Workshop on
Patient Support and Market Research Programmes

Spectrum of programmes falling under the terms of PSP and MRPs and the and the type of safety data collected

Pharmaceutical Industry Associations

Objectives

- Common understanding of the variety and diversity of Patient Support Programmes and Market Research Programmes

- Promote an understanding of the types of “safety data” generated

Agenda

- GVP Module VI Definitions
- Patient Support Programmes (PSP)
  - Common types of PSPs
  - Examples of various designs
  - Safety data generated
- Market Research Programmes (MRP)
  - Primary and secondary research
  - Quantitative and qualitative research
  - Safety data generated

Points to Note

- PSPs and MRPs are not formal studies driven by a structured protocol
- May not be product specific
- PSPs and MRPs involve direct interaction with patients and/or carers or healthcare professionals; their purpose is not to generate safety or efficacy information
- Purpose of PSPs is to support patient care which is typically done by supplementing and reinforcing care and guidance provided by the patient's HCP or by providing or arranging financial assistance for patients (e.g. reimbursement support, product discount)
- These PSPs are generally not designed to be organised data collection schemes

Current Definitions

GVP Module VI.B.1.2. Solicited Reports

- As defined in ICH-E2D guideline, solicited reports of suspected adverse reactions are those derived from organised data collection systems, which include clinical trials, non-interventional studies, registries, post-approval named patient use programmes, other **patient support and disease management programmes, surveys of patients or healthcare providers,** compassionate use or name patient use, or information gathering on efficacy or patient compliance. Adverse reactions reports obtained from any of these data collection systems should not be considered spontaneous**.** This is with the exception of suspected adverse reactions originating from certain compassionate use or named patient use where adverse events are not actively sought.
- For the purpose of safety reporting, solicited reports should be classified as study reports, and should have an appropriate causality assessment, to consider whether they refer to suspected adverse reactions and therefore meet the criteria for reporting.

GVP Annex 1 Solicited Sources of ICSRs

- Appropriate causality assessment by a healthcare professional or the marketing authorisation holder

Current Definitions

GVP Module VI.C.2.2.11. Reports from patient support programmes and market research programmes

- A patient support programme is 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.

- A market research programme refers to the systematic collection, recording and analysis by a marketing authorisation holder of data and findings about its medicinal products, relevant for marketing and business development.

Patient Support Programmes

Majority of patient support programmes (PSP) fall into one of three categories with the following objectives:

- To support patients and help them take their medications as prescribed (compliance/adherence)
- To help patients understand their condition and provide advice on managing disease e.g. lifestyle (exercise or diet), disease education
- To provide a service or financial assistance or reimbursement support for patients also known as patient assistance programs)

Reports of adverse events are usually obtained incidentally to the main purpose of the programme

- Not designed to "actively solicit" adverse event reports
- General questions related to the well-being of patients may stimulate the reporting of safety information
- Patients may also voluntarily mention an adverse event on their own initiative during the course of the interaction or at another time through other means (e.g. dedicated PSP phone line/email or general company contact number/email)

PSP – compliance /adherence

- Programmes are designed to use multiple methods of interaction and multiple media to assist in improving compliance
- Factors which may contribute to non-adherence include:
  - Forgetfulness
  - Confusion due to a complex treatment regimen
  - Struggle with self administration
  - Cost
  - Side effects
  - No perceived benefit

- Some of these factors lead to intentional non-adherence and others to unintentional non-adherence.
- Combinations of interactions with the patient may be used in a single programme
- Each contact has the potential for generating adverse event information

PSP – compliance/adherence

- Interactions to minimise unintentional non-adherence may include:
  - Patient education
  - Assistance administering the medication (homecare programmes)
  - Reminders via SMS text messaging or iphone apps

- New generation of PSPs aimed at minimising intentional non-adherence using health psychology to affect behavioural change through understanding the patients' attitudes and beliefs and typically involve:
  - Education and counselling where a nurse talks to a patient about their illness and treatment as opposed to providing material in print (although this may be done in addition)

- Interaction type impacts the likelihood of adverse event reporting

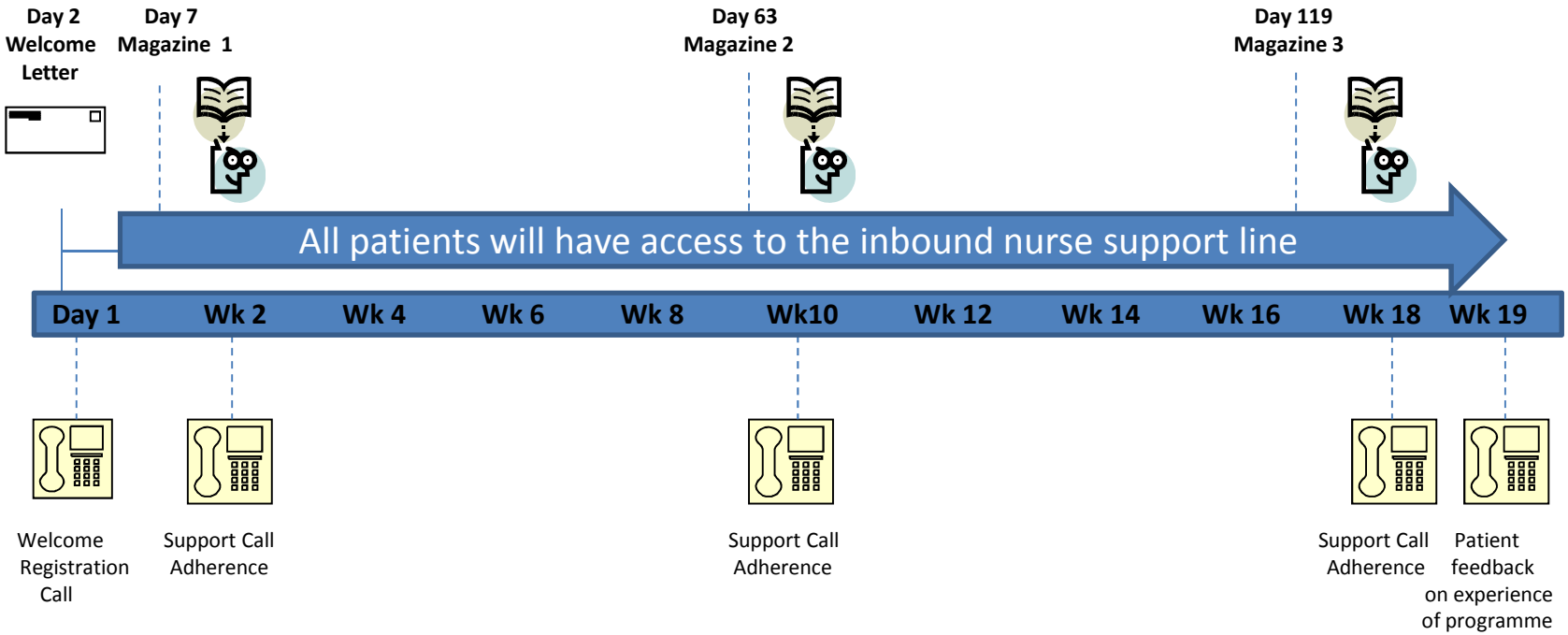
PSPs – Disease Management

- Not product specific; patients can be on different medications
- Patient education to increase disease awareness and improve disease management
- Typically conducted through groups sessions using educational material
- Aim to improve individual quality of life through education, e.g
  - Diabetes disease management programmes typically provide education on the role of diet and exercise, self monitoring of blood sugar, taking medication, reducing risks of complications from diabetes etc.
- Adverse Events may be mentioned voluntarily during the course of the interactions

Examples of PSPs

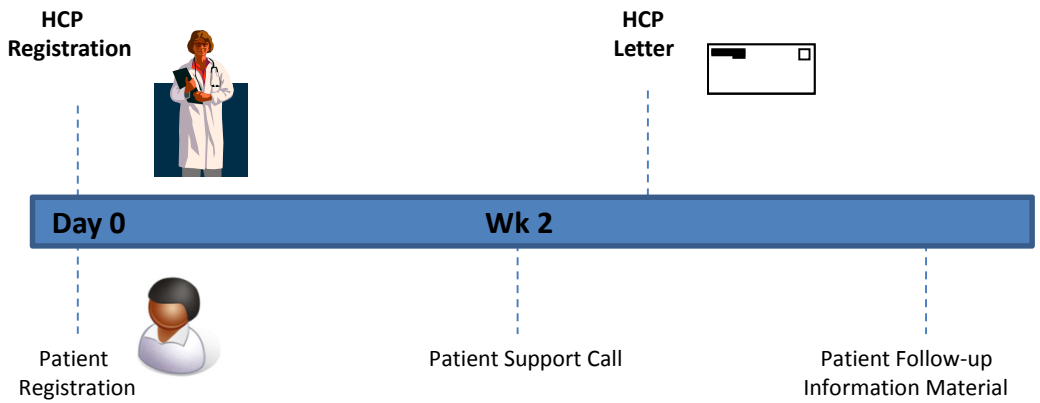
- A wide variety of PSPs use multiple methods of interaction and media; “ no one size fits all”
- Each PSP takes into account not only the illness or medication but also the characteristics of the patient involved
- Digital media is used increasingly which fits better with patient lifestyles (i.e. iphone apps or SMS text messages, social media etc).

Examples of PSPs – compliance/adherence



- Inbound nurse support line for advice
- Frequent outbound support calls conducted by trained nurses who follow a call guide providing educational support and counselling
- The patient is not asked directly about side effects but the following types of questions may stimulate adverse event reporting:
  - "Are you still taking your tablets?"
  - "Do you have concerns about taking your medication?"

Examples of PSPs – compliance/adherence



- HCP and patient involvement
- Screening questionnaire on enrolment may determine content of support call delivered by the Nurse Specialist. The programme can be personalised to the individual patient. Tailored questions which may stimulate AE reporting may include:
  - "I noticed that you said you are not completely comfortable taking your medication, can you tell me a little bit more about why that is?"
  - "What have you read in the patient information leaflet that makes you feel uncomfortable about taking it?"
  - "What goes through your head when you think about your health"?
  - HCP letter includes a summary of issues discussed with patient and encourages HCP to continue open dialogue with patient about their illness, medication and adherence

Examples of PSPs – compliance

Wk1	Wk2	WK3	WK4	Wk8	Wk12	Wk25	WK26	WK50	WK52
1st Nurse Visit	2nd Nurse Visit	Self – Injection	Self – Injection Pharmacist Call & Early Patient Assessment	Self – Injection Pharmacist Call – Subject to patient need	Hospital Clinical Visit	3rd Nurse Visit	Hospital Clinical Visit	4th Nurse Visit	Hospital Clinical Visit
Supported 24 x 7 Help Line									
All patients receive drug delivery on a 4 weekly basis until WK 12 – then moves to 4,8,12 weekly deliveries dependent on patient / clinician choice.									
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- Drug delivery service
- Week 1 & 2 – home visit by nurse for SC injection technique support
- Week 4 & 8 – pharmacist calls patient to confirm if still on treatment and rationale for stopping if applicable
- Week 25 & 50 – nurse home visit to assess injection technique, provide advice
- When a PSP involves home visits by a nurse to provide assistance administering medication, the nurse may also observe a suspected adverse drug reaction, e.g. inflammation around the injection site which would need to be reported. Calls into question whether all events observed even if considered not related to treatment should be reported (e.g. a cold/cough that other family members are also experiencing)

Other Examples of PSPs

Apps

- Increase in use of Apps to:
  - Provide reminders to patients to take medication
  - Encourage patients to self monitor
    - Log blood pressure
    - Log glucose measurements
- To make an App available for download on iTunes, the company has to provide an email address for technical issues.

SMS Text

- Used commonly as part of a PSPs to remind patients to take their medication
- Patients can opt-out of this service by texting “STOP” to the number shown on the text . There is no limit to additional wording added to the text and these STOP texts.

These mechanisms should not be used to report adverse events but could be and companies now need to put processes in place so that these types of emails and texts are reviewed regularly to identify and collect any adverse events mentioned.

PSPs - Types of Safety Data Generated

- Mostly reports from consumers
- Medical confirmation uncertain
  - If nurse not involved in the clinical care of the patients with no access to patient records
  - If nurse has observed an event when assisting with the administration of medication
- Causality assessments may be absent due to:
  - Uncertainty around whether the causality assessment should be provided by the patient or nurse involved in the programme
- Adverse events mentioned in the context of treatment adherence may be non-specific and follow-up with HCPs is often not possible, e.g:
  - ❑ "could not tolerate the drug"
  - ❑ "the drug had no effect"
  - ❑ "I missed a dose"
  - ❑ "my illness has got worse"
- Majority of reports are non-serious and often expected, more inconvenient to the patient rather than medically serious

PSPs – financial assistance

Provide a service or arrange financial assistance for patients medication (also known as patient assistance programmes)

- Call centres offering assistance with health insurance questions
- Call centres operating medical reimbursement assistance

Types of safety data generated

- Patients proactively call for assistance to complete insurance forms for example, and volunteer information on adverse events in response to wellbeing questions
- Outbound calling may occur to establish why a patient has not submitted reimbursement forms or refilled prescriptions. This is when MAH or company may hear that a patient has died and no other information is known

Market Research Programmes

- Primary market research when data is collected by respondents for specific market research purpose

- Secondary market research when a company purchases readily available data off the shelf which is not specifically collected on behalf of the company

Some market research may be a mixture of primary and secondary market research.

Market Research Programmes

Primary and secondary market research can be:

Quantitative:

- A questionnaire is used – effectively this is a script
- Mostly closed pre-coded questions but there may be some open ended questions to get more information and insight into an issue.
- Includes patient case data (this can be provided without patient consent, subject to local laws, as long as the case information is anonymised and non-identifiable)

Qualitative:

- Relies on open questions and probing
- Generally follows an interview using a discussion guide – this is not a script

Market Research Programmes

- Both approaches can be carried out using a variety of media – face to face, telephone, online, through social media with:
  - Healthcare professionals
  - Patients, caregivers and consumers

- Not always product specific and not a commercial communication or selling opportunity

- MRPs cover a wide range of programmes
  - Consumer Health Care study with medicine (lozenges) and flavour- which flavour does the consumer prefer?
  - Focus groups : Consumer focus group on advertising campaign. Discussion in smaller groups to choose the best advertisement
  - Investigate the market: Survey to better understand the relevant market place in preparation for the launch of a new product
  - Investigate the market: With HCPs and patients ascertain market size and investigate willingness to pay for a new product

Market Research Programmes

- Questions on reasons for switching medications or discontinuing treatment providing an insight into therapy decisions is a likely source of adverse event data

- Some closed questions in quantitative market research related to switching or discontinuing medications may actively solicit AEs.

Market Research Programmes

Why did the patient change this previous biologic treatment for the current one?

- Primary efficacy failure *(no initial response)*
- Secondary efficacy failure *(relapse after initial response)*
- Side effects
- Poor compliance
- Other

Types of Safety Data

- Adverse events given in a pre-determined list are almost always expected.
- General terms such as “side effects” may be used.
- High volumes of poorly documented adverse event data with mostly no ability to follow-up.
- Adverse events mentioned following open ended questions mostly include events that are expected, related to underlying disease or are reports of treatment non-compliance and lack of efficacy

Market Research Programmes

Primary Market Research

- Market research has no interest in the individual identity of the respondents.
- Whilst follow-up may be possible, often consent to follow-up is not provided by the respondent
- The respondent's opinion on relationship of the adverse event to treatment is often missing which makes it difficult for the company to assess causality due to the sparseness of the information provided

Secondary Market Research

- No follow-up can be performed
- No reporter or patient details are provided so duplicate checking is difficult
- No causality assessments provided

Points to Consider

- Wide variety of PSPs and MRPs and major differences in how safety information is generated from these programmes:
  - Check box surveys/questionnaires
  - Open ended telephone or personal interviews or discussions
  - Inbound telephone lines
  - Other (SMS texts, via company Med Info line etc)

- When are reports considered medically confirmed?
- Should causality assessment be routinely sought from consumers?
- Do the definitions in GVP Module VI and classification of all reports as solicited need further review?