Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Supplementary Budget Estimates 2015 - 2016, 21 October 2015

Ref No: SQ15-000846

OUTCOME: 2 - Access to Pharmaceutical Services

Topic: Brand Substitution Including Biosimilars

Type of Question: Written Question on Notice

Senator: McLucas, Jan

Question:

a) How many biologics have been 'a' flagged in the USA for substitution at the pharmacy level?

b) The Government has budgeted $880m in savings from 'a' flagging biologics. Could the Department provide a breakdown of that figure the current year, and for each year of the forward estimates?

c) Can the Department confirm that if a GP ticks the box, 'brand substitution not permitted' on a patient prescription then it can't be substituted at the pharmacy level?

d) In regards to evidence provided to the Department at estimates in regards to 'a' flagging in hospitals, can the department provide the committee with figures on how many biological medications are interchanged in hospitals and what do they treat? How widespread is the interchangeability of biologics in hospitals as a percentage of all medications that are dispensed in hospitals? What is the total spend on interchangeable biologics in hospitals?

e) How widespread is the interchangeability of biologics in hospitals as a percentage of all medications that are dispensed in hospitals? What is the total spend on interchangeable biologics in hospitals?

Answer:

a) One biosimilar has been approved by the US Food and Drug Administration (FDA) (Zarxio, Sandoz). There are no biosimilars denoted as "interchangeable" with an originator biologic in the lists of biological products with interchangeability evaluations published by the US FDA. The Australian and US systems for regulating biosimilars, and associated terminology, are not directly comparable.

b) The breakdown of underlying cash estimate for savings in the current year, and for each year of the forward estimates is:

2015-16 ($m)	2016-17 ($m)	2017-18 ($m)	2018-19 ($m)	2019-20 ($m)
11.287	91.717	181.425	252.832	346.034

c) Yes. A prescriber may tick the 'brand substitution* not permitted' box when writing a prescription, if they do not think it is appropriate for brand substitution to be offered to the patient. When this happens, under the *National Health Act 1953*, a pharmacist cannot dispense a brand other than that prescribed.

d) Biosimilars approved in Australia that are listed on the Pharmaceutical Benefits Scheme (PBS) are summarised in the table below. The table includes the intended treatment indications, corresponding originator biologics, PBS-subsidised hospital utilisation and expenditure for 2014-15. Biosimilars dispensed in hospitals in 2014-15 represented approximately 2 per cent of the more than 70 biologics on the PBS used in hospitals (by both script volume and expenditure).

None of the biosimilars currently listed on the PBS are 'a' flagged. The Pharmaceutical Benefits Advisory Committee has stated that it will consider each biosimilar application on a case by case basis. To this date it has considered two biosimilars for listing on the PBS in 2015 including whether they should be substitutable* at the dispensing level (that is, 'a' flagged).

Guidance on biosimilar use in hospitals from the Council of Australian Therapeutic Advisory Groups (May 2015) states that substitution of biosimilars may nevertheless occur if it is in accordance with a Drugs and Therapeutics Committee (DTC)-approved treatment protocol that allows substitution. The Department of Health is aware that substitution of biosimilars at the hospital pharmacy level, in line with the applicable DTC policy, occurs. As this use is outside the PBS, the Department does not have data on this type of utilisation or the associated expenditure by State and Territory governments.

e) See response to part d).

* Note: In Australian practice the following definitions apply:

- Interchangeability: The medical practice of changing one medicine (drug) for another that has been tested and shown to achieve the same clinical effect in a given clinical setting and in any patient on the initiative, or with the agreement of the prescriber.
- Substitution: Practice of dispensing one brand of a medicine (drug) instead of another equivalent and interchangeable brand of the same medicine at the pharmacy level.

Table PBS-subsidised hospital utilisation and expenditure for 2014-15

BIOLOGIC	TREATMENT	ORIGINATORS			BIOSIMILARS		
Name	**PBS Indication(s)**	**Originator Brand (Company)**	**2014-15 Hospital PBS Scripts**	**2014-15 Hospital PBS Expenditure**	**Corresponding Biosimilar Brand (Company)**	**2014-15 Hospital PBS Scripts**	**2014-15 Hospital PBS Expenditure**
Filgrastim	Neutropoenia in certain cancers and other specific blood diseases	Neupogen (Amgen)	4,187	$7.3 million	Zarzio (Sandoz) Tevagrastim (Aspen) Nivestim (Hospira)	6,020	$8.1 million
Epoetin alfa	Anaemia due to renal disease	Eprex/Erypo (Janssen-Cilag)	1,190	$10.8 million	Novicrit (as epoetin lambda)(Sandoz)	4,496	$4.0 million