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Australian Government
Department of Health

RECEIVED
15 JUL 2014
Parliamentary Section

cc: Mr Learmonth
Dr Bartlett
Mr Simpson

MINISTER DUTTON

Critical Date: 18 July 2014

Reason: To implement PBS listings from
1 September 2014.

**APPROVAL OF LISTINGS ON THE PHARMACEUTICAL BENEFITS SCHEME
FROM 1 SEPTEMBER 2014**

RECOMMENDATION:

R1. That you APPROVE the 1 September 2014 listings for the Pharmaceutical Benefits Scheme (PBS) at Attachment A.

Approved/Not Approved

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Peter Dutton
PETER DUTTON

14 / 7 / 14

MINISTER'S COMMENTS:

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ISSUES:

There are five proposals for the PBS, including one price change, for listing from 1 September 2014, that require your approval to proceed by 18 July 2014 (Attachment A refers).

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BACKGROUND:

On 22 October 2013, the Cabinet gave you approval to list items on the PBS, National Immunisation Programme and Life Saving Drugs Programme and co-dependent technologies on the Medicare Benefits Schedule that have been recommended by the Pharmaceutical Benefits Advisory Committee (PBAC) and will cost \$20 million or less in each of the forward estimate years, subject to the financial impact being agreed by the Department of Finance (Finance) before you make a decision to list

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The *Schedule of Pharmaceutical Benefits* is updated monthly and provides for new and amended PBS listings to be implemented from the first day of each month. A six week lead time for listing medicines on the PBS is required to finalise the legal requirements and any risk sharing arrangements, update IT systems and manage data requirements for all PBS listings.

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RELEVANCE TO ELECTION COMMITMENTS:

This Ministerial Submission is consistent with the Government's election commitment, announced on 22 August 2013 as part of *The Coalition's Policy to Support Australia's Health System*.

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Due to provisions in the Fifth Community Pharmacy Agreement (5CPA), price changes to PBS medicines occur on 1 April, 1 August and 1 December. Price changes outside of these price change points require the agreement of the Pharmacy Guild of Australia (the Guild). As per standard practice, the Department will notify the Guild of this price change.

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Sensitivity:

Stakeholders, including patients and pharmaceutical companies, are expected to welcome the listings.

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Regulatory burden implications and/or deregulation opportunities:

There will be no additional regulatory requirements as a result of these proposals. Existing regulatory procedures for the PBS are well understood and accepted by stakeholders.

Timing/Handling (including legislative changes):

Your decision on the proposals is required by 18 July 2014 so implementation of listings can occur from 1 September 2014. If this deadline is not met, the proposed listings will be delayed.

Consultations:

Portfolio Strategies Division was consulted in the preparation of this Submission.

COMMUNICATION ACTIVITIES:

Health Communications has been consulted in the production of the draft media release (Attachment C). The content of the media release highlights the new or amended PBS listings that will have the greatest impact on patients, prescribers and industry. The media release does not include the administrative changes, such as new brands of medicines, or nil-cost listings which are not routinely announced. The timing of the media release will need to be co-ordinated between your office and the Department, noting:

- the PBS listings remain subject to final agreement with sponsors, and should not be announced if sponsors cannot guarantee supply or have not finalised their risk-share agreement; and
- it has been long-standing practice that the Department formally confirms the listing date with individual sponsors one month prior to the listing date, to allow them time to prepare. Any announcement for 1 September 2014 listings therefore needs to occur by 1 August 2014.

Contact Officer details:

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Pharmaceutical Benefits Division

Clare Starr

10 / 7 / 2014

Acting FAS/AS Budget Branch
Portfolio Strategies Division

Paul Creech

10 / 7 / 2014

ATTACHMENTS:

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- B. Further details on key listings
- C. Draft media release

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Further details of PBS listings

The proposed new listing of certolizumab pegol (Cimzia®), for the treatment of ankylosing spondylitis, was recommended by the Pharmaceutical Benefits Advisory Committee (PBAC) at its March 2014 meeting. Ankylosing spondylitis is a type of chronic inflammatory arthritis that targets the joints of the spine. Ankylosing spondylitis can be progressively debilitating and in severe cases, can lead to significant disability. This condition results in back pain, stiffness and reduced mobility in the spine and can also effect the heart, lungs, kidneys, colon and eyes. Ankylosing spondylitis effects up to two per cent of Australians and is about three times more common in men than women.

The proposed new listing of everolimus (Afinitor®), for the treatment of stage IV clear cell variant renal cell carcinoma (RCC), was recommended by the PBAC at its March 2014 meeting. RCC is a form of kidney cancer and is the most common cancer of this organ. As RCC progresses, the tumour grows and enlarges and often spreads to other parts of the body such as such as the bones, liver or lungs. Everolimus works by blocking a protein in the cells that allows cancer cells to grow and survive.

The proposed new listing of fluticasone furoate and vilanterol trifenate (Breo® Ellipta®), for the treatment and management of asthma, was recommended by the PBAC at its March 2014 meeting. Asthma is a common chronic inflammatory condition of the airways with symptoms that include wheezing, coughing, chest tightness, and shortness of breath. An asthma attack can become life threatening if not treated properly, even in someone whose asthma is usually mild or well controlled. Asthma is the most widespread chronic health problem in Australia, effecting about one in ten people.

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