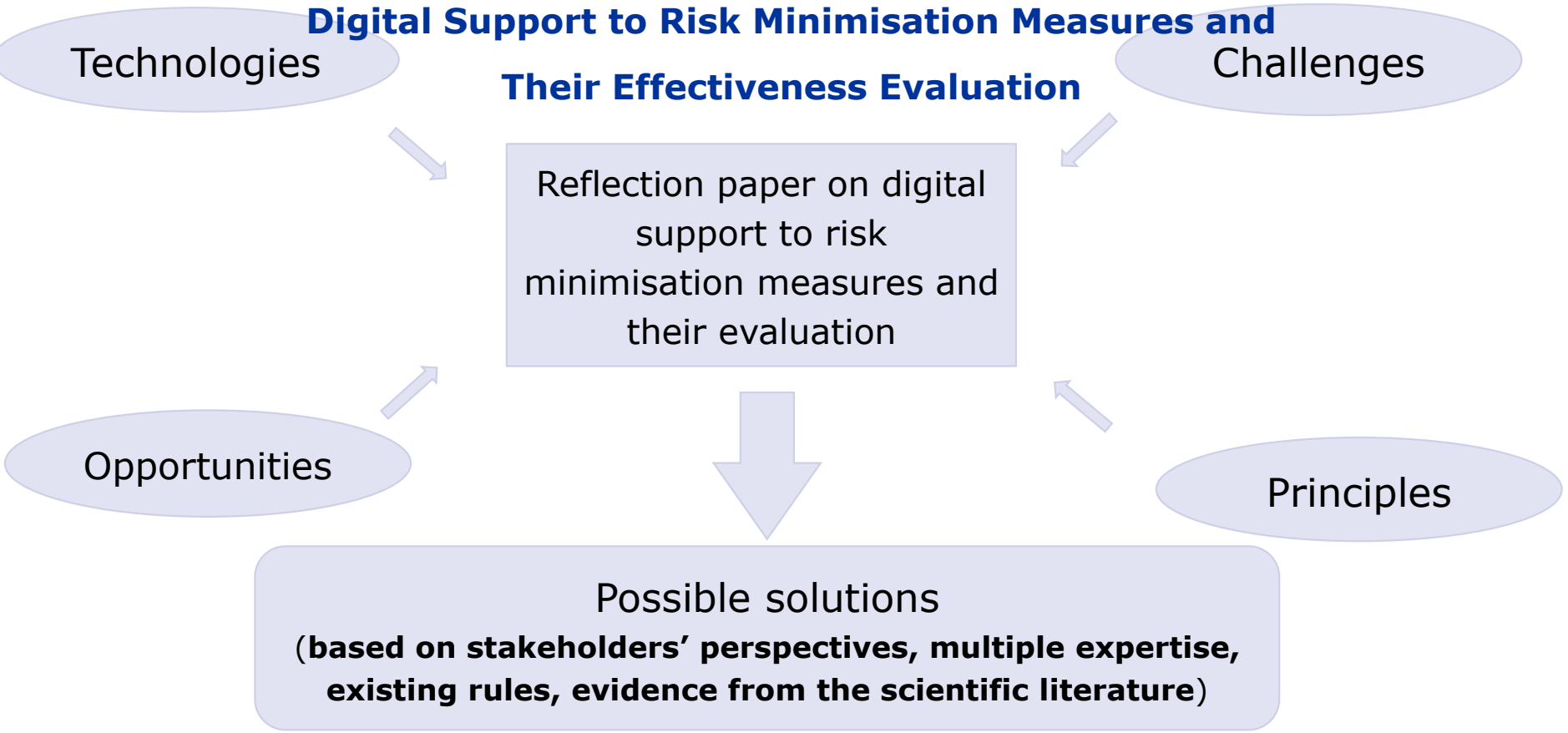
- Established a multistakeholder drafting group under EU-GVP activities
- Call for themes from stakeholders by 15 August 2022 (input received from EFPIA, Medicines for Europe and Vaccines Europe)
- Meeting on 6 October 2022 to discuss the draft table of contents (to be agreed as a working document in 2022)
- Drafting of reflection paper will start in 2023
- EMA and public consultations in 2024
- Possible basis for further actions and guidance

Content

Reflection Paper on

Digital Support to Risk Minimisation Measures and

Their Effectiveness Evaluation



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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
- Paediatrics
- Geriatrics (draft available – postponed)

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

Focus

Points raised by industry stakeholders?

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Thank you

and thanks to PRAC and EMA colleagues and other stakeholders

Further information

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