ETHICS AND COMPLIANCE ISSUES IN PATIENT RELATIONSHIPS, INCLUDING PATIENT ACCESS AND SUPPORT

PCF ATHENS – 2019

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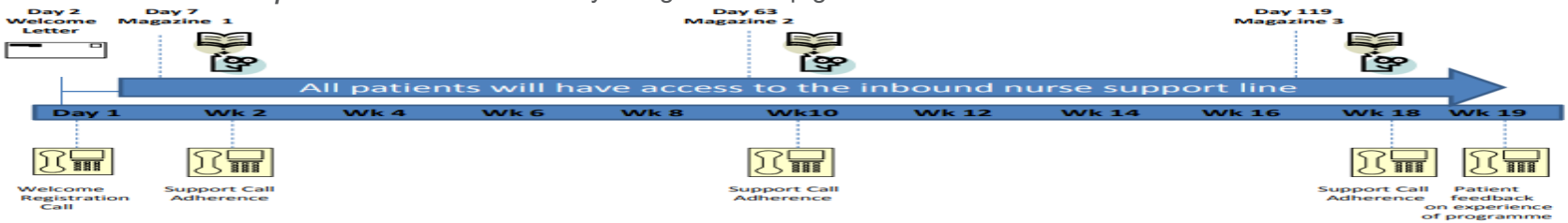
WHERE WE ARE TODAY

- Questions continue to plague Compliance Officers about how to execute Patient Support Programs in a compliant and ethical way
- How do we ensure non-interference between the HCP and the Patient?
- How do we ensure we are not providing an inducement to the HCP for prescribing our products?
- If the design is right, how do we ensure the project controls are set up to ensure appropriate execution of the program?
- Is there any guidance we can follow? How do we think ahead to not run afoul of promotional prohibitions, bribery concerns, interference and conflicts of interests? What besides the law (which is not specific to PSPs) can assist us?

Company “A” PSP

1/ *General Description :* The PSP is initially designed to help good use and adherence to treatment



1.1 Any compliance–related comments or area for vigilance in relation with this design ?

2/ *Additional context*

2.1 Outbound support calls are conducted by third party nurses who follow a guide provided by the company A. They are then providing a report to the Local sales rep of Company A . Local sales reps are incentivized on the number of patients that entered in the PSP, not at the account level but at the regional/district level

2.1.1 As Compliance Officers , what are the potential risks associated with this activity ? How do you mitigate those risks ? What are you going to tell your business partners?

2.2 On top of treatment compliance support ,there is a project in preparation to add treatment efficacy questions at week 10 and 18 in the idea of capturing real world evidence data

2.2.1 As Compliance Officers , what are the potential risks associated with this activity ? How do you mitigate those risks ? What are you going to tell your business partners ?

2.3 Taking advantage of the magazine at day 63 , Company A would like to provide all participating patients with information about their pipe-line pr

2.2.1 As Compliance Officers , what are the potential risks associated with this activity ? How do you mitigate those risks ? What are you going to tell your business partners ?

2.4 Entry in the PSP being a bit slow , Company A would like to get the support of a patient association (e.g. to motivate patients) . They are schedu meeting with them to discuss how to engage in this .

2.4.1 As Compliance Officers , what are the potential risks associated with this activity ? How do you mitigate those risks ? What are you going to tell your business partners ?

Company “B” PSP

1/ *General Description :* This PSP is initially designed to help patients to receive the medication as prescribed

HCP evaluate the case

HCP prescribed the medication → **Prescription is a decision of the HCP**

Parents decide if they wish to be in the program → **Not all patients need or wish to be in the program**

Patients under this program are visited by a nurse → **PSP is not “relieving” the HCO or HCP from their responsibilities**

Adverse effects are reported to PV department of company B → **There is no connection with sales**

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Company “B” PSP

2/ *Additional context*

2.1 Patients can voluntary register in this program. If they do a consent letter is required to be completed. Only the minimal and relevant information is required in this form. A third party company has been assigned to manage these consent forms and Company B will not receive detailed information about the patients enrolled in the program.

2.1.1 As Compliance Officers , Have considered working with the data privacy department to ensure that PSP programs satisfy all the required data protection laws?

2.2 The service provided to the “patient” is not perceived as an “added value to the HCP, HCO or a transfer of value to the parents of the patients.
The medication could be administered both by the nurse or by the parents. There is no added value to the HCP that prescribes or to the HCO where the HCP works. These nurses are employed by a third party that has no connection with the HCO.

2.2.1 As Compliance Officers, have you evaluated the service and question the potential direct or indirect transfer of value to the HCP or the HCO?

2.3 The nurses are employed by a third party with who Company B has a contract. There is full transparency between the role of the third party and its relationship with company B.
Company B has in place a robust due diligence process before contracting this vendors, responsible for managing the PSP.
The contract with the vendor contains the appropriate legal clauses, including compliance related clauses.

2.2.1 As Compliance Officers , What do diligence process do you have in place for vendors managing PSPs?

2.4 There are specific procedures in place directed to the collection of incidents or drug adverse effects, these procedures are incorporated in the PSP and clearly communicated to the third party vendor

2.4.1 As Compliance Officers , what other procedures have you incorporated into the PSP program to ensure pharmacovigilance obligations?

PARADIGM FOR PSP ANALYSIS

How can we develop an analytical framework for reviewing Patient Support Programs?

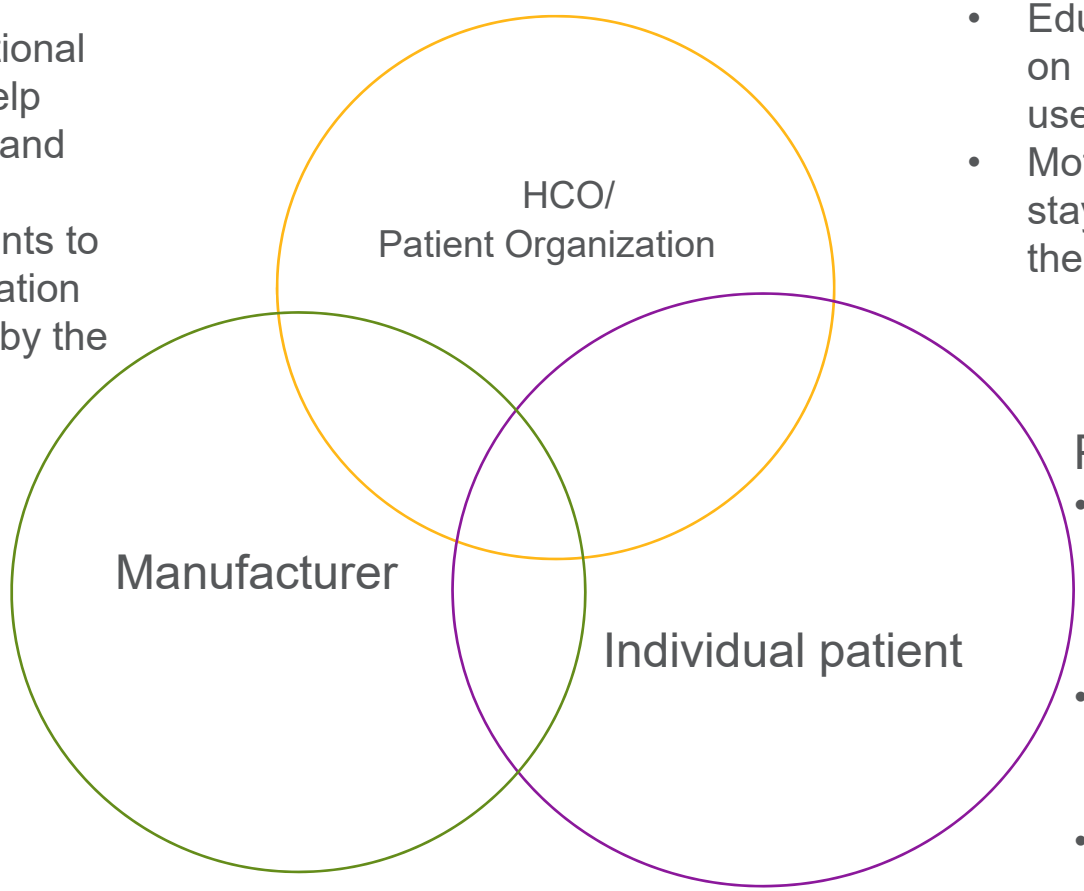
OUTLINING THE RESPONSIBILITIES OF EACH PARTY

Manufacturer:

- Provide educational resources to help patient understand the disease
- Empower patients to take the medication “as prescribed by the HCP”

HCO/PAO:

- Educate the patient on how to properly use the medication
- Motive patients to stay on track with their prescriptions.



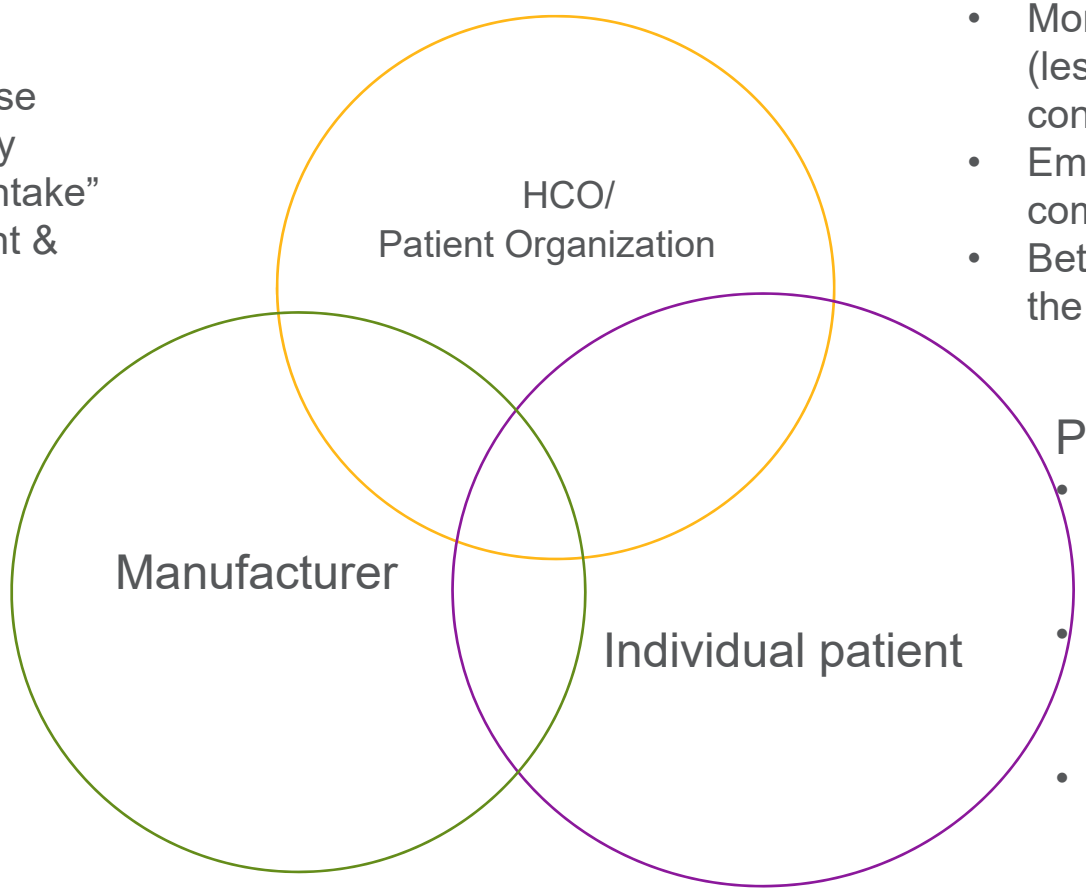
Patient:

- Request information concerning the disease or treatment and medicine.
- Take the medication as prescribed by the HCP
- Highlight if there is any impediment to follow the treatment

OUTLINING THE BENEFITS OF EACH PARTY

Manufacturer:

- Reduction of reported adverse effect “cause by inappropriate intake”
- Better treatment & drug results



HCO/PAO:

- More educated patient (less questions and concerns)
- Empowered patient and commitment to treatment
- Better / or faster results of the treatment

Patient:

- Awareness about the treatment and disease
- Empowerment and motivation to follow treatment
- Better and/ or faster results of the treatment.
- Improvement in the quality of life.

JOINT WORKING FRAMEWORK

Introduction

Joint Working describes situations where the NHS and pharmaceutical companies pool skills, experience and/or resources for the benefit of patients and share a commitment to successful delivery. Many such projects have been successfully implemented, across a range of health economies and disease areas.

Can we use this framework as a tool or road map to developing appropriate Patient Support Programs with HCOs (outside of the UK?)

Red Questions		Yes	No
1	The main benefit of the project is focused on the patient	☐	☐
2	All parties acknowledge the arrangements may also benefit the NHS and pharmaceutical partners involved	☐	☐
3	Any subsequent benefits are at an organisational level and not specific to any individual	☐	☐
4	There is a significant contribution of pooled resources (taking into account people, finance, equipment & time) from each of the parties involved	☐	☐
5	There is a shared commitment to joint development, implementation and successful delivery of a patient-centred project by all parties involved	☐	☐
6	Patient outcomes of the project will be measured and documented	☐	☐
7	All partners are committed to publishing an executive summary of the Joint Working Agreement	☐	☐
8	All proposed treatments involved are in line with national guidance where such exists	☐	☐
9	All activities are to be conducted in an open and transparent manner	☐	☐
10	Exit strategy and any contingency arrangements have been agreed	☐	☐

Amber Questions		Yes	No
11	Will the project be managed by a joint project team with pharmaceutical industry, NHS and any appropriate third party representation?	☐	☐
12	Do all parties and their respective organisations have appropriate skills and capabilities in place to manage the project thus enabling delivery of patient outcomes?	☐	☐
13	Have all partner organisations got clear procedures in place for reviewing and approving Joint Working projects?	☐	☐
14	Are all parties aware of and committed to using the Joint Working Agreement Template (or equivalent) developed by the DH and ABPI?	☐	☐
15	Are all partners clear on who within their organisations is the signatory to ensure Joint Working agreements can be certified?	☐	☐

2019 REVIEW OF PSPS IN INDUSTRY CODES

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GUIDANCE RELATED TO PSPS

	EMA: GVP - Module VI *(2017)*	EphRMA: Code of Conduct *(2018)*	ABPI Guidance *(2018)*	ABPI Code *(2019)*	Canadian Code *(2018)*	Australian Code *(2015)*
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-imbursement schemes.
	EphRMA: Code of Conduct Section 3.7 *(2018)*	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** *(2018)*	An organized system where a marketing authorization holder receives and collects information relating to the use of its medicinal products. Patient Support Programmes include post-authorization patient support and disease management programmes, surveys of patients and healthcare providers, information gathering on patient compliance, or compensation/reimbursement schemes.
	**Innovative Medicines Canada: Code of Ethical Practices** Section 14 *(2018)*	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 *(2017)*	EphRMA: Code of Conduct *(2018)*
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-imbursement 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 2018 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 *(2018)*	ABPI: Code of Practice *(2019)*
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?	✓	✗

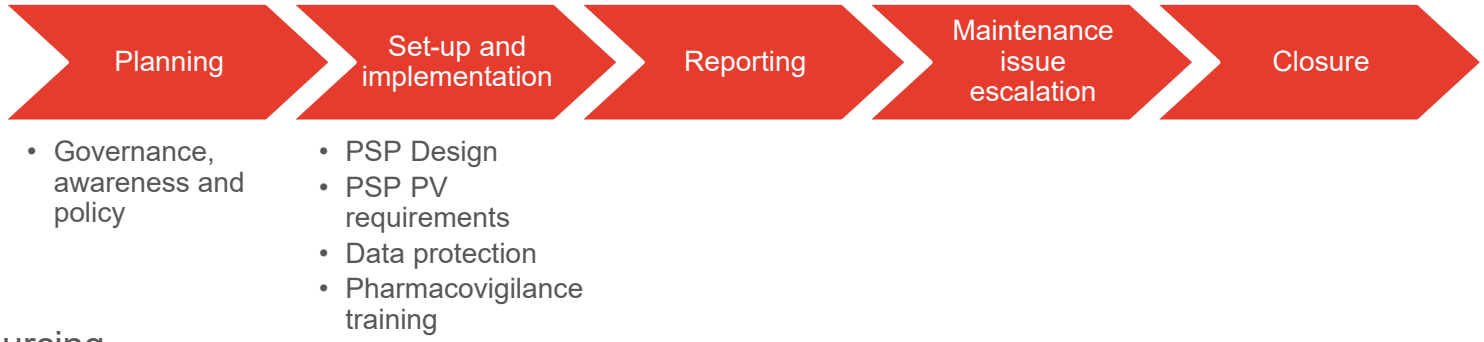
*Includes definition of and requirements for Medical and Educational Goods and Services

ABPI GUIDANCE NOTES FOR PATIENT SAFETY AND PHARMACOVIGILANCE IN PATIENT SUPPORT PROGRAMMES (2018)

- Scope of the guidance **'relates only PV aspects of PSPs'** and only "applies to PSPs with authorised medicines only'. Notes in the guidance 'are intended to help departments in companies initiating and conducting PSPs to appropriately consider and address PV obligations and regulatory authority expectations'.
- Now adopts the same definition of PSPs as the 'Guideline on GVP, Module VI'
- Examples of PSPs include
  - Compliance/adherence programmes where consenting patients on a medication are contacted to see how they are managing with their medication
  - Call centres where patients or patient carers can contact the MAH to obtain further information on medication or a particular disease area as part of a structured programme
  - 'Nurse educator' programmes where nurses (either employed directly by an MAH or through a third party) interact directly with patients to provide education or disease awareness, to help them properly administer medications and/or manage their disease
- It is recommended to have a single point of accountability to take overall responsibility for each PSP and gain the necessary cross-functional co-operation and endorsement
  - The PV function must be involved from the initial design stage to avoid generation of inappropriate data and ensure the project is compliant with appropriate regulations

ABPI GUIDANCE NOTES FOR PATIENT SAFETY AND PHARMACOVIGILANCE IN PATIENT SUPPORT PROGRAMMES (2018)

- Documenting PSPs
  - Clear documentation should be maintained for all PSPs
  - The documentation should outline how PSP objectives and all compliance requirements will be achieved and define the responsibilities of each stakeholder group applicable to the PSP
  - Documentation is recommended for all the following stages:



- 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 training and safety data exchange provisions should be defined in the contract between the MAH and the third-party.
  - The MAH should ensure that third-party staff are adequately trained prior to the start of the PSP and throughout its duration.

ABPI CODE OF PRACTICE *(2019)*

- **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 *(2018)*	Australian Code of Conduct *(2015)*
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 *(2018)*

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, bettering patient outcomes as well as possibly improving patient adherence to treatment.

- 14.2 – General Principals
  - 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 *(2015)*

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
- Suspected Adverse Drug Reactions noted during monitoring of a Patient Support Program must be reported to the TGA in accordance with the current TGA document Australian requirements and recommendations for pharmacovigilance responsibilities of sponsors of medicines (August 2013).

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.

