



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Management of safety data from Patient Support Programmes (PSPs) and Market research Programmes (MRPs)

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EU guidance on management of safety data

Good Vigilance Practices (GVP)-Module VI addresses legal requirements applicable to stakeholders regarding the collection, data management and reporting of suspected adverse reactions associated with medicinal products for human use authorised in the European Union (EU).

This module also contains requirements applicable to Marketing Authorisation Holders (MAHs) for the management and reporting of safety data arising in PSPs and MRPs, when made aware of them.

- Serious, non-serious cases of suspected adverse reactions originating in those programmes should be reported by MAHs as solicited reports.



EU guidance on management of safety data

Since release of GVP-Module VI, pharmaceutical industries raised concerns about the difficulty of implementation of requirements on management of safety data originating from PSPs and MRPs.

They have suggested simplifying and harmonising the reporting to competent authorities in the EU and to the USA.



Patient Support Programmes (PSPs)

Service that involves direct interaction with patients and/or patient carers for the purpose of

- Helping to manage a patient's medication and/or disease outcomes (e.g., adherence, awareness, education), or
- Providing or arranging financial assistance for patients who cannot afford their medication. (e.g. reimbursement support, product discount), or
- Providing healthcare professionals with support for their patients



Patient Support Programmes (PSPs)

The intention of these programmes is to support patient care

May be conducted by MAH or by third party on behalf of MAH.

Common examples include:

- i. Compliance programmes where consenting patients on a medication are contacted to see how they are managing with their medication.
- ii. Call centres where patients or patient carers can contact the MAH to obtain further information on medication or particular disease area as part of a structured programme.



Patient Support Programmes (PSPs)

- iii. “Nurse Educator” programmes where nurse working for MAH (company employees or third party) interact directly with patients to help them properly administer medications and/or manage their disease.
- iv. Call centres where patients can obtain assistance with health insurance questions and reimbursement support as part of a structured programme.
- v. Programmes which offer pure financial support, including insurance coverage, educational grants, scholarships and medical reimbursement assistance.



Patient Support Programmes (PSPs)

In the frame of those programmes MAH may collect information relating to the use of its medicinal products.

Patients/carers may reports events which occurred concomitantly to the use of medicinal product and which could be suspected adverse reactions.



Market Research Programmes (MRPs)

Systematic collection, recording and analysis of data and findings concerning medicinal products, relevant for marketing and business development.

- Often conducted by third party on behalf of MAH;
- Face to face, telephone, online, mail;
- Fully structured questionnaires – closed questions;
- Semi-structured – mix of open & closed questions;
- Not structured – all open questions (qualitative).
- When responding to questions, possibility for patients or HCPs to report adverse events which could be suspected adverse reactions.



Workshop on management of safety data from PSPs and MRPs

Workshop 7 June 2013 objectives:

- Bring together stakeholders responsible for the protection of public health and the conduct of PSPs and MRPs with the following objectives:
- Understand the spectrum of programmes that fall under the terms of PSPs and MRPs and the type of safety information which is collected in those programmes.
- Assess the optimum way of collecting safety data from PSPs and MRPs while ensuring compliance with EU legal obligations and ICH guidelines on management of ADRs.



Workshop on management of safety data from PSPs and MRPs

Invited stakeholders:

- EU Competent authorities (members of PRAC and Project Team Implementation of Pharmacovigilance legislation),
- EU PhV. Inspection Working Group,
- FDA (via teleconference), International liaison officers at EMA from Canada and Japan,
- Patients and Healthcare Professionals associations,
- Pharmaceutical industry associations,
- Market research organisations associations.



Workshop on management of safety data from PSPs and MRPs

Contribution from patients and HCPs to workshop:

- What experiences patients and HCPs have in participating in PSPs and MRPs?
- What information is exchanged between Patients (or HCP) participating in those programmes and MAHs?
- If adverse reactions are reported to MAHs in the context of PSPs or MRPs, do you know what MAHs are doing with this information?



Workshop on management of safety data from PSPs and MRPs

Contribution from patients and HCPs to workshop:

- What is view/opinion of patients and HCPs representatives on this type of programmes?
- Should this type of programmes run by MAHs be better defined and controlled?



Thank you

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