Patient Support Programmes

What every PIPA member needs to know!
Agenda

• Introductions
• What is a PSP?
• Role of PV & MI in PSPs
• Risks in PSPs
• Common inspection findings on PSPs
• Personal Action Plan
• Wrap up
Introductions

- Name
- Company
- Role and scope
- Experience of PSPs
- What you want to achieve from this workshop
WHAT IS A PSP?
What is a PSP

• ABPI Guidance Notes May 2011
  – A service for direct patient or patient carer interaction/engagement designed to help management of medication and/or disease outcomes (e.g. adherence, awareness and education), or to provide HCPs with support for their patients

• GVP Module VI (Rev1) Sept 2014
  – An organised system where a marketing authorisation holder receives and collects information relating to the use of its medicinal products. Examples are post-authorisation patient support and disease management programmes, surveys of patients and healthcare providers, information gathering on patient compliance, or compensation/re-imbursement schemes
What about these?

- Nurse injects patient at home
- Financial support to doctor to run educational lecture for patients
- Home delivery of medicine
- Pregnancy prevention programme for teratogenic drug
- Outsourced Medical Information service
- Outgoing calls to patient carer to provide support and advice
- Text reminder to patient to attend clinic for next dose
- Voucher to contribute towards cost of drug
- Patient help line
- Information pack for patients on their disease
- Website where patients can share experiences and download information
- Focus group to discuss barriers to prescribing
Split the cards

• Discuss why you think they fall under the definition or not
Is it important to know if a programme is a PSP?

• Points to consider
  – Safety data exchange requirements
  – Vendor Contracts
  – Training
  – Reconciliation
  – Oversight (repository, audit, sample checks)
  – Anything else?
Safety Collection in PSPs

• GVP Module VI (R1) VI.C.2.2.11. Reports from patient support programmes and market research programmes
  – Safety reports originating from those programmes should be considered as solicited reports
  – Marketing authorisation holders should have the same mechanisms in place as for all other solicited reports (see VI.C.2.2.2.)
Safety Collection in PSPs (VI.C.2.2.2)

• For all solicited reports MAHs should have mechanisms in place to record and document complete and comprehensive case information and to evaluate that information, in order to allow meaningful assessment and reporting of valid ICSRs.

• MAHs should therefore exercise due diligence in following-up those reports and in seeking the view of the primary source as regard the causal role of the studied (or supplied) medicinal product on the notified adverse event.

• Where this opinion is missing, the MAH should exercise its own judgement based on the information available in order to decide whether the report is a valid ICSR, which should be reported to the competent authorities.
GVP VI in summary

- Solicited reports
- Collect all AEs
- Seek a causality assessment from reporter
- If missing, MAH to provide own causality assessment
- All valid ADRs should be reported
Secondary Data

• Secondary use of data previously collected from consumers or healthcare professionals for other purposes.
  – Examples include medical chart reviews (including following-up on data with healthcare professionals), analysis of electronic healthcare records, systematic reviews, meta-analyses.

• For these studies, the reporting of suspected adverse reactions in the form of ICSRs is not required.

• Reports of adverse events/reactions should be summarised as part of any interim safety analysis and in the final study report unless the protocol provides for different reporting.
Efpiia Proposal submitted to EMA

- All adverse event reports to be collected and forwarded to the MAH throughout the duration of all PSPs
- Cases from PSPs will be classified as solicited
- Only serious AE reports from PSPs should have a causality assessment by the MAH and serious suspected adverse reactions to be reported to the regulatory authorities within 15 calendar days
Efpiain Proposal submitted to EMA

- Non-serious AE case reports
  - Should not require formal causality assessment (i.e. can be regarded as having presumed causality)
  - Should be only included in routine surveillance processes until first renewal of the product
  - Should not require data entry into the company safety database, follow up or reporting on an expedited basis as ICSRs to the regulatory authorities.
  - Abbreviated data entry (patient details, reporter details, the drug and the event) can be used if entering these cases on the safety database.
  - After the first renewal of the product, there should be no requirement to include non-serious case reports from PSPs in routine surveillance processes.
THE ROLE OF PV AND MI IN PSPS
A new programme

- Who decides a programme is needed?
- Who owns it?
- What governance is there?
- When do you find out?
- What is your role?
Typical Responsibilities

**PV**
- Safety language in contract
- AE Reporting processes
- Training of vendors (AE reporting)
- Reconciliation processes
- Ensure entry in to company repository

**MI**
- Process for enquiry routing and handling
- Training of vendors (product / disease info)
- Standard responses relevant to programme
- Copy approval of materials
## Typical Process Flow

<table>
<thead>
<tr>
<th>Programme is needed</th>
<th>Design and develop programme</th>
<th>Work with vendor to set up programme</th>
<th>Programme operates</th>
<th>Programme closes</th>
</tr>
</thead>
</table>
| Commercial inform MI team | PV and MI teams involved in discussions on programme design and set up | Training of vendor
Agree AE reporting processes
Agree enquiry handling processes
Programme recorded on MAH repository | Ongoing AE Reporting
Ongoing reconciliation
Ongoing enquiries
Perform spot check monitoring
Perform audit of vendor / programme | Final reconciliation
Marked closed on MAH repository |
Recap Part I

- A patient support programme is designed to help patients and usually involves support given directly or through HCPs.
- May result in AE reports which are always considered solicited.
- Vendors must have a contract and training.
- MAH must have processes to collect all AEs and perform causality assessments.
- Commercial function owns the programme but must involve PV & MI at an early stage and throughout.
- MAH must monitor and / or audit programme throughout (risk-based).
A RISK BASED APPROACH
A risk based approach to...

• Ongoing monitoring
  – Visits
  – Sample checks
• Audit
• Additional training
• Anything else?
What are the risks?

- Some programme elements pose a higher ‘risk’ for AE reporting than others
- Determining the programme elements is essential in risk assessment
- Risk assessments needs to be repeated if elements change
Risk Assessment exercise
COMMON INSPECTION FINDINGS
Example Inspection Findings

• Failure to collect, collate and expedite ADRs from PSPs
• Lack of awareness of PV team and / or QPPV of PSPs (including programmes run by business partners)
• Lack of, or inadequate agreements with vendors
  – Collect all AEs
  – Special situation reports
• Failure to provide training to vendors
• Lack of reconciliation activities
• Lack of audit or other monitoring
How to prevent or mitigate such findings?

• Consider
  – Why they happen
  – Who knows about it
  – What should have been done
  – When should it be done
  – How should it be documented
PERSONAL ACTION PLAN
Personal Action Plan

- What will you do?
- When will you do it by?
- Who do you need to consult?
- Who do you need to inform?
- How will you keep track

- Share your action plan with at least one other person on your table
WRAP UP
Summary of key learnings

• What is a PSP
  – What else might it be
  – why it is important to know
• Role of PV & MI in PSPs
  – Set up, ongoing and end
• Risks in PSPs
  – Assessing risks and applying efforts proportionately
• Common inspection findings on PSPs
  – How to mitigate against them
• Personal Action Plan
  – What steps you will take to be better prepared
Have we met your expectations?

Any other questions?