

# *Risk minimisation communication in non-EU countries*

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# DISCLAIMER

I am an employee of Bionika Pharmaceuticals.

I have about 25 years regulatory affairs & pharmacovigilance practice.

Previously, I spent 5 years in chemical business.

This presentation represents my personal view and is not necessarily the position of Bionika Pharmaceuticals.




# Risk Communication

- ▶ Is central to risk management strategy of pharmaceutical company
- Communicating safety information to patients and healthcare professionals is a public health & ethical responsibility
- Essential for achieving the objectives of pharmacovigilance in terms of promoting the rational, safe and effective use of medicines
- Preventing harm from adverse reactions, minimising risks and contributing to the protection of patients and public health
- ▶ It's time to enhance PV methods and focus on solution finding, not just problem identification
- ▶ Warning patients is important, but solving drug toxicity problems is even better



# EU - Regulation

- [Guideline on good pharmacovigilance practices \(GVP\) - Module XV – Safety communication \(Rev 1\) \(europa.eu\)](#) (Adopted 13/10/2017)
  - [Guideline on good pharmacovigilance practices \(GVP\) - Module XVI – Risk minimisation measures \(Rev 3\) \(Europa eu\)](#) (Adopted 06/08/2024)
  - [Guideline-good-pharmacovigilance-practices-gvp-module-xvi-addendum-i-risk-minimisation-measures-medicinal-products-embryo-fetal-risks\\_en.pdf](#) (Adopted 22/08/2025)
  - [Guideline on good pharmacovigilance practices \(GVP\) Module XVI Addendum I – Educational materials \(europa.eu\)](#) (Adopted 15/12/2015)
  - [Guideline on good pharmacovigilance practices \(GVP\) - Annex II – Templates: Direct Healthcare Professional Communication \(DHPC\) \(Rev 1\) \(europa.eu\)](#) (Adopted 13/10/2017)
  - [Guideline on good pharmacovigilance practices \(GVP\) - Annex II – Templates: Communication Plan for Direct Healthcare Professional Communication \(CP DHPC\) \(europa.eu\)](#) (Adopted 13/10/2017)
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# Risk Minimisation Communication

- ▶ Raise awareness about the potential risk with relevant HCPs in order that the risk is managed appropriately.
  - ▶ Enhance awareness of patients/caregivers on careful monitoring, early detection and steps to be taken.
  - ▶ Must be effective:
    - Should have clearly defined intended outcomes
    - defined implementation pathway and should fit into already existing treatment framework for other medications, where relevant.
  - ▶ Must NOT be burdensome to HCPs or patients:
    - and therefore should fit into local standard practice and healthcare systems.
  - ▶ Must be proportionate to the risk
  - ▶ Appropriate interactions between stakeholders (HA, HCP and patient representatives)
  - ▶ Without promotional nature or elements
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