

COVER SHEET

First external consultation on PI in Boxed Injectables Administered by HCPs	Duration: 24 August- 5 October 2022
Total respondents	57

Snapshot of respondents

Healthcare professionals	17
Representing a group of healthcare professionals	6
Interested medicine consumer	4
Representing a group of patients	0
Healthcare organisation	2
Sponsor	24
Agent representing a sponsor	2
Any other	2
Not answered	0
Total	57

Name	John
Email address	
Organisation	Pharmaceutical Defence Limited
Respondent type	I am representing a group of healthcare professionals
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response
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?	
There may be times when online access is not available. Such occasions could be visiting a patient in their home, when the internet is down or not available and in remote areas. The ability to refer to a hard copy PI should always be available.	
What areas of the PI do you find particularly valuable in a package insert?	
Administration protocols and dilutions	
What areas of the PI do you not find valuable in a package insert?	
Anything I am not looking for. Hard to nominate	
Do you use other resources to access information about the boxed injectable?	
Prefer not to but hard copy texts (AMH) can be referred to	
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?	
Additional information or suggestions	
You have not explained why this action is being proposed although I assume it is commercial.	
Attachment, if any	
Not Answered	
Response Id	
ANON-3A9P-AQD3-6	
Submitted date	
8/26/2022 3:26:17 PM	

Name	Liz
Email address	
Organisation	
Respondent type	Any other
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response
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?	
So that I am aware of the information regarding adverse reactions and allergies. It was noted that the PI for the COVID vaccines was folded to show a header section but the remainder if the PI was blank.	
What areas of the PI do you find particularly valuable in a package insert?	
Potential life threatening allergies and adverse reactions, and ingredients.	
What areas of the PI do you not find valuable in a package insert?	
Nil	
Do you use other resources to access information about the boxed injectable?	
Nil	
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?	
Nil	
Can you easily find the PI on the TGA website?	
No. The information should be clearly visible for the medical professional and the patient to discuss in an open transparent dialogue.	
Are there certain areas of the PI that you would find valuable to maintain as a hard copy package insert?	
No. Each package should be include the relevant information should an ingredient or new data become available.	
Additional information or suggestions	
The PI should be handed to each patient to ensure they have detailed information in case of reactions for emergency response etc.	
Attachment, if any	
Not Answered	
Response Id	
ANON-3A9P-AQDQ-4	
Submitted date	
8/30/2022 1:11:40 PM	

Name	
Email address	
Organisation	
Respondent type	I am a healthcare professional
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response anonymously
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?	
Internet resources, either MIMS Online or AusDI.	
Can you easily find the PI on the TGA website?	
I haven't tried but I'm sure it's straightforward.	
Are there certain areas of the PI that you would find valuable to maintain as a hard copy package insert?	
In some circumstances it's convenient to have administration information on hand for products contained in proprietary syringes.	
Additional information or suggestions	
Attachment, if any	
Not Answered	
Response Id	
ANON-3A9P-AQDW-A	
Submitted date	
8/31/2022 11:51:45 AM	

Name	Jim
Email address	
Organisation	Austin Health
Respondent type	I am a healthcare professional
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response
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?	
Information is available electronically.	
Can you easily find the PI on the TGA website?	
Yes.	
Are there certain areas of the PI that you would find valuable to maintain as a hard copy package insert?	
There is nothing in the PI that is of any value at the time of preparation. This is especially true in large teaching hospitals where hundreds of vials are used daily. This information is pointless.	
Additional information or suggestions	
Working in a public hospital, I deal with tens of thousands of boxed injectables. The PI is simply tossed out. Most institutions who prepare either within the Pharmacy Department or on the ward have this information readily accessible, or the information pertaining to the specific requirements for preparation, administration or stability are prepared in-house. One simple example. We prepare up to 50 infusions of pharmaceutical "x" weekly. Each infusion requires on average, 4 vials. We have 200 boxes of pharmaceutical "x" with 200 PI, which end up (luckily) being recycled.	
Attachment, if any	
Not Answered	
Response Id	
ANON-3A9P-AQD9-C	
Submitted date	
9/1/2022 4:54:11 PM	

Name	Julian
Email address	
Organisation	Chris O'Brien Lifehouse Hospital
Respondent type	I am a healthcare professional
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response
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?	
I get it off either the TGA website or via a link in CIAP	
Can you easily find the PI on the TGA website?	
Yes	
Are there certain areas of the PI that you would find valuable to maintain as a hard copy package insert?	
Drug, dosage, strength, Storage conditions and routes of administration	
Additional information or suggestions	
Attachment, if any	
Not Answered	
Response Id	
ANON-3A9P-AQAR-2	
Submitted date	
9/1/2022 6:30:11 PM	

Name	
Email address	
Organisation	Personal
Respondent type	I am an interested medicine consumer
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response anonymously
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?	
To find out relevant information regarding dosages, other medication contraindications warnings, side effects- acute and chronic, and any other information about the medicine I would like to know and refer to. I like the hard copy as it is correct for the medicine you are taking, if you go to digital it is possible for the consumer to make a mistake and look up the wrong medicine leading to potentially catastrophic effects. Websites come under maintenance or aren't always updated so you can't guarantee that the relevant information will always be accessible at the time it is required by the consumer. A hard copy takes away the guesswork and it is always on hand with the medicine and able to be referred to.	
What areas of the PI do you find particularly valuable in a package insert?	
To find out relevant information regarding dosages, other medication contraindications warnings, side effects- acute and chronic, and any other information about the medicine I would like to know and refer to.	
What areas of the PI do you not find valuable in a package insert?	
Nothing. After checking with my mum on her medications (she has at least 10 prescription medicines), none of them contained the instructional and informative leaflet that they should automatically come with. This is appalling. You're asking for feedback but have already stopped providing this information in the box.	
Do you use other resources to access information about the boxed injectable?	
The information contained on the leaflet is the first go to source, along with the doctor who prescribed it. Anything after that is tertiary sources- the internet can have misleading or incorrect information so it should be taken with a grain of salt and see if it lines up with the information on the leaflet. If you no longer provide this in the box, we have no way to easily verify this information.	
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?	
Additional information or suggestions	
They need to be provided for health and personal reasons. Online web pages can be not updated, down for maintenance, have error messages, or could access the wrong prescription medicine information. Perhaps you can provide the online website in addition to the physical hard copy leaflets. Maybe include a QR code linking directly to the specific page of the medicine you are taking, so there is less room for error.	
Attachment, if any	

Not Answered
Response Id
ANON-3A9P-AQAG-Q
Submitted date
9/2/2022 12:27:15 PM

Name	
Email address	
Organisation	
Respondent type	I am a healthcare professional
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response anonymously
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?	
Can be useful if the electronic copy is not available (e.g. computer/internet downtime or if there is no copy in MIMS).	
What areas of the PI do you find particularly valuable in a package insert?	
The useful parts of a hard copy PI are those used at the point of care - preparation and administration, including appropriate dilution (concentration and compatible diluent) and duration of injection/infusion.	
What areas of the PI do you not find valuable in a package insert?	
Most of it! I would only use it if I didn't have access to my hospital's administration guidelines or an appropriate reference like the Australian Injectable Drugs Handbook.	
Do you use other resources to access information about the boxed injectable?	
<ul style="list-style-type: none"> - Local hospital guidelines and policies - Australian Injectable Drugs Handbook - Product information online via MIMS or AusDi 	
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?	
<ul style="list-style-type: none"> - Local hospital guidelines and policies - Australian Injectable Drugs Handbook - Product information online via MIMS or AusDI 	
Can you easily find the PI on the TGA website?	
<p>Sometimes. It's easier when there is a clear brand name; products that are called 'Company generic name' sometimes get lost with all the other products that company makes.</p> <p>Sometimes it's difficult finding the ARTG from the TGA home page!No</p> <p>(Note I have</p>	
Are there certain areas of the PI that you would find valuable to maintain as a hard copy package insert?	
No. In the hospital setting, they are rarely opened to review, and staff routinely throw them in the bin. The hospital where I work has an extensive suite of electronic administration guidelines and access to a computer where injectables are prepared, so	
Additional information or suggestions	
One of the problems some of the older staff have is that the font size of the included PI is really small! This leads to a risk of error if someone can't see the text clearly.	
Attachment, if any	
Not Answered	
Response Id	
ANON-3A9P-AQAE-N	
Submitted date	
9/2/2022 5:02:49 PM	

Name	
Email address	
Organisation	
Respondent type	I am an interested medicine consumer
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response anonymously
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?	
Because it is clear that the information included pertains to that particular batch at that given moment in time. PI's can be updated and superseded online, that's if you can find them at all.	
What areas of the PI do you find particularly valuable in a package insert?	
The known adverse events, and impacts on pregnant and lactating women, if known.	
What areas of the PI do you not find valuable in a package insert?	
It is all interesting.	
Do you use other resources to access information about the boxed injectable?	
Only TGA or FDA websites if its not included in the box.	
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?	
TGA if its not in the box	
Can you easily find the PI on the TGA website?	
Yes generally.	
Are there certain areas of the PI that you would find valuable to maintain as a hard copy package insert?	
Yes - contraindications and known adverse events.	
Additional information or suggestions	
Informed consent is imperative. Removing hard copy from the box doesn't give the patient any time to lookup that information prior to administration of the injectable. Relying on Dr to provide their interpretation of the information also sketchy if they don't have it on hand and is easily dismissed with a simple she'll be right and the wave of a hand.	
Attachment, if any	
Not Answered	
Response Id	
ANON-3A9P-AQA3-3	
Submitted date	
9/2/2022 10:56:02 PM	

Name	
Email address	
Organisation	
Respondent type	I am a healthcare professional
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response anonymously
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?	
To quickly access information especially regarding preparation instructions and administration.	
What areas of the PI do you find particularly valuable in a package insert?	
How to prepare the medicine, how to administer the medicine, storage and stability	
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?	
Electronic version if paper version is not available.	
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?	
MIMS online However, for medicines that are under the special access scheme the PI is not available on MIMS and I rely on the printed PI box insert.	
Can you easily find the PI on the TGA website?	
Cannot comment as have not used the TGA website.	
Are there certain areas of the PI that you would find valuable to maintain as a hard copy package insert?	
Drug class, excipients, dosing, preparation, administration, storage, stability (ie. expiry of medicine after preparation)	
Additional information or suggestions	
Keep PI in boxed injectables.	
Attachment, if any	
Not Answered	
Response Id	
ANON-3A9P-AQAP-Z	
Submitted date	
9/3/2022 9:19:42 AM	

Name	Mazdak
Email address	
Organisation	Eastern Health
Respondent type	I am a healthcare professional
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response
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?	
I find it a waste of resources. I have always thrown them out. Even when I need information about the product in my hand, I use electronic sources as the print font is too small to read and I can't search for what I need on paper!	
What areas of the PI do you find particularly valuable in a package insert?	
None. The print font is too small for me to read and I doesn't have a search function! I can imagine someone with sharp eyes but with no access to the electronic PI may use the printed PIs.	
What areas of the PI do you not find valuable in a package insert?	
I never use them. The print font is too small for me to read and I doesn't have a search function!	
Do you use other resources to access information about the boxed injectable?	
I use MIMS and other electronic resources when at work. Outside work, I google the drug name and "TGA PI" and access the TGA website to read the PI on my device. Perhaps, a QR code on the injectable box that could take me straight to the mobile friendly version of PI is a better substitute for a printed leaflet.	
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?	
I use MIMS and other electronic resources when at work. Outside work, I google the drug name and "TGA PI" and access the TGA website to read the PI on my device. Perhaps, a QR code on the injectable box that could take me straight to the mobile friendl	
Can you easily find the PI on the TGA website?	
Not easy. There are a lot of clicks to get to the PI and the pages are not designed for mobile phone screen. Perhaps, a QR code on the injectable box (or ideally on all medicine boxes) that could take me straight to the mobile friendly version of PI is	
Are there certain areas of the PI that you would find valuable to maintain as a hard copy package insert?	
No. Perhaps boxed warnings and pregnancy warnings (D and X) could be printed on the box.	
Additional information or suggestions	
Nowadays that many Australians have learnt how to use QR codes, perhaps mandating QR codes on all medicine boxes that would take health professionals straight to the mobile friendly version of TGA-approved PIs with one or two clicks, and consumers to the mobile friendly version of TGA-approved CMIs, seems to be a smarter substitute for printed package inserts and millions of sheets of paper wasted every year in Australia for CMI printing.	
Attachment, if any	
Not Answered	

Response Id
ANON-3A9P-AQAV-6
Submitted date
9/3/2022 9:57:33 AM

Name	Kim
Email address	
Organisation	
Respondent type	I am an interested medicine consumer
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response
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?	
It is easily accessible and not easily deleted or tampered with.	
What areas of the PI do you find particularly valuable in a package insert?	
Ingredients and all side effects.	
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?	
Sometimes I would go online and go to the manufacturer.	
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?	
Additional information or suggestions	
I think that a concrete source of information suggests a more reliable source, given that online information can be easily adjusted depending on agendas within the political and health arenas.	
Attachment, if any	
Not Answered	
Response Id	
ANON-3A9P-AQAY-9	
Submitted date	
9/3/2022 1:34:53 PM	

Name	
Email address	
Organisation	
Respondent type	I am a sponsor
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response anonymously
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?	
Additional information or suggestions	
<p>██████████ supports the removal of the PI as a hard copy document from boxed injectables. An alternative is to use a QR code on the carton which links to the TGA PI site.</p>	
Attachment, if any	
Not Answered	
Response Id	
ANON-3A9P-AQA6-6	
Submitted date	
9/5/2022 2:10:27 PM	

Name	Sean
Email address	
Organisation	Metro South Health - Princess Alexandra Hospital
Respondent type	I am a healthcare professional
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response
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?	
I don't usually find it useful.	
What areas of the PI do you find particularly valuable in a package insert?	
Only the IV preparation/administration instructions if not available on web based platform	
What areas of the PI do you not find valuable in a package insert?	
Everything except the above	
Do you use other resources to access information about the boxed injectable?	
AIDH, MIMS, Micromedex	
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?	
AIDH, MIMS, Micromedex	
Can you easily find the PI on the TGA website?	
via MIMS yes	
Are there certain areas of the PI that you would find valuable to maintain as a hard copy package insert?	
Perhaps a 2D barcode on the box that links to the PI would be reasonable	
Additional information or suggestions	
Replace the package printout with a 2D barcode that links to the PI	
Attachment, if any	
Not Answered	
Response Id	
ANON-3A9P-AQAD-M	
Submitted date	
9/6/2022 9:55:26 AM	

Name	
Email address	
Organisation	
Respondent type	I am a sponsor
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response anonymously
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?	
Specific Instructions for Use are helpful	
What areas of the PI do you not find valuable in a package insert?	
The size of the document	
Do you use other resources to access information about the boxed injectable?	
Electronic Product Information	
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?	
TGA website or Sponsor website	
Can you easily find the PI on the TGA website?	
Not with the new TGA portal, but yes these can be located on the TGA website	
Are there certain areas of the PI that you would find valuable to maintain as a hard copy package insert?	
Instructions for Use, only if dilution or reconstitution is required.	
Additional information or suggestions	
Suggest only IFU for those that require special instructions, dilution, reconstitution.	
Attachment, if any	
Not Answered	
Response Id	
ANON-3A9P-AQAX-8	
Submitted date	
9/6/2022 4:57:20 PM	

Name	
Email address	
Organisation	
Respondent type	I am a healthcare professional
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response anonymously
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?	
<p>electronic resources available online through the hospital/personal subscription including</p> <ul style="list-style-type: none"> - Australian Injectable Drug Handbook - RCH Paediatric Injectable Guidelines - Australian Medicines Handbook & Children's Dosing Companion - MIMS (for the PI if ne 	
Can you easily find the PI on the TGA website?	
<p>I would not personally use the TGA website to find a PI UNLESS search engine results are directed toward the TGA ebs page.</p> <p>On review on the updated layout of the TGA website, the process to find a PI is cumbersome (but I imagine most users would not sear</p>	
Are there certain areas of the PI that you would find valuable to maintain as a hard copy package insert?	
<p>Personally no in general, but can appreciate other health professional would find an abbreviated PI useful - I observe nurse will refer to the PI (If available) in preference to searching electronic resources which likely reflects time constraints/compute</p>	
Additional information or suggestions	
<p>If the consideration is for inclusion of an abbreviated PI in boxed injectables, I would suggest a new PI layout that focuses on ensuring timely retrieval of information for healthcare professionals, then simply allow Sponsors to exclude sections to provide an abbreviated version. The current PI layout does not allow for easily retrieval of information, particularly, when sub headers don't stand out for the user i.e. administration instruction contained in the 'Dose and Method of Administration Instructions' section.</p> <p>I would be supportive of Sponsors using the layout of dedicate resource providers i.e. AIDH, for a single page PI/monograph for inclusion i.e. use the same format for the information presented by the dedicated resources, but contents would be aligned with the PI for specific product without information related to other brands or alternate/'non approved' administration instructions</p>	
Attachment, if any	
Not Answered	

Response Id
ANON-3A9P-AQAM-W
Submitted date
9/9/2022 12:45:28 PM

Name	
Email address	
Organisation	
Respondent type	I am a healthcare professional
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response anonymously
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?	
I don't think that a PI in injectables is necessary	
What areas of the PI do you find particularly valuable in a package insert?	
The most useful aspects from a practical perspective would be dilution and administration details	
What areas of the PI do you not find valuable in a package insert?	
With the availability of electronic references and sources of information, all of it is becoming redundant	
Do you use other resources to access information about the boxed injectable?	
Yes - AIDH, MIMS, AMH etc	
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?	
AIDH, MIMS, AMH	
Can you easily find the PI on the TGA website?	
Not usually the site I would access to look for this information	
Are there certain areas of the PI that you would find valuable to maintain as a hard copy package insert?	
No	
Additional information or suggestions	
Attachment, if any	
Not Answered	
Response Id	
ANON-3A9P-AQAC-K	
Submitted date	
9/12/2022 11:56:19 AM	

Name	Leanne
Email address	
Organisation	Australian College of Nurse Practitioners
Respondent type	I am representing a group of healthcare professionals
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response
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?	
Hard copies in boxes can be useful when dosage or administration needs to be confirmed or checked and there is no other readily accessible source of information	
What areas of the PI do you find particularly valuable in a package insert?	
Items 1-4 only, Name, Composition, Form and Clinical Particulars	
What areas of the PI do you not find valuable in a package insert?	
5 and 7-10 inclusive, these can be accessed through other resources as needed, unless there are specific warnings. Item 6 - particulars - could be included only if there are specific warnings, etc.	
Do you use other resources to access information about the boxed injectable?	
Members of our organisation use a wide variety of electronic sources of information, and in some cases, paper based information.	
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?	
Many of our members primarily access information through clinical software and associated databases	
Can you easily find the PI on the TGA website?	
Yes	
Are there certain areas of the PI that you would find valuable to maintain as a hard copy package insert?	
1-4, plus 6 'as needed'	
Additional information or suggestions	
An abbreviated PI would be useful to ensure safety and minimise waste.	
Attachment, if any	
Not Answered	
Response Id	
ANON-3A9P-AQA4-4	
Submitted date	
9/12/2022 11:13:48 PM	

Name	
Email address	
Organisation	
Respondent type	I am a healthcare professional
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response anonymously
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?	
If the patient has questions in relation to the injectable I access information through the Australia Immunisation Handbook and may choose to print out the CMI or PI from the TGA website if it would be helpful for the patient. This information is more lik	
Can you easily find the PI on the TGA website?	
Yes, very easily	
Are there certain areas of the PI that you would find valuable to maintain as a hard copy package insert?	
No	
Additional information or suggestions	
Attachment, if any	
Not Answered	
Response Id	
ANON-3A9P-AQAZ-A	
Submitted date	
9/14/2022 5:30:52 PM	

Name	
Email address	
Organisation	
Respondent type	I am a healthcare professional
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response anonymously
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?	
I have previously worked in an oncology day unit where the PI information handout was used/checked by nursing staff when administering any injectable medicine.	
What areas of the PI do you find particularly valuable in a package insert?	
Administration guides Dosage	
What areas of the PI do you not find valuable in a package insert?	
NA	
Do you use other resources to access information about the boxed injectable?	
If it cannot be found on the PI we will look online at MIMS or AMH for further instruction.	
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?	
Additional information or suggestions	
Attachment, if any	
Not Answered	
Response Id	
ANON-3A9P-AQFR-7	
Submitted date	
9/14/2022 5:33:33 PM	

Name	Tiernan
Email address	
Organisation	St Vincent's Hospital Lismore
Respondent type	I am a healthcare professional
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response
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?	
The TGA website where all relevant information (and more) is available in a more readable format (larger font), or eMIMS and other resources.	
Can you easily find the PI on the TGA website?	
Yes. A cursory google search including the words 'TGA' with the drug will also reveal any available information.	
Are there certain areas of the PI that you would find valuable to maintain as a hard copy package insert?	
Not at all.	
Additional information or suggestions	
I believe the benefits to cost and the environment through removing the PI are significant, and far outweigh any benefits.	
Attachment, if any	
Not Answered	
Response Id	
ANON-3A9P-AQFH-W	
Submitted date	
9/14/2022 6:28:34 PM	

Name	
Email address	
Organisation	
Respondent type	I am a healthcare professional
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response anonymously
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?	
Often the hard copy PI has more information in than online resources, especially information regarding the administration of the medication. I also find the way the information is organised easier to navigate and allows me to find the information I need quickly. Often I need to view multiple online resources to get the information I need.	
What areas of the PI do you find particularly valuable in a package insert?	
I particular find the administration section very useful. It provides information on how the product should be prepared for administration.	
What areas of the PI do you not find valuable in a package insert?	
I don't particular find the dosage section of the PI useful. Often the dosage written doesn't follow the guidelines that recommended.	
Do you use other resources to access information about the boxed injectable?	
Yes I use the Australian injectable drugs handbook, the handbook of injectable drugs, micromedex, martingale and MIMs online.	
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?	
I use online resources such as MIMs and the Australian Injectable Drugs Handbook.	
Can you easily find the PI on the TGA website?	
Yes but it takes a few steps to get to the PI. I often find that I need to go through multiple links within TGA website to find it. I generally avoid using the TGA website because I find it too time consuming when I can use other resources quickly.	
Are there certain areas of the PI that you would find valuable to maintain as a hard copy package insert?	
Defiantly the administration and preparation section of the PI	
Additional information or suggestions	
The way the PI is folded in the box can be difficult to refold making it harder to put it back if needed. A similar way to fold it would be great. Sometimes it can be hard to read as the paper is so thin the writing on both sides can be transparent. Maybe using a bit thicker paper or single sided may be better.	
Attachment, if any	
Not Answered	
Response Id	
ANON-3A9P-AQFK-Z	
Submitted date	
9/14/2022 8:00:26 PM	

Name	
Email address	
Organisation	
Respondent type	I am a healthcare professional
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response anonymously
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?	
IT issues and access to computer sometimes limited where the medication is being administered. I prefer backup source of information available for health professionals to refer to advice on how to prepare and administer, rather than guessing or continuing bad practice due to not having source of information available at the time of administration.	
What areas of the PI do you find particularly valuable in a package insert?	
Preparing medication Administering medication Contraindications can be useful for quick reference but doesn't need to be available at the point of administering (should have been screened before the point of administration).	
What areas of the PI do you not find valuable in a package insert?	
Clinical data Mechanism of action Pharmacokinetics/dynamics Indications Side effects Storage	
Do you use other resources to access information about the boxed injectable?	
PI on TGA website AMH Injectable handbook MIMS / AusDi Organisational guidelines	
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?	
TGA website AMH Organisational guidelines	
Can you easily find the PI on the TGA website?	
Yes	
Are there certain areas of the PI that you would find valuable to maintain as a hard copy package insert?	
How to prepare dose How to administer dose	
Additional information or suggestions	
Attachment, if any	
Not Answered	

Response Id
ANON-3A9P-AQFE-T
Submitted date
9/15/2022 4:31:23 AM

Name	
Email address	
Organisation	
Respondent type	I am a healthcare professional
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response anonymously
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?	
Administration instructions without the need of technology. They also prompt me to read the PI if I am unsure of how to use the product. They also include the monitoring points and information on how to make up that specific product.	
What areas of the PI do you find particularly valuable in a package insert?	
Instructions for making up the product. Administration instructions. any specific monitoring to complete. Lastly, the constituents of the product in the case of allergy checks	
What areas of the PI do you not find valuable in a package insert?	
Storage instructions if they do not differ from the external packaging. I can see the benefits from each section when individually assessed.	
Do you use other resources to access information about the boxed injectable?	
Australian Injectable handbook. MIMS. AMH	
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?	
Either through the PI included in the packaging or via the full PI on MIMS. I also use the Australian Injectable handbook if required	
Can you easily find the PI on the TGA website?	
Yes, it is just a matter of using the TGA's search bar.	
Are there certain areas of the PI that you would find valuable to maintain as a hard copy package insert?	
Precautions, Making up instructions, Administration instructions and specific monitorings	
Additional information or suggestions	
Attachment, if any	
Not Answered	
Response Id	
ANON-3A9P-AQFP-5	
Submitted date	
9/15/2022 10:07:05 AM	

Name	Peter
Email address	
Organisation	Collie Pharmacy Group
Respondent type	I am a healthcare professional
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response
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?	
Provides a quick reference in my clinic room, or preparation room. Most info is online now and it saves me having to switch between my admin windows and online texts	
What areas of the PI do you find particularly valuable in a package insert?	
route of admin, dosing info, side effect profile, frequency of admin, drug disease interactions, pregnancy, breast feeding, a full disclosure of contents, if its halal and gluten free. Often the patient wants to see this before admin how to snap open the	
What areas of the PI do you not find valuable in a package insert?	
pharmacokinetics	
Do you use other resources to access information about the boxed injectable?	
not often	
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?	
Additional information or suggestions	
larger print font - even with reading glasses its often too small.	
Attachment, if any	
Not Answered	
Response Id	
ANON-3A9P-AQFF-U	
Submitted date	
9/15/2022 12:30:36 PM	

Name	
Email address	
Organisation	
Respondent type	I am a sponsor
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response anonymously
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?	
From the feedback we have received from HCPs a hard copy PI in the box is not useful. Products prepared for surgery are removed from their packaging by someone other than the HCP performing the surgery and discarded.	
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?	
The company provides a Medical Information service. Questions submitted are responded to within 24 hours. The electronic PI access via the TGA website is efficient, convenient and user friendly.	
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?	
Via the TGA's website. Additional queries can be submitted directly to the company if necessary.	
Can you easily find the PI on the TGA website?	
Yes, this service is convenient, efficient and user friendly.	
Are there certain areas of the PI that you would find valuable to maintain as a hard copy package insert?	
Additional information or suggestions	
Removing the need for a hard copy PI in boxed injectables will significantly reduce waste associated with printing. For NEW injectable medicines, a hard copy PI may be valuable for the first year or two depending on the estimated volumes of product supplied in that period.	
Attachment, if any	
Not Answered	
Response Id	
ANON-3A9P-AQFY-E	
Submitted date	
9/15/2022 3:53:00 PM	

Name	
Email address	
Organisation	
Respondent type	I am an agent representing a sponsor
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response anonymously
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?	
Additional information or suggestions	
<p>As a manufacturer and sponsor, including the paper PI inside the box of an injectable product should not be mandatory and use e-labelling only would be preferable because :</p> <ol style="list-style-type: none"> 1) The main argument is that his medicines are for professional use only. In fact, these people are aware of all the information about the medicines. In addition, they all have access to the Internet and can therefore easily consult the latest approved documents if necessary. 2) E-labeling can permit for patient to have access to the package insert too where as patients could not have access to package insert. 3) Finally, for issues related to the pharmaceutical industry and supply, it is preferable to have only electronic labelling; this allows for easier and faster management. 	
Attachment, if any	
Not Answered	
Response Id	
ANON-3A9P-AQFW-C	
Submitted date	
9/26/2022 2:36:52 PM	

Name	
Email address	
Organisation	
Respondent type	I am a sponsor
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response anonymously
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?	
We would like to clarify this consultation should not be specific to a boxed injectable (pre-filled syringe (e.g. vaccine)), but to any injectable product that is administered by a healthcare professional and not self-administered. We support the re	
Can you easily find the PI on the TGA website?	
Yes, the TGA website search function is an easy way to navigate to the current PI. The use of electronic links, such as a QR code on the package/carton could also make the PI readily available.	
Are there certain areas of the PI that you would find valuable to maintain as a hard copy package insert?	
All information should be made electronic, and no hard copy package insert should be required for the reasons mentioned above.	
Additional information or suggestions	
We would like to clarify this consultation should not be specific to a boxed injectable (pre-filled syringe (e.g. vaccine)), but to any injectable product that is administered by a healthcare professional and not self-administered. We support the removal of the PI as a package insert and agrees that the provision of the PI electronically on the TGA website is sufficient. Some PIs are greater than 35 pages and having such a large package insert adds weight, takes up unnecessary box space and is harder to read in small fonts. In addition, making changes to the PI and incorporating these changes in the packaging takes time. The electronic PI on the TGA website is always current and incorporates all new safety and efficacy information that may not be in the current hard copy package insert. Yes, the TGA website search function is an easy way to navigate to the current PI. The use of electronic links, such as a QR code on the package/carton could also make the PI readily available. All information should be made electronic, and no hard copy package insert should be required for the reasons mentioned above.	
Attachment, if any	
Not Answered	

Response Id
ANON-3A9P-AQFU-A
Submitted date
9/27/2022 4:37:04 PM

Name	
Email address	
Organisation	
Respondent type	I am an agent representing a sponsor
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response anonymously
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?	
Additional information or suggestions	
<p>The mandatory provision of the PI in the boxed injectables is out dated. Injectable products are prescription medicines and are administered by a healthcare professional or under the guidance of a professional. The majority of Healthcare professionals at the bedside, who are unsure about the use of the injectable product will use google to find the dosage and administration information as the box with the instruction may still be in the pharmacy. Others use clinical practice software to obtain the warning and contraindications as well other relevant information prior to prescribing the product. For injectable product that are uniquely administered or when patients or a carer giver administers an injectable product, the sponsor often provides a more detailed leaflet with graphics to assist the user in addition to the PI. The removal of the mandatory aspect of this requirements will not prevent sponsors from providing a PI or instructions for use with the product, if the product requires that level of detail to be administered correctly.</p> <p>In addition for unique products on line tutorials, and electronic information is far more accessible and instructive than the hardcopy PI in in tiny 8 point font.</p>	
Attachment, if any	
Not Answered	
Response Id	
ANON-3A9P-AQFT-9	
Submitted date	
9/27/2022 4:40:46 PM	

Name	Senan
Email address	
Organisation	Juno Pharmaceuticals Pty Ltd
Respondent type	I am a sponsor
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response
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?	
NA I am a sponsor not a health care professional.	
What areas of the PI do you find particularly valuable in a package insert?	
NA I am a sponsor not a health care professional.	
What areas of the PI do you not find valuable in a package insert?	
NA I am a sponsor not a health care professional.	
Do you use other resources to access information about the boxed injectable?	
NA I am a sponsor not a health care professional.	
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?	
TGA's Ebs website	
Can you easily find the PI on the TGA website?	
Yes, very easily	
Are there certain areas of the PI that you would find valuable to maintain as a hard copy package insert?	
NA I am a sponsor not a health are professional.	
Additional information or suggestions	
Why is a boxed injectable defined as "A boxed injectable is a pre-filled syringe that comes packaged in a box alongside the PI for that medicine." Other boxed injectable (eg anti-infective) are also boxed injectables but usually supplied in vials or ampoules. Please extend the definition to include all boxed injectables including packs that contain vials and ampoules.	
Attachment, if any	
Not Answered	
Response Id	
ANON-3A9P-AQ2K-C	
Submitted date	
10/4/2022 11:37:43 AM	

Name	Tracey
Email address	
Organisation	Australian Rheumatology Association
Respondent type	I am representing a group of healthcare professionals
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response
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?	
The hard copy PI is currently used in the hospital and primary care setting for health professionals, particularly nursing staff who may be administering the medication and who are not familiar with the specific administration or reconstitution instructions. In hospitals, it is convenient to have the hard copy available in the medication trolley during the administration rounds rather than referring to a computer. In primary care, it is convenient to have the hard copy available in the box for the same reason.	
What areas of the PI do you find particularly valuable in a package insert?	
<ul style="list-style-type: none"> • Double checking appropriate dosing (weight/renal impairment) • Administration and reconstitution instructions • Storage requirements post reconstitution • Potential adverse effects/monitoring requirements 	
What areas of the PI do you not find valuable in a package insert?	
<ul style="list-style-type: none"> • Qualitative and quantitative composition • Pharmaceutical form • Clinical trial data • Pharmacological properties • Pharmacokinetic properties • Preclinical safety data 	
Do you use other resources to access information about the boxed injectable?	
<ul style="list-style-type: none"> • SHPA Injectable Drugs Handbook • CIAP • AMH • MIMS 	
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?	
The electronic copy is currently used in some GP Practices, community pharmacies, specialist Rheumatologist practices and private infusion clinics. This is usually accessed via the TGA website or eMIMS.	
Can you easily find the PI on the TGA website?	
Yes, the TGA website is very intuitive and easy to locate the PI for medications when required.	
Are there certain areas of the PI that you would find valuable to maintain as a hard copy package insert?	
For the practices that currently utilise the PI electronically, there would be no additional areas of the PI that would be also required as a hard copy.	
Additional information or suggestions	
The Australian Rheumatology Association (ARA) and its members consider climate change and the associated health impacts to be a health emergency that impacts health professionals, patients, and the community. The ARA supports the removal of the PI package insert in an effort to reduce	

carbon emissions, providing patient safety is not compromised. The ARA recognises that this may result in a change in practice in some health care settings, however the positive impact on reducing the carbon footprint within health care would be encouraged.

Attachment, if any

Not Answered

Response Id

ANON-3A9P-AQ2G-8

Submitted date

10/4/2022 11:38:06 AM

Name	Zubin
Email address	
Organisation	SERVIER LABORATORIES (AUST.) PTY. LTD.
Respondent type	I am a sponsor
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response
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?	
TGA website Guildlink	
Can you easily find the PI on the TGA website?	
Yes.	
Are there certain areas of the PI that you would find valuable to maintain as a hard copy package insert?	
No. The PI's are easily accessible online and a physical copy isn't required.	
Additional information or suggestions	
N/A	
Attachment, if any	
Not Answered	
Response Id	
ANON-3A9P-AQ22-K	
Submitted date	
10/4/2022 11:53:43 AM	

Name	Hemlata
Email address	
Organisation	COD Research Pvt. Ltd
Respondent type	I am a healthcare professional
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response
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?	
Immediate access to product related information	
What areas of the PI do you find particularly valuable in a package insert?	
Adverse Drug reaction section	
What areas of the PI do you not find valuable in a package insert?	
None	
Do you use other resources to access information about the boxed injectable?	
Yes, medical journal and books and other regulatory authority website for same product label	
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?	
Additional information or suggestions	
PI can be updated based on global safety information in order to harmonize the safety information on PI	
Attachment, if any	
Not Answered	
Response Id	
ANON-3A9P-AQ2S-M	
Submitted date	
10/4/2022 3:09:01 PM	

Name	Sylvia
Email address	
Organisation	Novartis Pharmaceuticals Australia Pty Ltd
Respondent type	I am a sponsor
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response
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?	
While we understand this series of questions are important and aimed at healthcare professionals (HCPs), we feel it would have been fairer and appropriate to provide some context and background information on the case for change which they may not be aware of, or have a full appreciation of the consequences. HCPs may not necessarily understand the complexities and limitations of maintaining a pack insert in relation to the risk of outdated safety information and the potential supply constraints that including a pack insert can cause. Armed with this important background information and context, we feel HCPs would have been in a much better position to have a well informed and more balanced position on this particular question.	
What areas of the PI do you find particularly valuable in a package insert?	
This question is for HCPs	
What areas of the PI do you not find valuable in a package insert?	
This question is for HCPs	
Do you use other resources to access information about the boxed injectable?	
This question is for HCPs	
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?	
This question is for HCPs	
Can you easily find the PI on the TGA website?	
Yes for sponsor	
This question is for HCPs	
Are there certain areas of the PI that you would find valuable to maintain as a hard copy package insert?	
Novartis' strong preference would be to remove the PI altogether as a pack insert, as it is of limited use to the patient; the fact that it can be readily accessed online and is often subject to frequent revisions that increase the risk of constraints on	
Additional information or suggestions	
<p>Novartis acknowledges the importance of having comprehensive information available for therapeutic products, however, believes inclusion of the full PI as a printed pack insert is not practical for 2 main reasons:</p> <ol style="list-style-type: none"> 1. Currency of Information 2. Supply chain issues <p>1. Currency of Information Currency of Product Information has long been a challenge for industry to manage overseas imports containing a printed pack insert.</p> <p>Sponsors have an obligation to ensure provision of the most up to date current Product Information to HCPs. Electronic distribution of PI ensures the most current version of the PI is available. The PI in the pack will not be updated at the same time as the electronic version also creating two versions of the PI in the market.</p>	

A similar situation was demonstrated with the undertaking of electronic Consumer Medicine Information (CMI) where the most current version of the CMI is available electronically at the point of dispense, on the TGA website or on a sponsor's website. The majority of sponsors have also removed the hard copy CMI from the pack due to issues of currency, keeping up with the updates and the need for product recall in the event of important safety updates creating enormous environmental impact and stock wastage. This presents a strong precedence for change.

Product Information can be quite long with increasing length over a product's lifecycle. Novartis's COSENTYX[®] for example can barely fit the full Product Information at 8-point font on a double-sided leaflet. At this size, it can create administration errors and be challenging to find the required information with urgency.

2. Supply Chain Issues

As the Product Information is a live document, this is an equally burdensome exercise for production sites to maintain demanding supply timelines with safety updates, changes to indications or any other changes to PI.

A combination of COVID-19 and the Ukraine war for example has seen production lead times increase to up to 12 weeks to implement new artwork components. There are also other supply chain factors to consider which impact our ability to pivot to a new leaflet in a timely manner; such as current stock in market, minimum order quantities, potentially long shelf-life and forecasting accuracy.

The COVID-19 pandemic has demonstrated Australia's vulnerability to a medicines supply chain that is heavily impacted by its isolated geography and disruptions overseas that are difficult to predict or anticipate. The introduction of a country-specific pack insert to the production process at an overseas site can increase the risk of stock shortages and furthermore can be a barrier to accepting overseas stock that would stand to remediate a shortage in Australia.

In the case of first launch stock where we are limited by the date of ARTG inclusion at the end of the PI document, we are met with unnecessary launch hurdles. The inequity of access to life-saving medicine for Australians compared to patients worldwide goes against the common interests of the Australian healthcare sector.

Novartis would like to put forward the positive experience of one of our launch products for relapsing multiple sclerosis (RMS), in which following TGA agreement, we received a four-month exemption to not include the PI as a pack insert for a Patient Familiarisation Program (PFP). This equated to approximately 400 patients who were granted early access upon registration to an at-home MS therapy at the peak of the COVID pandemic in 2020.

In conclusion, Novartis would urge the TGA to consider the following regarding printed PI in the pack:

- Importance of access to the most current PI for HCPs and patients.
- Importance of product availability to Australian patients and the increased complexity in maintaining current PI in packs.
- The key challenges and barriers to clinicians changing long-standing behaviours based simply on convenience and encouraging them to access the most accurate and up to date PI on-line. Many clinicians may see the paper pack insert as a simple convenience and may not be aware of burden on industry, the risk to reliable supply and not being aware of important safety updates to the PI. Clinicians need to be made aware of the important case for change beyond a perceived convenience of having a printed PI on hand and compel them to modify the way they access the PI.
- Sponsors could amend their cartons to include a QR code (via the notification pathway) which would link to the approved Product Information. In the interest of access equity, this could be the TGA website for example as not all Sponsors would utilise Guildlinks. In such a case,

Novartis would be interested to know if TGA would be willing to supply sponsors with a product specific QR code that can withstand PI revisions to remain current on the carton.

- Sponsors could amend their cartons to simply state that Product Information can be obtained from the Sponsor website, much like the case of the directions for the patient to obtain the CMI.
- Instructions for Use document could be provided in the pack as a readily available, easy to read document.

It is believed that a carefully targeted communication plan agreed by both industry and regulator will facilitate a smooth transition. The experience of other like-minded regulators should also be considered. For example, the PMDA who rolled out their guidance on the digitalisation of package inserts effective from Aug 2021.

Attachment, if any

Not Answered

Response Id

ANON-3A9P-AQ2E-6

Submitted date

10/4/2022 3:14:14 PM

Name	Ailsa
Email address	
Organisation	Amgen Australia Pty Ltd
Respondent type	I am a sponsor
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response
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?	
Not applicable. As a Sponsor, Amgen does not administer products directly to patients.	
Can you easily find the PI on the TGA website?	
Not applicable.	
Are there certain areas of the PI that you would find valuable to maintain as a hard copy package insert?	
Not applicable.	
Additional information or suggestions	
Attachment, if any	
https://consultations.tga.gov.au/tga/pi-insert-in-boxed-injectables-round-1/consultation/download_file?squid=question-2022-08-24-5206407582-filesubquestion-1661299610-08&user=ANON-3A9P-AQAQ-1	
Response Id	
ANON-3A9P-AQAQ-1	
Submitted date	
10/5/2022 9:04:08 AM	



Amgen, Inc
One Amgen Center Drive
Thousand Oaks, CA 91320-1799
805-447-1000

October 04, 2022

Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
Australia

Subject: Submission in Response to the Product Information as a Package Insert in Boxed Injectables Consultation Paper

Dear Therapeutic Goods Administration:

Amgen is a global biotechnology and pharmaceutical company based in Thousand Oaks, California, United States. We appreciate the opportunity to provide our comments on the consultation paper on *Product Information as a package insert in boxed injectables*, issued in August 2022.

Amgen Australia believes product information (PIs) should not be required to be included as a package leaflet in the boxes for injectables administered by healthcare professionals (HCPs), given alternative mechanisms available including TGA and company websites to provide users with current product information to support the safe and effective administration of products.

The obligation to include the PI within the package is applied as an administrative condition of registration for injected products as it is not a legislated requirement. Other jurisdictions, such as EU, require shorter, more user-friendly package inserts. Many countries are exploring removing the leaflets from packages for products administered in hospital settings or removing leaflets altogether. For example, in 2019, the Ministry of Health, Labour and Welfare (MHLW) in Japan introduced new regulations that officially introduced electronic labeling and is set to replace paper labeling in commercial packs for prescription drugs and medical devices. The regulations started being enforced on 1 August 2021 with a 2-year transition period towards a paperless system in July 2023. Even in Australia, we see instances where the requirement to include the entire PI has been waived such as with the COVID-19 vaccines.

Given today's technological advancements, it is rare for an HCP to not have access to a digital device (smart-phone, tablet, computer) to access the most current approved product information. The requirement for PIs to be provided electronically on the TGA website means that a trusted repository of information exists. The electronic versions are searchable and can be adjusted to improve readability and maneuverability. Amgen Australia has been working to implement ways to improve accessibility to the electronic PI, such as the inclusion of a QR code or addition of website details on the outer product packaging so that HCPs can access the current PI directly from their devices.

Pharmaceutical manufacturing processes are complex, with multiple steps for planning, procurement, production, quality control and distribution. This necessitates a significant lead time between approval of

an updated PI and the updated information in the form of a package insert reaching the end user. Updates to the label can be driven by new safety data. Given the lead time for the end user to receive the latest PI in the package due to supply chain implementation and stock already in market, the HCP accessing the PI from the package may be unaware that the safety information is not current, which could increase a drug safety risk. The electronic PI enables HCPs to refer to the most current information regarding the drug's safety profile.

Given the significant length of PIs, there are logistical challenges to generate the printed artwork that then gets folded to fit into relatively small product cartons. This results in a highly folded and difficult to read document. As mentioned in the consultation information, package configurations may need to be larger to fit the PI as a package insert leading to larger boxes that require space for storage, particularly in refrigerators and freezers where storage space may be limited. Recently, a new indication was added for an Amgen product which increased the PI length and the leaflet size enough to require a larger carton packaging configuration. More compact cartons enable easier storage and reduced carbon emissions associated with transportation, cold storage and packaging components. The potential requirement for larger cartons required to include the printed PI is inconsistent with the Australian Packaging Covenant's aims to reduce environmental impacts of consumer packaging and Amgen's sustainability goals.

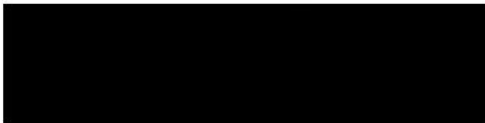
Additionally, the decision of what medicine and dosage is best for a patient is often determined prior to the package and its associated package leaflet being dispensed. This calls into question the benefit of including the PI within the product package given it is unlikely to inform prescribing decisions. The availability of electronic PIs is optimal to provide the most current information to prescribers and inform their decisions.

The consultation document suggests that the feedback sought is limited to boxed injectables in the form of a pre-filled syringe. We also encourage TGA to consider electronic PI for all injected HCP administered products, including powders and liquids which need to be prepared for injection. Injections requiring preparation before use follow the same labelling requirements as pre-filled syringes with an additional requirement specified in subsection 8(1) of Therapeutic Goods Order 91 to include the preparation steps on the label, or on a leaflet inserted into the primary pack of the medicine. To comply with the requirements of TGO 91, if the PI was removed from the package, sponsors would still be required to provide information for preparation steps for the product. For the majority of injected HCP administered products this could be achieved by including a shorter document based on the preparation and administration instructions that are infrequently updated throughout the life cycle of the product.

In summary, Amgen is in favour of removing the condition of registration to include the PI as a package insert for all injectables. Due to the manufacturing complexities, prescribers and HCPs should refer to the electronic PI for the most current information. Amgen supports industry efforts to make electronic PIs more accessible.

We look forward to the outcome of this consultation as well as the expected subsequent consultation regarding the PI as a package insert for self-administered products. We would be pleased to provide further input or clarification to any of our comments, as appropriate. The information for our local Amgen Australia contact is also provided below.

Respectfully yours,



Amgen Inc.



Amgen Australia Pty Ltd
Level 11, 10 Carrington Street
SYDNEY NSW 2000

Name	Jasmine
Email address	
Organisation	Sandoz Pty Ltd
Respondent type	I am a sponsor
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response
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?	
Additional information or suggestions	
Attachment, if any	
https://consultations.tga.gov.au/tga/pi-insert-in-boxed-injectables-round-1/consultation/download_file?squid=question-2022-08-24-5206407582-filesubquestion-1661299610-08&user=ANON-3A9P-AQ2V-Q	
Response Id	
ANON-3A9P-AQ2V-Q	
Submitted date	
10/5/2022 10:10:01 AM	

5 October 2022

RE: Public consultation on Product Information (PI) as a package insert in boxed injectables

Dear Sir/Madam,

Sandoz considers the removal of package inserts in boxed injectables as a major opportunity for improving access to information for healthcare professionals and patients. There is a significant safety impact to both healthcare professionals and patients in terms of recency of information with the long timeframes for product artwork generation from approval of PIs to packaging updates of leaflets. The move to availability of electronic PI on the health authority website supports the need for a shift to a digital-only model, focusing on quality use of medicines.

Electronic Prescribing

The Australian Healthcare System is transitioning towards an integrated digital health system. All states and territories have implemented electronic prescribing and dispensing, and the Northern Territory has plans to implement the electronic medical records system in 2023. This enables the continuity of care for patients in the in-patient and out-patient setting whereby safety information can be communicated via telehealth and additional information found in the leaflet via electronic means.

In a hospital setting, injectables that comprise of multiple dose units are often distributed to different wards where paper-based leaflets are discarded and healthcare professionals including nurses or pharmacists are not able to refer to these.

Accuracy/recency of information

The utilisation of PIs as part of a package insert poses a high risk to patients in terms of recency and accuracy of safety information due to the timeframe required for implementation. This involves the process of change management between local affiliate and the overseas manufacturing site, from the time of approval of PIs, update of the 2D artwork for leaflet approval of the artwork to be production ready, removal of the package inserts and replacement of the new leaflet as the artwork component for the boxed injectables. This takes over 6 months, depending on the frequency of production cycles for most products (and even longer for certain products) to implement distribution of current information to patients as a leaflet in product packs. In addition to the time to implement updated artwork, the product with the outdated PI is available in the market until the end of batch expiry. This results in a total of 4-5 years that a product may be available in the market with outdated safety information in the PI as a pack insert.

Further, for some products, safety information to patients and healthcare professionals are addressed in the risk management plans and routinely communicated to healthcare professionals. The inclusion of product leaflet in packs for these products may create confusion with potentially contradictory information.

Access

Further to the recency of information, there are numerous sources available to both healthcare professionals and patients to access up to date product information. This includes the TGA website (eBS), MIMS Online, Medical Director, sponsor's medical information/specialist phone lines, and patient programs which are available. For instructions for use on injectables and drug monographs, frontline healthcare professional's main key resource is the Australian Injectables Drugs Handbook which is

available as both online and as a hard copy. The product information can also be readily accessed via the TGA app MedSearch for healthcare professionals working remotely.

Environmental Concerns

The end-user's concern on whether cartons and components of a medication are recyclable is a recurring theme. The removal of a leaflet from boxed injectables reduces the requirement to handle and store the hardcopy. On average, Sandoz uses approximately 130,000 m² of paper for leaflets in boxed injectables per year. However, with the removal of these mandatory package inserts for injectables, there is a substantial reduction of approximately 90% in leaflet paper consumption which would contribute significantly to the environment.

Other concerns

Sandoz would like to take the opportunity to note that the consultation [Product Information as a package insert in boxed injectables](#) defines a "A boxed injectable is a **pre-filled syringe** that comes packaged in a box alongside the PI for that medicine". We would like to seek clarification on the definition and believe that a boxed injectable must not be limited to the presentation of a pre-filled syringe and should include other presentations such as vials and ampoules for future consultations. This is critical as vials and ampoules may be more commonly administered by healthcare professionals than a pre-filled syringe which may be intended for use by the patient.

In summary, Australia is more than ready to transition to electronic-only leaflet (PI or CMI as the case may be). The digital resources available are well established and familiar to most healthcare professionals (the target audience of a PI). With some education and targeted communication, this can be made mainstream in the interest of access to current information for the benefit of healthcare professionals, and patients and carers alike. We look forward to TGA leading the initiative with a sense of urgency expected for a change that has been in plan for over a decade with all the input and support from the stakeholder engagement required to manage this move effectively.

Yours faithfully,





Sandoz Pty Ltd

Name	
Email address	
Organisation	
Respondent type	I am a sponsor
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response anonymously
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?	
Additional information or suggestions	
Please find attached [REDACTED] response to this consultation from a sponsor's point of view. Please note that we did not respond to the previous questions in this survey, as those were directed towards HCPs.	
Attachment, if any	
https://consultations.tga.gov.au/tga/pi-insert-in-boxed-injectables-round-1/consultation/download_file?squid=question-2022-08-24-5206407582-filesubquestion-1661299610-08&user=ANON-3A9P-AQ28-S	
Response Id	
ANON-3A9P-AQ28-S	
Submitted date	
10/5/2022 11:08:55 AM	



Response to TGA Consultation: Product Information as a package insert in boxed injectable medicines.

Overview:

The Therapeutic Goods Administration (TGA) is requesting feedback on the current usage of the information included with boxed injectable medicines and whether the requirement to include a paper Product Information (PI) as a package insert in boxed injectable medicines is still relevant for those administered by health care professionals (HCPs). In Australia, the PI is currently required to be provided both in the box of injectables and as an electronic document available on the TGA website. The TGA is engaging with the industry to collect views on the usefulness of including the paper PI inside the box of an injectable product and seeking industry feedback.

Response:

wishes to thank the TGA for the opportunity to provide feedback on this topic. supports the proposal to remove the requirement for PIs to be included in injectable packs, for the reasons included below:

- The PI does not include preparation information that is relevant at the time of administration.
- Other mechanisms are available to access the PI and prescribing/administration information that does not compromise quality use of medicine.
- The benefits in logistics and downstream timing and stock management.
- Reduction in carbon footprint.
- Some other jurisdictions have implemented or are piloting electronic PI.


Providing the PI, as a package insert is NOT the only way HCPs currently have access to the PI, as the HCPs also have access to the following to refer to at the time of medicine administration:

- Clinical Information Access Portal (CIAP), which contains the electronic copy of Australian Injectable Drugs Handbook (AIDH)
- The MIMS which contains information on the medicines
- Local therapeutic guidelines (e.g. PROMPT)
- The electronic copy of the PI through the TGA website
- Regular training on how to administer an injectable medicine

Currently in addition to the sponsors providing the ePI through the TGA website, the package labelling includes a statement to direct HCPs to refer to the PI. There is also an option that exists, to provide access to the ePI by including a 2D barcoding on the packaging, which enables HCPs to scan these 2D barcodes at the time of administration (at the bedside). These methods can reduce errors, as the HCPs will always have access to the latest copy of the PI.

There is a time lag between when changes are made to a PI and when the changes can be printed and incorporated into the manufacturing cycle for products, posing logistical challenges. This could pose issues, as the HCPs may not always have access to the latest PI package insert.

Removing the need to provide the PI package insert can reduce medicine shortages, recalls and supply delays due to the reasons provided in the paragraphs above relating to printing time.




Having the PI as an electronic document only, will also reduce the environmental/carbon foot print and reduce wastage. Including the PI as a package insert requires additional resource such as printing ink, large volumes of paper, larger sized packaging to fit the insert, increased packaging weight and therefore more space required for transportation, requiring more vehicles, increased fuel consumption and storage space.

The usage of PI package insert has been studied by surveys in countries such as Belgium and US. A recent survey conducted in 36 EU countries by the European Association of Hospital Pharmacists (EAHP), on the use of product information (paper vs electronic PI in hospital setting), showed that the adoption of ePI could make access to product information easier for healthcare professionals. Almost 60% of respondents reported that healthcare professionals use the digital version when they wish to obtain information on a medicine. Hospital pharmacists (93%) are those most frequently using the digital format of the product information followed by physicians (71%) and nurses (43%). The results of the survey showed the need to integrate future looking and practical proposals for an ePI in the upcoming revision of the EU pharmaceutical legislation.^[1,2]

In some other jurisdictions (e.g. Singapore, Belgium and Luxembourg), local pilots commenced to only provide electronic PI to HCPs. A local pilot in Belgium and Luxembourg, which was coordinated by the Belgian innovative pharma industry trade association: 'pharma.be' was carried out. A derogation was approved by the EU commission in December 2017 to remove the paper leaflet for Centrally Authorized product for hospital use only and for a limited duration of 2 years (01-Aug-2018 to 31-Jul-2020). The results were measured via surveys sent out to hospital pharmacies and participating companies at the start of the project and after 1 and 2 years. Based on the positive T12months survey results the EU Commission (and national HAs) approved a second call for candidates and an extension of 2 years, until 31-Jul-2022. Recently, EC also approved a third prolongation of the project and opened a call for new candidate products to be included. Currently, Swissmedic is also working on a positioning paper for QR code/DMC code relating to secondary package leaflets.^[1,2,3]

Removing the need to include the PI, as a package insert will not affect home administration of injections, as the PI is only intended for HCPs and not for patients to use. Home administration situations are managed differently by providing patients with additional information and training on how to administer the medicine.

From a product safety point of view,  is supportive of the proposal to remove PI from injectable packs. The currency of safety information is actually a benefit if there is no potential for “outdated” paper documents in injectable medicine packs.

Links to references:

<https://www.efpia.eu/news-events/the-efpia-view/statements-press-releases/electronic-product-information-new-report-shows-it-is-time-to-move-from-principles-to-action/#> (1)

<https://www.eahp.eu/practice-and-policy/ehealth-and-mhealth/ePIsurvey> (2)

<https://pharma.be/fr/politique-de-confidentialite> (3)

Name	Michelle
Email address	
Organisation	The Pharmacy Guild of Australia
Respondent type	I am representing a group of healthcare professionals
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response
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?	
Additional information or suggestions	
Attachment, if any	
https://consultations.tga.gov.au/tga/pi-insert-in-boxed-injectables-round-1/consultation/download_file?squid=question-2022-08-24-5206407582-filesubquestion-1661299610-08&user=ANON-3A9P-AQ2Q-J	
Response Id	
ANON-3A9P-AQ2Q-J	
Submitted date	
10/5/2022 12:10:48 PM	



The Pharmacy
Guild of Australia

SUBMISSION

Product Information as a package insert in boxed injectables

Date 5 October 2022

National Secretariat

Level 2, 15 National Circuit, Barton ACT 2600
PO Box 310, Fyshwick ACT 2609
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www.guild.org.au



Ref: SP1000-84017067-2019

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Guild response to consultation questions.....	2
Option 1: I use and refer to the hard copy PI that is included with boxed injectables administered by healthcare professionals.....	2
Option 2: I do not use or refer to the PI that is included in boxed injectables administered by a healthcare professional.....	2
Additional consultation question	4

GUILD RESPONSE TO CONSULTATION QUESTIONS

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?

No response. We are responding instead to Option 2.

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

No response. We are responding instead to Option 2.

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

No response. We are responding instead to Option 2.

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

No response. We are responding instead to Option 2.

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 injectables?

Community pharmacists can currently access information applicable to boxed injectables not only through the PI included in the packing, but also through medicines information databases such as the Monthly Index of Medical Specialties (MIMS) and AusDI, as well as the Australian Injectable Drugs Handbook, Australian Medicines Handbook (AMH) and the TGA website.

Can you easily find the PI on the TGA website?

The PI of most products, including boxed injectables, can be found on the TGA website by using the search function on a health product, however the process of finding PI information on the TGA website is cumbersome. We recommend that the TGA removes the disclaimer/licence acceptance requirement from their eBusiness Service webpage.

The TGA advises on their website that not all PIs and CMI are available, therefore the PIs for all boxed injectables would need to be available on the TGA website if PI hard copies cease to be included in the packaging.

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

Valuable inclusions in hard copy package inserts are:

- The approved name (generic name) of the active ingredient(s),
- Approved therapeutic indications,
- Dose information for different ages or weights,
- Method of administration (IM, SC, etc),
- Reconstitution instructions,
- Contraindications,
- Pharmaceutical properties including incompatibilities,
- Clear directions of how to use the product, including a graphic/visual demonstration,
- Storage conditions and
- Any special precautions for disposal.

This would provide pharmacists, nurses and doctors with access to information if the online resources were inaccessible at any time, as well as having the information immediately available at the point of care prior to the administration of the injectable medication.

Clear directions of how to use the product, including a graphic/visual demonstration, are particularly useful to include in hard copy package inserts, particularly when the health provider is time poor. It can be quicker to refer to such an insert than searching for the online PI.

We note that the consultation is specifically for the boxed injectable products administered by healthcare professionals, however, the TGA should also consider the situations where such injections may also be available for consumer use. As an example, consumers may purchase adrenaline or naloxone ampoules for use on someone in their care. In these examples, while there are more consumer-friendly products available (autoinjector pens or nasal spray) for use by a non-healthcare professional as well, there is nothing prohibiting use of ampoules and supply disruptions for the consumer-friendly products may mean consumers can only obtain the ampoules. In such cases, clear directions for use and a graphic/visual demonstration are useful for the consumer as well as for the health professional explaining these products to them. In these instances, a Consumer Medicines Information may be more useful.

We note that careful consideration should be given to the amount of content included in both hard copy PIs and CMIs for boxed injectables, as they are often quite dense, with small font and a large layout that tends not to be user-friendly. Regarding CMIs, a simplified version should be included in boxed injectables with instructions for use and other key information, but it should not necessarily include all the legal requirements of a standard CMI.

Additional consultation question

Please provide any additional information or suggestions:

Hard copy pack inserts such as PIs and CMLs may not be up to date, which may lead to incorrect or outdated information being provided to health professionals and patients. It would be beneficial if packages included a barcode or QR code that can be easily scanned to quickly access an online, up-to-date version of the information when needed.

We note the TGA's comment that removing the PI as a package insert could reduce paper waste and allow package sizes to be smaller. This would benefit both pharmaceutical manufacturers and health professionals as smaller packages would be more efficient for storing in refrigerators and on shelves. However, it is essential that all packaging of boxed injectables not only complies with Therapeutic Goods Order 91 (TGO 91), but also provides a minimum space of 80x40mm for pharmacists to affix a dispensing label.

We reiterate our suggestions above, to:

- a) Ensure that all PIs and CMLs are available on the TGA's website;
- b) Include barcodes or QR codes on boxed injectables that link to the online PI, and;
- c) Retain certain elements of the PI as a hard copy package insert, including graphic/visual instructions for use.

We also recommend that the TGA primarily consider feedback from health practitioners who administer boxed injectables, including nurses and pharmacists, especially early-career health professionals, in this consultation to accurately assess the use in practice of PI package inserts.

The Pharmacy Guild of Australia (the Guild) is the national peak organisation representing community pharmacy. It supports community pharmacy in its role of delivering quality health outcomes for all Australians. It strives to promote, maintain, and support community pharmacies as the appropriate providers of primary healthcare to the community through optimum therapeutic use of medicines, medicines management and related services. Community pharmacies are the most frequently accessed and most accessible health destination, with over 358.4 million individual patient visits annually and the vast majority of pharmacies open after-hours, including on weekends.¹

¹ PBS Date of Supply, Guild Digest 2022

Name	GlaxoSmithKline Australia Pty Ltd
Email address	
Organisation	GlaxoSmithKline Australia Pty Ltd
Respondent type	I am a sponsor
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response
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?	
<p>In the experience of the Sponsor, healthcare professionals are typically familiar with accessing online information, specifically with the use of prescribing software, online tools such as calculators, and registries such as Australian Immunisation, Medicare and the PBS. This experience gives them a sound understanding of how to access digital copies of PI's through the number of channels where they are currently available.</p> <p>However, access to this information can be predicated on a sufficiently effective internet connection which is not always available, especially in regional locations. In these instances, a package insert of the PI may be beneficial. Despite this, since a large amount of non-injectable products do not contain package insert PI's, there may already be measures in place to allow access to this information in offline prescribing settings.</p>	
What areas of the PI do you find particularly valuable in a package insert?	
<p>PI's provide crucial information to healthcare professionals such as indication, dosing, instructions for use, as well as adverse events, contraindications, warnings and precautions. Providing this information in the form of a package insert is important</p>	
What areas of the PI do you not find valuable in a package insert?	
<p>GSK acknowledges that packaging requirements of injectable products, which can often have PI's exceeding 40 pages, can lead to small, although regulatory compliant, font sizes in the package insert version of the PI. This, in addition to the fact that the paper version can often have a large number of paper folds, can lead to legibility issues for some users.</p> <p>As a result, healthcare professionals may have difficulty quickly reading the document, and in doing so there is a potential to miss relevant factors which may pose safety risk to patients.</p> <p>The digital PI format allows the written material to be presented in larger font sizes, and mean healthcare professionals can digitally 'search' through the document to quickly identify potential safety concerns for patients.</p> <p>As well as this, the digital format gives the opportunity for Sponsors to include photo and video content specific to the use of the product (for example a demonstration of method of use), increasing the safety and quality use of the medicine.</p>	
Do you use other resources to access information about the boxed injectable?	
<p>Yes. Please see response to next question "Where do you access information about the boxed injectable?"</p>	
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?	
<p>GSK provides both PI and CMI documents through a wide variety of digital platforms in addition to the package insert for injectable products. GSK provides a simple URL link on the product packaging which directs the patient or healthcare professional to t</p>	

Can you easily find the PI on the TGA website?

The TGA website is a useful tool to allow access to PI's, and GSK acknowledges the efforts of the TGA to update the website to provide a better user experience for viewers.

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

GSK believes that the entirety of the PI can be effectively delivered in a digital format. GSK acknowledges that package inserts of the 'instruction for use' document will continue to be included in several of GSK's boxed injectable products, which provide

Additional information or suggestions

GlaxoSmithKline Australia Pty Ltd (GSK) welcomes the opportunity to provide comment on the TGA's consultation on Product Information as a package insert in boxed injectables. GSK understands the role of the TGA to support a high-quality health system through regulations and contributing to this aim through best practice regulation of the delivery of high quality and timely medical information to healthcare professionals.

GSK is the sponsor 18 injectable vaccines, a number of which are provided as part of the National Immunisation Program, and several other injectable pharmaceutical products.

GSK obtains continual product and packaging feedback from both patients and healthcare professionals through product feedback channels and pharmacovigilance activities. The Company continually updates product information documents in line with TGA requirements and acknowledges the current requirements of sponsors to provide package inserts within injectable products.

GSK believes the TGA requirement to include a package insert PI is inconsistent with the current prescribing habits of healthcare professionals, the ecological objectives of the TGA, and has a significant impact on the safety and quality use of medicines.

In addition to the points addressed above, GSK would like to outline additional considerations which support GSK's position to remove paper PI's in boxed injectable products.

GSK supports the use of electronic PI's in an effort to decrease the environmental impact of the pharmaceutical industry by preventing the unnecessary consumption of paper and ink products. The scale of distribution for injectable products means millions of paper PI's are printed each year. GSK's understanding is that an extremely small proportion of healthcare professionals use the paper format in any capacity, making it difficult to justify their extensive production, especially with the availability of digital PI's which can be printed on an individual ad hoc basis.

Another benefit of the removing package insert PI's from injectable products is to allow for greater flexibility in the supply of new products to ensure timely and effective public access, meaning Sponsors are able to bring crucial medicines to patients sooner. The requirement for package insert PI's increases logistical complexity and unnecessarily slowing patient access to products, which has been further highlighted in the recent COVID-19 environment.

Finally, GSK acknowledges the overall move of the Australian healthcare system to telehealth and digital prescribing options, which necessitates an integrated digital health system where current and up to date information can be quickly accessed. GSK believes removing the requirement for paper inserts in boxed injectables and aligning PI requirements across all products is pursuant to these digital access goals.

Attachment, if any

Not Answered

Response Id

ANON-3A9P-AQ2F-7

Submitted date

10/5/2022 2:47:00 PM

Name	Mark
Email address	
Organisation	Pharmaceutical Society of Australia
Respondent type	I am representing a group of healthcare professionals
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response
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?	
<p>It is important to consider that an individual's preference for format or design of any document can vary. This may mean that it is not just about selecting one form over another – hardcopy vs. electronic – there may also be a need for review of their current respective formats. The hardcopy PI, in their current form, was considered by some pharmacists to be more accessible than the online version. The size of the text, large blocks of text, layout and minimal use of graphics were some of the features that made the hardcopy version easier to navigate and interact with.</p> <p>PSA received some feedback that an online only version could be supported (see also feedback below on QR code access) if the format of the online PI:</p> <ul style="list-style-type: none"> • is designed for online reading and utilised, for example, reader-friendly fonts such as those without serifs, or well-spaced text • uses graphics for important and standard information (e.g. categories for prescribing medicines in pregnancy, boxed warnings, advice on operating machinery or driving, significant drug interactions) • gives prominence (e.g. placed at the top of the document) to critical information for the administration of the injectable (i.e. technique) and any critical issues that could arise from administration (e.g. drowsiness, anaphylaxis). 	
What areas of the PI do you find particularly valuable in a package insert?	
All sections of information are useful, however, the order of information should be reviewed to prioritise those that are critical at the time of administration.	
What areas of the PI do you not find valuable in a package insert?	
On balance, it was felt that clinical information / published studies are more readily available in resources such as the Australian Medicines Handbook which is one of the references, listed in the Pharmacy Board of Australia guidelines, that pharmacists would access in their professional practice.	
Do you use other resources to access information about the boxed injectable?	
<p>Pharmacists must have ready access to contemporary references in their professional practice. Pharmacists give consideration to all relevant current information, in the Australian context, and this may require the use of more than one reference source.</p> <p>In view of promoting contemporary practice, some pharmacists indicated support for an option to facilitate PI access via a QR code on the product packaging. This also supports PSA's view that pharmacists have an obligation to work towards reducing the environmental footprint of the healthcare sector through actions including service design, choice of consumables and waste reduction. Pharmacists recognise the use of printed PIs can be a significant waste of resources (if other appropriate options are available) and an unnecessary environmental burden arises from continued printing of these documents.</p>	
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?	

Pharmacists who indicated they did not tend to access the PI included in boxed injectables, mentioned they would refer to other sources including eMIMS and the TGA web site.

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?

Additional information or suggestions

Attachment, if any

Not Answered

Response Id

ANON-3A9P-AQ2D-5

Submitted date

10/5/2022 4:51:40 PM

Name	Daria
Email address	
Organisation	Ipsen Pty Ltd
Respondent type	I am a sponsor
The TGA would like your permission to publish your consultation response. Please indicate your publishing preference.	Publish response
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?	
<p>This response to TGA's consultation is provided from the perspective of Ipsen Pty Ltd as an Australian sponsor.</p> <p>A hard copy of the PI in the box can be useful for ease of use and as an optional alternative to electronic versions for HCPs who may not be in a setting to easily access electronic devices at the point of administration of the medicine.</p> <p>It can act as a final opportunity to review patient safety information (risk of not being able to easily and quickly access important information can outweigh the benefits of removal of the insert).</p>	
What areas of the PI do you find particularly valuable in a package insert?	
<p>Section 4.2 Dose and Method of Administration.</p> <p>Also, any illustrated or more detailed instructions included only at the end of the pack insert which are not always available in the approved electronic PI.</p>	
What areas of the PI do you not find valuable in a package insert?	
<p>The majority of the information in the PI should already have been considered prior to prescribing the medicine and/or opening the box. For example, the clinical data, contraindications and safety precautions would likely have been read and examined in order to make an educated treatment and prescribing decision.</p> <p>It is more appropriate to include the information that is most relevant and important to an HCP at the point of administration. HCPs are unlikely to read an insert containing 30 pages worth of text in very small font on a large sheet of folded paper at the point of administering the medicine to the patient. In such a case, it may cause undue concern to or instil a lack of confidence in a patient to watch their doctor or nurse begin reading about the medicine at the point of opening the box.</p>	
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?	
<p>When searching by trade name using the TGA website search function, there can be many results that seem identical (e.g. type of result is in smaller, less obvious font stating if the result is AUSPAR, ARTG, articles, etc.) and it is not always obvious whi</p>	
Are there certain areas of the PI that you would find valuable to maintain as a hard copy package insert?	
<p>Section 4.2 Dose and Method of Administration.</p> <p>As a sponsor, it would be preferred to require the inclusion of instructions for administration as a minimum. This could include the method of administration text, step-by-step instructions, illustrations, a</p>	
Additional information or suggestions	

It is Ipsen Pty Ltd's recommendation that the mandatory requirement for including the PI in the box of injectable products provided the following points can be addressed:

Any hard-copy pack insert information should be clear and easy to follow in a sufficiently sized font.

A pack insert should be useful to facilitate proper use of the medicine. It should enable ease of access to only information essential to HCPs at the point of administration. At this point, HCPs are unlikely to read existing inserts with approx. 30 pages of text contained in very small font on a large sheet of paper to find relevant information.

Greater flexibility for more rapid change to the content of the hard copy insert should be considered. Typically, it can take most pharmaceutical companies a minimum of three months for changes to the pack insert/PI to appear in the supplied product carton. More flexibility could improve the time delay between reflecting changes in the electronic version and the hard copy insert.

It is suggested to allow the inclusion of non-promotional materials such as information to access Patient Support Programs or other information that is beneficial to patients via use of a website or a QR code.

Attachment, if any

Not Answered

Response Id

ANON-3A9P-AQFJ-Y

Submitted date

10/5/2022 6:12:27 PM