



Revised GVP module XVI

Some initial reflections from community pharmacists

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HCPWP topic group on Additional Risk Minimisation Measures

HCPWP topic group (2015-2017) published several [recommendations](#) to EMA and PRAC to for consideration to improve the implementation and adherence to Risk Minimisation Measures (RMMs).

1. Involve HCPs **earlier on in the development** process of additional & routine risk minimisation measures
2. Guides / checklists should cover **all HCPs involved** in medication use
3. Information provided to patients could be **better balanced / articulated** e.g. include side effect frequencies, info on risk of other medicines in same class / alternatives
5. Consider making information available on the **outside of the package** and in the SmPC, as a summary / prompt / removable card to facilitate dialogue with patients
6. **Target communications** with appropriate tool(s) and to appropriate audience(s), using mixed media channels
7. Consider also the use of **scientific publications / communications / events** for dissemination

TG on RMMs - Additional considerations

- Incorporation of RMMs into **Institutional protocols / guidelines**;
- Incorporation of RMMs into the **education** of HCPs' (i.e. Continuing Education and Continuous Professional Development);
- Widening access to **shared eHealth records** (with indications / diagnoses / reported adverse drug reactions or side effects);
- Encourage **multi-professional collaboration** & shared responsibilities.

Additionally, reflection on **dissemination practices** concerning RMMs for European level stakeholder / representative bodies could also be considered.

GVP XVI – Initial reflections

- Revised GVP module XVI takes on board the key recommendations made by the HCPWP Topic Group on RMM.
- Useful to clarify terminology and remove duplication (i.e. patient cards vs. alert cards)
- Targeted dissemination and pragmatic integration in healthcare practice remain key attention points for ensuring sufficient uptake
- National/regional differences in organisation & delivery of healthcare services require a tailored approach for implementing RMM (e.g. differences in level of digitalisation/infrastructure)
- Need for further integration of RMM into education of HCPs and point-of-care electronic tools/systems



THANK YOU!



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