EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Good Pharmacovigilance Practices (EU-GVP)

General update & GVP Module XVI Revision 3 with new Addenda II and III

Pharmacovigilance Platform Meeting
17 November 2021

Presented by Priya Bahri

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

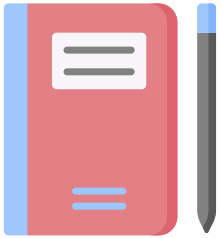
- Public consultation of Module XVI rev 3 and new Addendum II in 2021
- Comments review and finalisation ongoing
- Comments on Module: 697 comments from 27 stakeholder organisations
- Comments on Addendum II: 73 comments (about 2/3 accepted)
- Publication of final Module XVI rev 3 and Addendum II planned for Q2 2022, depending on COVID-19 prioritised work
- Multi-stakeholder group to discuss digital support to aRMM planned to be kicked off in 2022 – nominations from EU industry organisations welcome

Guides

Checklists

NEW Risk awareness forms

NEW Demonstration kits



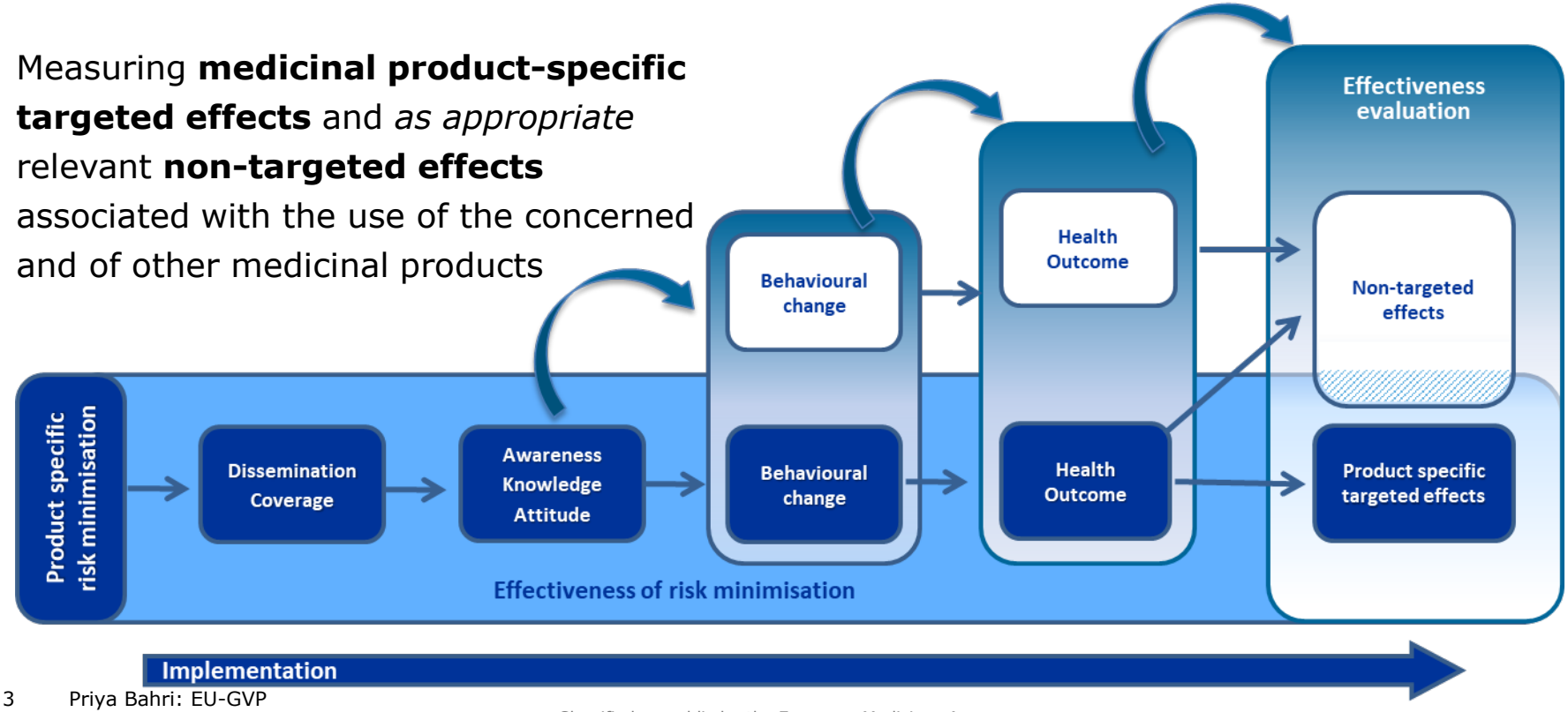
NEW Patient diaries for risk minimisation

Patient cards

Credits for icons: flaticon.com

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: Objectives of effectiveness evaluation

Investigate to what extent the RMM has:

- been disseminated to the target audiences as planned
- led to the intended knowledge and behavioural changes in the target audiences, or whether other behaviour-related outcomes have occurred
- met its objectives in terms of improved patient and population health within relevant timeframes, or whether other health outcomes have occurred

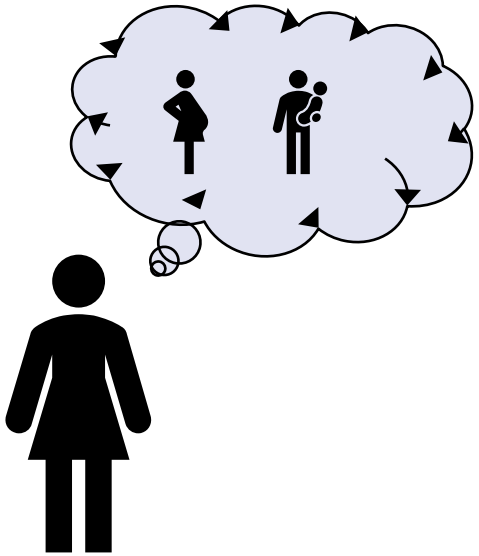
→ Requires different approaches and combination of research methods at each step of the implementation process :

- Qualitative methods
- Surveys methods
- Non-interventional methods
- Randomised trials

GVP Module XVI Addendum III on pregnancy-specific RMM

- New Module XVI Addendum III public consultation planned for 8 or 10 weeks (at least until 28 February 2022)
- Publication of final Module XVI Addendum III planned for Q4 2022, depending on COVID-19 prioritised work

GVP Module XVI Addendum III on pregnancy-specific RMM



Scope:

- pregnancy prevention programme (PPP) means a complete set of defined RMM (i.e. no “full or half” PPP)
- description of PPP
- pregnancy-specific RMM

Criteria:

Strength of evidence of teratogenic risk determines PPP or pregnancy-specific RMM

Visual guidance

EUROPEAN MEDICINES AGENCY

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, public consultation in 2020)
- Paediatrics
- Geriatrics (explanatory note)

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 in 2022 from EMA perspective

- Module XVI rev 3 and Addenda
- Annex IV rev 5 to implement the applicable new CT Regulation
- Chapter III
- Multi-stakeholder group to discuss digital support to aRMM
- GVP Explanatory note on pharmacovigilance for use of medicines in geriatric patients, depending on COVID-19 prioritised work
- GVP Modules I - IV to support robust MAHs' pharmacovigilance systems in global environments and updates to other Modules/Chapters pending the scope of legal revisions and depending on COVID-19 prioritised work

Thank you

Acknowledgements: Núria Semis-Costa and Thomas Goedecke

Further information

Priya Bahri, Ph.D.
Principal Scientific Officer
Pharmacovigilance Office
priya.bahri@ema.europa.eu
Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands
Telephone +31 (0)88 781 6000
Send us a question Go to www.ema.europa.eu/contact

Follow us on **@EMA_News**