

**Simplified Price Disclosure
Stakeholder Information Session
6 December 2013
Supplementary Question and Answers**

Several questions were asked by participants during the information session. The questions and answers included the following.

What is the ‘relevant day’ and why is it changing in the Act?

- The ‘relevant day’ specifies the date for the PBS-listed ex-manufacturer price used for the purposes of comparing the PBS price with the average market price.
- The *National Health Act 1953* is being amended to change the relevant day from the last day of the data collection period to the day after the end of the data collection period.
- This amendment will allow other price reductions that would be due on that day to be taken into account before the PBS and market prices are compared.
- There will continue to be a three month processing period for submission of data and preparation of supporting calculations before the price disclosure determination is made by the Minister's delegate.

Is the 10 per cent rule being preserved?

- Yes. The 10 per cent test which ensures that the PBS price for a medicine is not reduced unless the weighted average market price is at least 10 per cent less than the PBS price will be preserved under the new arrangements.
- The PBS price used for this comparison is the PBS-listed ex-manufacturer price on the relevant day.

Why is the legislation being amended to include 1 April, 1 October in any year and “or another prescribed day?”

- It is intended that from 1 October 2014 price disclosure-related reductions occur on 1 April and 1 October each year.
- However, reductions sometimes cannot go ahead on the intended day. For example, for the 2013 Main Cycle, reductions needed to be split across two dates. Most reductions occurred on 1 April 2013, but some were delayed until 1 August 2013.
- It is proposed that the amended National Health (Pharmaceutical Benefits) Regulations 1960 retain 1 August and 1 December as possible reduction days. These days could be used, if required, so that any delayed reductions occur as close as possible to the intended 1 April or 1 October day.

Will the first month of data for new brands continue to be excluded from price disclosure arrangements?

- Yes. There is no change to this under the Simplified Price Disclosure arrangements.

Why were the Expanded and Accelerated Price Disclosure Guidelines updated recently when new Guidelines will be required for Simplified Price Disclosure?

- It was important to update the EAPD Guidelines to ensure that the base on which Simplified Price Disclosure commences is clear.

When are the Simplified Price Disclosure Guidelines going to be released?

- Simplified Price Disclosure Guidelines will be released when the drafting of the amended Regulations is completed in early to mid-2014.

Will stakeholders have an opportunity to provide feedback and request clarification regarding Simplified Price Disclosure Guidelines?

- Yes. Stakeholders will be advised prior to the next update of the Guidelines so they will have an opportunity to provide input.

How will stakeholders know when there are updates to the PBS website regarding Simplified Price Disclosure?

- An email will be sent to responsible persons when information becomes available on the website.
- Anyone can register at pbs.gov.au to receive notifications of PBS news items.

Is the Department of Health doing a 'road show' on Simplified Price Disclosure as it did for Expanded and Accelerated Price Disclosure?

- The proposed changes are more straightforward than the Expanded and Accelerated Price Disclosure changes, so there isn't the same need.
- In addition, resource constraints mean we will not be able to do a road show this time.
- It is important that peak bodies and stakeholder representatives help to distribute more broadly information to their members.
- There will be detailed information available on the PBS website to assist companies in making a smooth transition to Simplified Price Disclosure.
- If further information is required after Fact Sheets and other information is provided in the New Year, please let us know. Email: eapd@health.gov.au

Why is it important for companies to start their data submission process early and check data before submitting?

- Acting early allows companies to verify the products for which information is required and identify the data to be submitted. For example, if a company has passed commercial responsibility for a brand to another company but not yet changed the 'responsible person', there are steps that may take additional time – see the updated Guidelines for details.
- Companies need to allow time to respond to requests for clarification or additional information. Companies also need to ensure that requests for data clarification or confirmation receive careful consideration. In some cases, a request to a company to review the accuracy of data has drawn confirmation, but a subsequent second or third request has resulted in corrections.

Can data provided for price disclosure be used for other purposes?

- Yes. Price disclosure data can be used for purposes other than price disclosure calculations where it is authorised by law, or by agreement.
- The use of information disclosed to the Department is authorised for purposes relevant to the exercise of powers and functions under the Act. This includes use of price disclosure data for pricing and listing decisions.
- Use of price disclosure data may assist, for example, where data supports a request for a price change. If the data did not support a price change, that could be brought to the attention of the requesting company.
- The Department will continue to consider disclosed data to be commercial-in-confidence and apply strong protections to prevent inadvertent and improper use.



Transition from current into SPD cycles

Current Cycle	Current scheduled reduction day	SPD Cycle	SPD Reduction Day
2014 EAPD Main Cycle	1 April 2014 (remains)	SPD 1	1 October 2014 1 April 2015
2015 EAPD Main Cycle (with 2013 Supp A and Supp B folded in)	1 April 2015	SPD 1	1 October 2014 1 April 2015
2014 EAPD Supplementary A	1 August 2014 (remains)	SPD 2	1 April 2015
2014 EAPD Supplementary B	1 December 2014	SPD 1	1 October 2014 1 April 2015