



Risk Minimisation Communication in Non-EU Countries

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Abstract: Communicating risk and safety information to patients and healthcare professionals is a public health and our ethical responsibility. Risk communication is central to risk management strategy of pharmaceutical companies. This way will be achieved the objectives of pharmacovigilance in terms of promoting the rational, safe and effective use of medicinal products. It is imperative in the pharmaceutical sector and industry, preventing occurrence and harm of adverse drug and medical reactions, minimising risks, which leads to protection of the patients and public health. In this article we will elaborate the risk and risk minimisation communication. Countries of interest are North Macedonia, Serbia, Bosnia and Herzegovina, Montenegro, Albania and Kosovo, making comparison with the European Union (EU). Risk minimisation communication should enhance awareness of patients/caregivers on careful monitoring, early detection and steps to be taken in order to achieve the safe use of medicinal products. The objectives of ensuring the safe use of the medicinal product and minimising risks, including their adverse health outcomes are facilitated by risk minimisation measures (RMMs). We will give an indepth look at regulation compliance from the markets of interest within country-specific environments.

Keywords: risk minimisation communication, pharmacovigilance, safety, non-EU countries

INTRODUCTION

Marketing authorisation for a medicinal product in the EU may be granted subject to taking certain measures for ensuring its safe use to be included in the risk management system (1, 2). These measures support keeping the risk-benefit balance of a medicinal product positive (3). Risk management system is a set of pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to a medicinal product, including the assessment of the effectiveness (1). It is described in the risk management plan (RMP). Objectives of ensuring the safe use of the medicinal product and minimising risks, including their adverse health outcomes are facilitated by RMMs (4). Risk communication is a key element in pharmacovigilance and it is two-way process. In EU is regulated with the Guideline on good pharmacovigilance practices (GVP) - Module XV - Safety communication (Rev 1) (europa.eu) (5); Guideline on good pharmacovigilance practices (GVP) - Module XVI - Risk minimisation measures (Rev 3) (Europa eu) (4); Guideline on good pharmacovigilance practices (GVP) Module XVI Addendum I - Educational materials (europa.eu) (6); Guideline on good pharmacovigilance practices (GVP) - Annex II - Templates: Direct Healthcare Professional Communication (DHPC) (Rev 1) (europa.eu) (7); Guideline on good pharmacovigilance practices (GVP) - Annex II - Templates: Communication Plan for Direct Healthcare Professional Communication (CP DHPC)

(europa.eu) (8), Guideline-good-pharmacovigilance-practices-gvp-module-xvi-addendum-i-risk-minimisation-measures-medicinal-products-embryo-fetal-risks_en.pdf (9).

METHODOLOGY

Analytical and comparative methodology are used. In this paper is analyzed the regulation on risk and risk minimisation communication of medicinal products in EU and countries of interest.

DISCUSSION

Risk minimisation communication should raise awareness about the potential risk with relevant healthcare professionals (HCPs) in order that the risk is managed appropriately. It should enhance awareness of patients/caregivers on careful monitoring, early detection and steps to be taken. Must be effective, with 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. It must be proportionate to the risk and without promotional nature or elements.

Countries of Interest

Countries of interest are: North Macedonia Serbia, Montenegro, Bosnia and Herzegovina, Albania and Kosovo. All countries follow the EU regulation for medicinal products, including pharmacovigilance.

GVP Module XVI

Risk Minimisation Measures

Provides details of the measures which will be taken to reduce the risks associated with respective safety concerns. For individual products with substantially different indications or target populations a risk minimization plan specific to each product should be made. There is need for review of risk minimisation at regular intervals.

Routine Risk Minimisation Measures:

- Summary of Product Characteristics (SmPC)
- Product information Leaflet (PIL)
- Pack size (controlling the number of dosage units);

Limited Validity/Size of Prescription

- Legal status of medicine (defined in Annex II.B as conditions or restrictions for supply or use of medicinal product)

- Restricted medical prescription (e.g. administration in hospital only)
- Special medical prescription (e.g. for narcotic or psychotropic substances; potential for addiction, abuse or use for illegal purposes)

Additional Risk Minimisation Measures:**Health Care Professional Educational Programme**

- Dear Health Care Professional Letter (DHPC)
- Physician's guide to prescribing
- Pharmacist's guide to dispensing
- Algorithm/checklist before prescribing/dispensing
- Specific training programme

Patient Educational Programme

- Patient Alert Card
- Patient Reminder Card
- Patient Information Brochure/Booklet
- Patient Diary

Controlled Access Programme

- Other (e.g. pregnancy prevention programme)

Risk Minimization Control Tools

- Healthcare professional qualification
- Healthcare facility accreditation
- Traceability of distribution system
- System for documented exchange of patient information
- Check of patient certificates of medical interventions

North Macedonia, Serbia, Montenegro, Bosnia and Herzegovina, Kosovo, Albania

EU approved RMPs (english), RMMs and DHPCs translations into local language are submitted to the Agencies for their approval and implementation in each country.

All local PV guidelines are published on the national competent authority's webpages. In all countries except Bosnia and Herzegovina submission is through the archive.

In Bosnia and Herzegovina submission is electronically. RMMs dissemination should be done within 14 days before start of the medicinal product distribution for the new marketing authorisations; within 30 days for the already marketed medicinal products.

In *Montenegro educational materials approved by Serbian agency ALIMs (on Serbian language) or Croatian agency HALMED (on Croatian language) may be distributed without approval, with added local contact details of the marketing authorisation holders.

Dissemination can be done either of the 3 ways: via e-mail, by post or in person.

It is also published on the agency's webpage and also on the webpage of the marketing authorisation holders.

In Montenegro there is display of a letter to healthcare professionals received within the information system of primary health care - CInMED (Montenegrin agency). Direct messaging is available from 2015.

CONCLUSION

Risk and risk minimisation communication is well defined by GVP Guidelines and is similar in EU and non-EU countries, although there is no possibility for mutual recognition. Proactive changes in pharmacovigilance (PV) regulation and solution finding will improve risk minimisation communication. It is not enough just problem identification. Warning patients is important, but drug toxicity problems should be solved by RMMs at the earliest time. Safety communication should reach the right audiences at the right time in order to be effective. Assessment of effectiveness of the communication should be evaluated via surveys, registries, medical records, spontaneous reporting systems, post-authorisation safety studies etc. and shared with the national competent authorities.

Aligning PV regulation across different countries can be beneficial to streamline PV activities and meet local needs/*Montenegro. We can observe that regional aspects are moving towards global aspects, which way harmonization can be achieved.

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