



Australian Government
Department of Health and Ageing

Dear Responsible Person

EXPANDED AND ACCELERATED PRICE DISCLOSURE

I am writing to provide you with an update on the Australian Government's intended Expanded and Accelerated Price Disclosure (EAPD) policy and to provide you with some key timeframes in preparation for its commencement.

In 2010-11, the Australian Government intends to implement a major Pharmaceutical Benefits Scheme (PBS) sustainability package, following on from the PBS reforms initiated in 2007. An important element of this package is the significant strengthening of price disclosure through the proposed EAPD policy.

Price disclosure brings the price that Government pays for drugs listed on the F2 Formulary of the PBS closer to the actual price at which those drugs are supplied in the market, through periodical price reductions. In order for this to happen, the Government requires Responsible Persons to provide information relating to the sales of those PBS listed drugs.

As you are aware, subject to the passage of legislation, it is intended that from 1 December 2010, all drugs on the F2 Formulary of the PBS will be subject to EAPD. Amendments to the *National Health Act 1953* (the legislation) giving effect to these reforms are currently tabled before parliament.

The detailed operational requirements of EAPD are contained in proposed amendments to the *National Health (Pharmaceutical Benefits Schedule) Regulations 1960*. Preparation of these proposed amended regulations is currently being finalised for consideration by the Executive Council, providing the legislation is passed by parliament and receives Royal Assent. It is therefore expected that the Department will shortly be able to provide Responsible Persons with more detailed information regarding the requirements of the proposed EAPD, through information packs and the PBS website (www.pbs.gov.au).

The Department will be hosting a number of information sessions, in conjunction with the independent service provider who will be responsible for the analysis of EAPD data, leading up to the first data reporting period early next year. These information sessions will provide Responsible Persons with more information about the procedural and operational requirements of EAPD, and provide an opportunity to raise any questions they may have about the new arrangements. Invitations to these sessions will be sent out shortly, once dates and locations have been confirmed.

Attached to this letter is a short overview of the key dates for the implementation of the EAPD Program for ease of reference.

The Department is also in the process of establishing an EAPD webpage on www.pbs.gov.au. The webpage will be updated periodically and all companies are encouraged to subscribe to receive the automated email notifications of updates to the website, via a "PBS Information – Subscriptions" link on the website.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'Adriana'.

Adriana Platona
Assistant Secretary
Pharmaceutical Evaluation Branch
4 November 2010

EAPD – Next Steps

Date	Event	Location
12 November 2010	Information provided to industry via information packs and PBS website	www.pbs.gov.au
Week commencing 22 November 2010 (TBC)	EAPD overview questions and answers sessions hosted by the Department	Canberra (TBC)
1 December 2010	Proposed EAPD commencement date	N/A
Mid December 2010 (TBC)	EAPD Information sessions – compliance, operational and procedural requirements – hosted by the Department and the service provider	Melbourne, Sydney and Canberra (TBC)
February 2011 (TBC)	Further EAPD Information sessions – compliance, operational and procedural requirements – hosted by the Department and the service provider	Melbourne, Sydney and Canberra (TBC)
31 March 2011	End of the first reporting period	N/A

NOTE:

The reforms proposed in the legislation and regulations provide that EAPD is expected to commence on 1 December 2010. While Responsible Persons may be required to collect sales, volume and incentive data, from this date, the data will not be due for submission until after the end of the first reporting period which is proposed to finish on 31 March 2011. The first possible reporting deadline for disclosure of data will not occur until mid May 2011.