Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Consultation: Product Information (PI) as a package insert in boxed injectables

The TGA is seeking input on the value of providing hard copy Product Information as a package insert in boxed injectable products administered by healthcare professionals

Version 1.0, August 2022

TGA Health Safety Regulation

Confidentiality
All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

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The Therapeutic Goods Administration (TGA) aims to understand the current usage of the information included with boxed injectables. We note different groups may or may not use included information when provided in hard copy with the product and may be satisfied that it only be accessible online.

We seek your views and feedback on the value of the Product Information (PI) as a package insert in boxed injectables that are administered by a healthcare professional (e.g. vaccines).

A boxed injectable is a pre-filled syringe that comes packaged in a box alongside the PI for that medicine. An example of a boxed injectable is a seasonal influenza vaccine that is administered by a healthcare professional.

Background

The PI provides healthcare professionals with a summary of the scientific information about the safe and effective use of a prescription medicine. The PI contains information including the approved usage, dosage and administrative instructions, contraindications, precautions, and adverse events information. The PI typically ranges between 10-35 pages.

In Australia the PI is required to be provided both in the box of injectables and also as an electronic document available on the TGA website. This consultation seeks feedback on whether the requirement to include a paper PI as a package insert in boxed injectables is still relevant for those administered by healthcare professionals.

The inclusion of the PI in boxed injectables is an administrative practice to apply a condition of registration under subsection 28(2B) of the Therapeutic Goods Act 1989.

Scope

To determine if the PI is a necessary package insert in boxed injectables administered by healthcare professionals, or whether provision of the PI electronically on the TGA website is sufficient.

Injectables that are not administered by healthcare professionals are not being considered in this consultation but will be considered in a subsequent consultation shortly.

Why are we consulting?

The PI is inserted by pharmaceutical companies during the manufacturing process and a larger box is required to accommodate the PI along with the injectable. Removing the PI as a package insert may reduce the box size and make storage of products in refrigerators or on shelves in doctors' surgeries and hospitals easier.

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.

The PI can also be accessed online as a PDF using the TGA's PI/CMI search facility. An electronic PI provides:

- Up-to-date information about the medicine. Currently, the physical PI package insert may be missing any recently added important safety information.
- Accessibility through various online platforms and devices, such as a tablet or a smart phone. The electronic PI can be accessed from a wide range of online platforms.

How to respond

We would like your feedback on how you use and refer to the PI for boxed injectables. Please respond to the option that best suits your usage:

Option 1: I use and refer to the hard copy PI that is included with boxed injectables administered by healthcare professionals.

Why do you find a hard copy in the box useful?

What areas of the PI do you find particularly valuable in a package insert?

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

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

Option 2: I do not use or refer to the PI that is included in boxed injectables administered by a healthcare professional.

Where do you access information about the boxed injectable?

Can you easily find the PI on the TGA website?

Are there certain areas of the PI that you would find valuable to maintain as a hard copy package insert?

The TGA invites comments from interested parties. Comments can address any or all of the options in this consultation paper.

The closing date for comments is 5 October 2022.

Next steps

The Department will consider the responses received and will provide options to the Government for consideration.

Please provide any additional information or suggestions

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	PMAB	August 2022

Therapeutic Goods Administration

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