



## SHPA response to Product Information (PI) as a package insert in boxed injectables, October 2022

### Introduction

The Society of Hospital Pharmacists of Australia (SHPA) is the national, professional organisation for the 6,100+ Hospital Pharmacists, and their Hospital Pharmacist Intern and Hospital Pharmacy Technician colleagues working across Australia's health system, advocating for their pivotal role improving the safety and quality of medicines use. Embedded in multidisciplinary medical teams and equipped with exceptional medicines management expertise, SHPA members are progressive advocates for clinical excellence, committed to evidence-based practice and passionate about patient care.

SHPA welcomes the opportunity to comment on the requirement of Product Information (PI) as a package insert in boxed injectables. SHPA supports the intention from the Therapeutic Goods Administration that 'a smaller box size will have a positive impact on the environment with a reduction in carbon emissions in freight size, transportation, cold storage, and a reduction in paper printing'. SHPA's [Pharmacy Forecast Australia 2022](#) report demonstrates that pharmacists recognise there is an urgent need for the Australian pharmacy profession to take practical and strategic actions to reduce the pharmaceutical industry's carbon footprint. SHPA provides feedback below following consultation with its members in the Medication Safety Specialty Practice Group.

### **SHPA provides in-principle support for Option 1: 'I use and refer to the hard copy PI that is included with boxed injectables administered by healthcare professionals.'**

#### **1. Why do you find a hard copy in the box useful?**

SHPA supports Option 1 despite recognising the need to reduce the sector's carbon footprint, as some medication administration areas may not have full accessibility to a computer or smart device. Clear instructions for nursing staff are required at point of administration to ensure safe administration practices occur.

Furthermore, some injectable medicines are administered outside of hospital settings such as in Residential Aged Care Facilities (RACF) where access to electronic resources and PIs may be limited. As such, until it is standardised practice that access to a computer or smart device is achieved in all settings wherever medicines are administered, SHPA believes a hard copy PI is included with boxed injectables to reduce the risk of administration errors.

As hospitals, aged care facilities and health services increasingly digitise their healthcare environments and medicines workflows, this presents an opportunity for medication charts or other digital documents containing medicines information, to be linked to a medicine's PI in digital infrastructure such as electronic medical records or Electronic Medication Management (EMM) software.

#### **2. What areas of the PI do you find particularly valuable in a package insert?**

In reference to the supplied consultation document '*Information contained in the Australian Product Information*', SHPA believes that the following sections are required to be included in a PI for the safe and effective administration of medicines at the point of administration:

- 1. Name of Medicine
- 2. Qualitative and Quantitative Composition



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- 3. Pharmaceutical form - Appearance is particularly important to gauge if the correct product is being administered
- 4. Clinical Particulars – 4.2 Dose and Method of Administration, particularly the compatibility with other fluids if it is to be co-administered
- 6. Pharmaceutical particulars – Special Precautions for Disposal
- 6.2 Incompatibilities
- 10. Date of revision

### 3. What areas of the PI do you not find valuable in a package insert?

Given that at the point of administration, the medication has already been prescribed, it would be assumed the following information has been considered prior to administration and therefore is not required for inclusion:

- 4. Clinical Particulars – 4.1 Therapeutic Indication, 4.5 Interactions
- 5. Pharmacological Properties
- 6. Pharmaceutical Particulars
- 7. Medicines Schedule – This should be on the outer packaging of the box so healthcare professionals are aware where to store it prior to opening the package.
- 8. Sponsor
- 9. Date of First Approval

### 4. Do you use other resources to access information about the boxed injectable?

- Therapeutic Goods Administration (TGA) PI and Consumer Medication Information (CMI) Search Facility
- The Australian Injectable Drugs Handbook (AIDH)
- Nursing staff may seek advice regarding administration from the hospital ward pharmacist, where available
- Electronic Medication Management (EMM) software

### Please provide any other information or suggestions about the inclusion of the PI in boxed injectables.

If further information is required, SHPA recommends that QR codes are provided on the boxed injectables' packaging that can redirect to the most up to date information.

Consideration must be made to settings that have barriers to electronic resource accessibility, for example in some rural and remote areas or RACFs.

Reducing the volume of information in the PI could provide the added benefit of providing more clarity for nursing staff by the font size and administration diagrams being increased.

If you have any queries or would like to discuss our submission further, please do not hesitate to contact Jerry Yik, Head of Policy and Advocacy on [jyik@shpa.org.au](mailto:jyik@shpa.org.au).

