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Risk communication in non-EU countries

Abstract

Communicating safety information to patients and healthcare professionals is a public health responsibility and is 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. The main emphasis of this article is on direct healthcare professional communication (DHPC). Countries of interest are Macedonia, Serbia, Bosnia & Herzegovina, Montenegro, Albania and Kosovo. Safety communication should deliver relevant, clear, accurate and consistent messages and reach the right audiences at the right time for them to take appropriate action. Readers will get an indepth look at regulation compliance from the emerging markets within country-specific environments.

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

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Introduction

Medicinal products are characterized by its efficacy, quality and safety. No one medicinal product can be 100 % safe. Communication is a key element in pharmacovigilance. Risk communication is a two-way process and is very important. Communicating safety information to patients and healthcare professionals (HCPs) is a public health responsibility and is 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.[1-5]

Countries of interest

These are the countries where the company Bionika Pharmaceuticals is most active, mainly in the neighbouring countries: Serbia, Montenegro, Bosnia & Herzegovina, Albania and Kosovo. Bionika Pharmaceuticals is manufacturing medicinal products, medical devices, food supplements & medical cosmetics and is located in North Macedonia, in the Balkan Peninsula, Southeast Europe. All countries follow the EU regulation for medicinal products.

Discussion

GVP Module XV

a) Safety communication should deliver relevant, clear, accurate and consistent messages and reach the right audiences at the right time for them to take appropriate action;

b) Communication should be tailored to the audience and address uncertainties related to a safety concern;

c) The most appropriate quantitative measures concerning communication should be used;

d) HCPs and patients should be consulted

e) Effectiveness of the communication should be evaluated

f) Must comply with data protection and confidentiality

DHPC - when it should be created

a) Suspension, withdrawal or revocation of marketing authorization for safety reasons;

b) An important change to the use of a medicine (restriction of an indication, new contraindication, change in the recommended dose due to safety reasons);

c) Restriction in availability or discontinuation of a medicine with potential detrimental effects on patient care;

d) New major warnings or precautions for use in the product information;

e) New data identifying a previously unknown risk or a change in the frequency or severity of a known risk;

f) New evidence that the medicinal product is not as effective as previously considered;

g) New recommendations for preventing or treating adverse reactions or to avoid misuse or medication errors with the medicinal product;

h) Ongoing assessment of an important potential risk (insufficient data)

DHPC - Template

In the communication the following parts should be included:

a) Active substance, name of the medicinal product and main message (e.g. introduction of a warning or a contraindication)

b) Background on a safety concern

c) Call for reporting

d) Company contact point

e) Annexes (if applicable additional scientific information, list of literature references)

DHPC is an additional risk minimization measure as part of Risk Management Plan.

Single consistent message should be sent to HCPs in each national competent authority (NCA), which should be approved by PRAC/CHMP or NCA before.

This is usually done by the originator or as agreed with other marketing authorization holders (MAHs).

Dissemination should be decided on a national level (timetable).

If submission of safety variation is needed it should be approved before.

DHPC Letter should be signed by all local Qualified Persons for Pharmacovigilance.

Recipient list should be agreed with the NCA and shared between MAHs (communication plan).

NCA publishes DHPC on their webpage.

It should be without promotional message.

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

In North Macedonia, Montenegro and Kosovo submission is through the archive.

In Serbia and Bosnia & Herzegovina submission is electronically.

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

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

In Albania this procedure is not applicable. In case of need the NCA – AKBPM publishes the risk communication on their webpage.

Conclusion

Risk communication and DHPC processing is well defined by GVP Guidelines and is similar in EU and non-EU countries, although there is no possibility for mutual recognition like in EU. HCPs are used to this practice. For success good cooperation should be achieved between MAHs and NCAs. Joint activity of all MAHs is required and they can share their PV experience and knowledge. All MAHs should deliver single message. Safety communication should deliver relevant, clear, accurate and consistent messages and reach the right audiences at the right time for them to take appropriate action. Effectiveness of the communication should be evaluated and shared with the NCAs.

Maybe we should consider also creation of the Dear Patient Letter in the near future.

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Conflicts of interest

Author declares that there is no conflict of interest.

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