



Patient Support Programmes: Risk & Risk Management Best Practices

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NAVIGANT

AGENDA

- Introductions
- Setting the Stage: Relevant Laws and Industry Codes
- Common risks that arise with Patient Support Programmes (PSP)
- PSP Structure(s) and How to Build Controls to Manage Risks
- Questions & Discussion

INTRODUCTIONS

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AUDIENCE POLLING

Instructions for Answering Polling Questions

Enter **Sli.do** in your smart phone browser.
Use the Event Code **#IPC2018**
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Tap the poll for your session and answer the question.

Switch to Sli.do

MODULE 1:
SETTING THE STAGE:
RELEVANT LAWS AND
INDUSTRY CODES

RELEVANT LAWS

INDUSTRY CODES

Guidance Related to PSPs

	 EMA: GVP - Module VI	EphRMA: Code of Conduct	 ABPI Guidance	 ABPI Code	 Canadian Code	 Australian Code
Definition of PSP included?						
Guidance is pharmacovigilance-focused?						
Includes requirements for designing a compliant PSP?						
Includes information on handling data?						
Includes information on AE reporting?						

Definitions of PSPs

	Guidance Document	Definition
	EMA:GVP Module VI VI.C.2.2.11. (2017)	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 professionals, information gathering on patient compliance, or compensation/re-imbusement schemes.
	EphRMA: Code of Conduct Section 3.9 (2017)	Patient or carer service; Commercial focus/purpose; Direct patient benefit; Promotional tool; Directly impacts clinical care; Impacts patient directly and immediately; Always involves marketed medicinal product; Managed by company's scientific service or commercial team; Generally includes patient prescribed a company's medicinal product in the usual manner
	ABPI: Guidance Notes for Patient Safety and Pharmacovigilance in Patient Support Programmes (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 healthcare professionals (HCPs) with support for their patients
	Innovative Medicines Canada: Code of Ethical Practices Section 14 (2016)	Patient Support Programs are programs offered by Member companies for the benefit of patients. The programs aim at increasing or facilitating patient understanding of a disease and / or treatment, better patient outcomes as well as possibly improving patient adherence to treatment. Such programs may also serve to ensure or assist with access and/ or reimbursement of a product. The programs must have a primary objective of bettering patient health outcomes. Any benefit experienced by the prescribing or dispensing Health Care Professional must be incidental to the primary objective
	Medicines Australia: Code of Conduct Section 17 (2015)	A Patient Support Program is a company developed program that is intended to assist patients in gaining benefit from their medical treatment and to improve health outcomes and promote the quality use of medicines. Patient Support Programs may only be offered to patients who have already been prescribed a prescription-only Product.



European Guidance Related to PSP

	EMA: Guideline on good pharmacovigilance practices (GVP) - Module VI	EphRMA: Code of Conduct
Definition of PSP included?		
Guidance is pharmacovigilance-focused?		
Includes requirements for designing a compliant PSP?		
Includes information on handling data?		
Includes information on AE reporting?		



GVP Module VI

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 professionals, information gathering on patient compliance, or compensation/re-imbusement schemes.
- Safety reports originating from those programmes should be considered as solicited reports
 - 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 professionals, compassionate use or name patient use, or information gathering on efficacy or patient compliance.



EphMRA 2017 Code of Conduct

Differences Between Market Research, PSPs, and NIS

Characteristics of a PSP

- Patient or carer service
- Commercial focus/purpose
- Direct patient benefit
- Promotional tool
- Directly impacts clinical care
- Impacts patient directly and immediately
- Always involves marketed medicinal product
- Can be managed by company's scientific service or commercial team
- Generally includes patient prescribed a company's medicinal product in the usual manner



UK Guidance Related to PSP

	ABPI: Guidance Notes for Patient Safety and Pharmacovigilance in Patient Support Programmes	ABPI: Code of Practice
Definition of PSP included?		*
Guidance is pharmacovigilance-focused?		
Includes requirements for designing a compliant PSP?		*
Includes information on handling data?		
Includes information on AE reporting?		



ABPI Guidance Notes for Patient Safety and Pharmacovigilance in Patient Support Programmes (2011)

- Scope of the guidance is ‘intended to help companies address the PV obligations and regulatory authority expectations related to PSPs’
- Defines PSPs as ‘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 healthcare professionals (HCPs) with support for their patients.’
- Suggested PV elements for documenting in PSPs
 - Objective of the PSP and needs defined by each stakeholder group
 - PSP Design
 - PSP Description (incl. Operational Details, Handling Customer Interactions, Safety Data Handling, and Patient Materials)
 - Systems and Data Requirements
 - Data Protection

6e. Summary of report handling in PSPs

- Reporting Handling in PSPs

Report type	Seriousness	Requirement for:		
		HCP confirmation attempts	Causality assessment*	Signal detection**
Spontaneous/ stimulated	Serious	Yes	No	Yes
	Non-serious	Yes	No	Yes
Solicited	Serious	Yes	Yes	Yes
	Non-serious	Yes	Yes	Yes



ABPI Guidance Notes for Patient Safety and Pharmacovigilance in Patient Support Programmes (2011)

- Adverse Event Training
 - All those involved in running a PSP should undergo training on product information and AE training to support recognition of AEs and ensure appropriate and timely reporting of AEs to the MAH.
 - It is particularly important when the PSP is outsourced that the MAH should ensure it has systems in place to monitor compliance of the outsourced provider.
- Outsourcing
 - If a third party is identified to run the PSP on behalf of the MAH, it should undergo detailed assessment (due diligence) by the MAH to determine whether it has the capabilities, processes and personnel in place to enable it to run the programme
 - PV and safety data exchange provisions should be defined in the contract between the MAH and the third party.
- Signal Detection
 - Data from PSPs should be identifiable in the safety database such that signal detection may be carried out separately on the specific set of data, in order to avoid detection of false positive signals



ABPI Code of Practice

- **Clause 18.2**

- Health professionals may be provided with items which are to be passed on to patients and which are part of a formal patient support programme, the details of which have been appropriately documented and certified in advance as required by Clause 14.3
- The items provided must be inexpensive and directly benefit patient care. They may bear the name of the company providing them. They must not be given out from exhibition stands. They must not be given to administrative staff unless they are to be passed on to a health professional.

- **Clause 19.1**

- Medical and educational goods and services which enhance patient care, or benefit the NHS and maintain patient care, can be provided subject to the provisions of Clause [18.1](#). They must not be provided to individuals for their personal benefit. Medical and educational goods and services must not bear the name of any medicine but may bear the name of the company providing them.

- **Clause 20**

- Joint working between one or more pharmaceutical companies and the NHS and others is acceptable provided that this is carried out in a manner compatible with the Code. Joint working must always benefit patients.
- The Department of Health defines joint working between the NHS and the pharmaceutical industry as situations where, for the benefit of patients, one or more pharmaceutical companies and the NHS pool skills, experience and/or resources for the joint development and implementation of patient centred projects and share a commitment to successful delivery.



Ex-EU Guidance Related to PSP

	Canadian Code of Ethical Practice	Australian Code of Conduct
Definition of PSP included?		
Guidance is pharmacovigilance-focused?		
Includes requirements for designing a compliant PSP?		
Includes information on handling data?		
Includes information on AE reporting?		



Innovative Medicines Canada Code of Ethical Practice

Section 14 – Patient Support Programs and Medical Practice Activities

●14.1 – Definitions

- Patient Support Programs are programs offered by Member companies for the benefit of patients. The programs aim at increasing or facilitating patient understanding of a disease and / or treatment, better patient outcomes as well as possibly improving patient adherence to treatment.

●14.2 – General Principles

- Intent
 - *These programs / services must not serve solely to cover day to day activities or resources considered part of the practice's operational expenses nor should they replace or compete with services or resources provided and funded by the existing healthcare system. Effort should be made for the healthcare system to absorb the cost of long term initiatives.*
- Ensure Integrity of the Industry
- Conflict of Interest
- Design and Oversight

●14.3 – Standards

- Patient Support Programs or Medical Practice Activities must have clear objectives, timelines and scope
- Reasonable efforts should be made to ensure Patient Confidentiality, Transparency and Privacy
- Data and Outcomes

●14.4 – Request for Support by Stakeholders



Medicines Australia Code of Conduct

Section 17 - Patient Support Programs

- A PSP is a company developed program that is intended to assist patients in gaining benefit from their medical treatment and to improve health outcomes and promote the quality use of medicines.
- PSPs may only be offered to patients who have already been prescribed a prescription-only Product.
- PSPs should be conducted in an open and transparent manner
 - Any payments made to healthcare professionals for facilitating, enrolling or educating patients in a Patient Support Program must be declared to consumers on the enrolment form.
- Information provided to patients may be product specific but not promotional
- There must be:
 - a clinical rationale for the PSP
 - anticipated number of patients to be enrolled in the program
 - the type of educational/informational material to be provided to a patient
 - contact if any (for example phone calls, SMS, email), that may be made to a patient and the duration of the program.
- Companies must ensure compliance with requirements listed in this section
- Data and Outcomes

Section 2.5 - Prescribing Software

- A company may pay for the inclusion of medical education for healthcare professionals or patient aids, patient support program registration and patient aids and patient support program materials in a prescribing software package.

MODULE 2:
COMMON RISKS THAT ARISE
WITH PATIENT SUPPORT
PROGRAMMES (PSP)

MODULE 3:
PSP STRUCTURE(S) AND HOW
TO BUILD CONTROLS TO
MANAGE RISKS