

## **Parenteral Nutrition Down Under Inc. (PNDU)**

### **Working with Pharmaceutical Companies Policy (Policy)**

#### **BACKGROUND *(Reason or Purpose)***

The purpose of this Policy is to provide clear principles and guidance about how PNDU interacts with pharmaceutical companies to achieve its objectives, without compromising its integrity and its ability to support its members. These will ensure that its activities are not in any way influenced by the commercial interests of the pharmaceutical companies with which it interacts.

An interaction is defined as any type of activity undertaken with a pharmaceutical company, including, for example, providing a quote for a press release, speaking at an industry event, collaborating on the production of educational materials or events, participating in a clinical trial, or seeking financial support for a consumer-support activity. This applies regardless of whether or not there is a transfer of funds, other material goods or knowledge.

PNDU is a self-funded, non-profit support group for consumers and carers in Australia and New Zealand on Parenteral Nutrition (PN) for Intestinal failure (IF). PNDU is credited and referenced officially by the major stakeholders and providers of PN for IF as being the support group for and voice of consumers and carers of PN for IF in Australia and New Zealand.

PNDU's mission statement is to 'support, research and inform consumers, carers and providers of Parenteral Nutrition for Intestinal Failure'.

The objectives of PNDU are:

- a. To support Australian and New Zealand patients receiving home parenteral nutrition for intestinal failure (also known as consumers) and/or their families and carers, with a focus on education, advocacy and increasing awareness.
- b. To exchange experience and knowledge of how others cope with intestinal failure and home parenteral nutrition in everyday life.
- c. To support and/or sponsor research and other activities to ensure the highest quality treatment options for those receiving home parenteral nutrition.
- d. To work with health professionals, organisations and like-minded persons to achieve these goals.

PNDU, as a charitable organisation, relies on the generosity of its members and donors and on fundraising to fund its activities. PNDU can also seek grants/sponsorship from commercial organisations, government and philanthropic funds. PNDU is committed to developing a variety of long term dependable income sources to fund its work.

PNDU attracts attention from pharmaceutical companies that have a particular interest in the development of treatments and other services for PN for IF consumers. Pharmaceutical companies may sometimes be willing to sponsor and fund certain activities PNDU undertakes.

Working with pharmaceutical companies that manufacture and market drugs and treatments can give PNDU important background knowledge and provide positive networking opportunities.

Pharmaceutical companies, however, will have a commercial interest in PN for IF. In many cases, the partnership is not equal, in that a pharmaceutical company has many more resources at its disposal than PNDU. For these reasons, PNDU takes particular care in how it interacts with pharmaceutical companies and other for-profit healthcare providers.

PNDU acknowledges that there are a limited number of pharmaceutical companies with an interest in PN for IF.

In all its activities, PNDU respects and promotes the fundamental value of transparency. PNDU believes that it is important to establish transparent policy about financial support from pharmaceutical companies.

PNDU is committed to working with pharmaceutical companies in a genuine partnership to build a mutually beneficial and enduring association that furthers the objectives of both partners, and preserves PNDU's independence and integrity. Mutual understanding of each other's internal culture and external constraints, as well as clear goals from the partnership, will ensure success.

This Policy refers to pharmaceutical companies. However, PNDU's activities with other commercial interests within and outside the health sector will also conform to this Policy and will be guided by the PNDU Management Committee (MC).

**PRINCIPLES:**

- A. PNDU will engage in dialogue with pharmaceutical companies about PN for IF treatments for the betterment of its members.
- B. PNDU will independently set its own priorities, policies and plans and ensure all interactions with pharmaceutical companies are compatible with the mission and objectives of PNDU.
- C. All interactions must comply with this Policy and will be approved by the MC.
- D. PNDU will always consider potential conflicts of interest before interacting with any pharmaceutical company.
- E. PNDU will not enter into interactions with pharmaceutical companies that may potentially have an adverse effect on PNDU's credibility or integrity.
- F. PNDU's logo and name may not be used by any pharmaceutical company to promote a product. PNDU MC will have ultimate discretion on all uses of PNDU's name, logo and identifying symbols.
- G. PNDU will not endorse individual pharmaceutical products or suppliers of healthcare services.

- H. PNDU will appropriately recognise company grants/sponsorship. Recognition should not be interpreted as endorsement of particular policies or products.
- I. PNDU will follow all local laws and regulations (Medicines Australia Code of Conduct Edition 18 and Medicines New Zealand Incorporated Code of Practice Edition 16) in relation to interactions with pharmaceutical companies.
- J. PNDU is committed to total transparency in all dealings with pharmaceutical companies.
- K. PNDU will seek to develop relationships with multiple pharmaceutical companies, so as not to develop a special relationship with only one company.

## **PRACTICE:**

### **1. Openness and Transparency:**

- a. This Policy will be published on PNDU's website. PNDU will ensure that all pharmaceutical companies with which it interacts are familiar with the Policy background, principles and practice, as outlined in this document. It will do this by giving the pharmaceutical company a copy of this Policy and/or referring it to the Policy on PNDU's website.
- b. Where possible, PNDU will disclose all financial support and other benefits from pharmaceutical companies on request, and will publish the amount and source of all funding, including donations and grants/sponsorship, in its Annual Report, quarterly newsletter and/or website.
- c. In return for corporate membership of PNDU, a pharmaceutical company's logo may be displayed in an appropriate location on PNDU's website and/or in its quarterly newsletter.
- d. PNDU will acknowledge financial support for projects with a statement similar to "This project was funded by an unrestricted grant/sponsorship from <company name>. This company had no influence over the outcomes of this project".
- e. PNDU will maintain a register of all interactions with pharmaceutical companies which will be available on request by PNDU members and the community.
- f. The MC welcomes members to raise any concerns about PNDU's relationship with pharmaceutical companies. These questions and concerns will be discussed at the next MC meeting and a reply will be given to the concerned member.

### **2. Maintaining Independence**

- a. PNDU will maintain an independent position on all issues that impact consumers, based on its own informed analysis of scientific information, consumer input and independent expert opinion.
- b. PNDU retains the right to withdraw from any interaction with a pharmaceutical company should the terms of an agreement with it be broken.

- c. PNDU retains the right to publicly object to positions or actions of a pharmaceutical company irrespective of any agreement with it.
- d. PNDU will only accept a restricted grant/sponsorship if it retains full control of the event, publication or project for which the grant/sponsorship is given.
- e. PNDU reserves the right to receive grant/sponsorship support from multiple pharmaceutical companies where possible, to avoid the appearance of alliance with any one pharmaceutical company, its products, political agenda or regulatory concerns.

### **3. Funding of Projects**

- a. PNDU will only encourage funding for projects that have been identified as priorities in the regular PNDU planning process. These will be projects that align with PNDU's mission and objectives, and comply with local laws and regulations.
- b. PNDU is committed to having a diverse range of funding sources where possible for any project.
- c. PNDU may accept financial or in kind support from one or more pharmaceutical companies for a specific project. This support may provide PNDU with a reliable source of income over a number of years to cover direct costs for the project, such as, but not limited to, equipment, suppliers, consultants and travel, as well as indirect costs associated with the project, such as administration and other incidental costs.
- d. Projects that are initiated by a pharmaceutical company will be approved by the MC before they proceed.
- e. PNDU will require a written and signed project agreement with all pharmaceutical company sponsors prior to initiation of a project. Agreed roles and responsibilities will be clearly defined for all parties.
- f. In accordance with Medicines Australia Code of Conduct and Medicines New Zealand Incorporated Code of Practice, pharmaceutical companies which provide PNDU with financial support for a project will disclose this publicly, ideally on their website.
- g. One-off unconditional charitable donations from pharmaceutical companies to PNDU are not linked to a specific project or activity. As such, they do not create any obligation for PNDU to publicly acknowledge the donation. However, PNDU may disclose or acknowledge such donations from time to time as appropriate, for example, in PNDU's Annual Report, and/or quarterly newsletter.
- h. Pharmaceutical companies may also make non-monetary contributions to PNDU, such as;
  - Seconded staff or professional services provided with no charge or invoice to PNDU

- Equipment or donations (e.g. computers and other equipment)
- Meeting rooms
- Services
- Other non-monetary contributions (e.g. furniture, printing services).

#### 4. Promotion

- a. *(Australia only. Not applicable in New Zealand)* No promotional activities related to approved prescription medications are permitted within Australian legislation and Medicines Australia Code of Conduct. PNDU will not engage in any activity that may be associated with promotional strategy for any prescription medication in Australia.

##### **Types of activities that may be considered promotional under Australian legislation:**

- Disseminating unbalanced, non-validated or partial information on products, services or medical devices distributed or marketed by a pharmaceutical company;
  - Being quoted in a pharmaceutical company's communication in favour – or against – a product;
  - Participating as a speaker/attendee in a pharmaceutical company's product launch event;
  - Participating in an ad hoc meeting sponsored by a pharmaceutical company to inform patients on their products;
  - Agreeing that a pharmaceutical company displays or disseminates a consumer organisation's own material on the pharmaceutical company's exhibition stand at any trade exhibition or scientific conference; and
  - Appearing in promotional materials for a certain product or to testify as a "consumer" of that medicine.
- b. *(New Zealand only. Not applicable in Australia)* For promotional activities in New Zealand, PNDU will follow the principles and practices contained within Medicines New Zealand Incorporated Code of Practice Edition 16, published August 2014, or any update of this Code.
- c. PNDU will not endorse any specific drug or treatment.
- d. Excepting receipt of certain promotional products at conferences and scientific meetings deemed acceptable for the purposes of information and internal demonstration, or for PNDU's use in facilitating a PNDU event, PNDU will not accept or distribute promotional products provided by a pharmaceutical company and will not allow distribution of such products at PNDU events.
- e. PNDU will not permit quoting of it or its representatives in industry press releases that relate to a marketed product or a product under development. If PNDU feels the need to communicate to media about a product, it will issue its own press release, independently of industry.

- f. If a pharmaceutical company quotes PNDU's opinion or refers to PNDU's own communication materials without PNDU's consent, PNDU will object to the pharmaceutical company by registered letter (with a copy to the national industry association of the pharmaceutical company).

## **5. Education**

- a. PNDU will keep key volunteers and any staff informed on PN for IF research, the drug development process and the way the pharmaceutical industry operates.
- b. PNDU will work with, amongst others, PACIFHAN (International Alliance of Patient Organisations for Chronic Intestinal Failure & Home Artificial Nutrition) and IAPO (International Alliance of Patients' Organizations), and learn from their experiences of working with pharmaceutical companies.
- c. PNDU will seek to ensure that all medical information it publishes has been reviewed by independent clinicians. Any reproduction of published medical information by PNDU will have the approval of the original author or copyright holder, or at the very least, reference to the author and publication.

## **6. Independent and Impartial Support**

- a. PNDU will not engage in projects with pharmaceutical companies where there is an implicit expectation or obligation to promote a branded, commercial product.

In some circumstances, however, PNDU may independently choose to support a specific (branded) product or service following informed analysis of scientific data and consumers' needs. (For example, when speaking to a regulatory authority or independently lobbying a government body to improve consumers' access to treatment.) Testimonials or support for a specific (branded or unbranded) product will be prepared and presented by PNDU based on its own informed analysis of scientific data, consumer input and independent expert opinion. All activities and references to products will comply with local laws.

## **7. Other**

- a. PNDU understands that as an organisation for and representative of consumers on PN for IF in Australia and New Zealand, it may be asked to review consumer information material to ensure that it has validity and understanding for its audience. In considering such request, if there is any possibility of perceived PNDU endorsement of a product by accepting a fee for such service, PNDU will not accept any fee for the service. PNDU representatives may, however, be reimbursed for any out-of-pocket expenses associated with the activity.
- b. The MC will review and decide on any offer of hospitality, including travel and accommodation for a PNDU representative that is provided or funded by a pharmaceutical company.

## 8. References

- a. **Consumers' Health Forum & Medicines Australia 2015**  
“Working together. A guide to relationships between health consumer organisations and pharmaceutical companies” <https://chf.org.au/sites/default/files/working-together-brochure-2015.pdf>
- b. **Medicines Australia Code of Conduct Edition 18**  
<https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/01/20150617-PUB-Code-Edition-18-FINAL.pdf>
- c. **International Alliance of Patients' Organisations IAPO**  
“A Consensus Framework established for ethical collaboration between patients' organisations, healthcare professionals and the pharmaceutical industry”  
[http://iapo.org.uk/sites/default/files/files/Consensus\\_Framework-vF.pdf](http://iapo.org.uk/sites/default/files/files/Consensus_Framework-vF.pdf)
- d. **Medicines New Zealand Incorporated Code of Practice Edition 16 Published August 2014**  
<http://www.medicinesnz.co.nz/assets/Documents/Ed-16-Final-Updated-22-Sept-2015.pdf>