Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Budget Estimates 2015 - 2016, 1 – 2 June 2015

Ref No: SQ15-000653

OUTCOME: 2 - Access to Pharmaceutical Services

Topic: Biosimilars

Type of Question: Written Question on Notice

Senator: Brown, Carol

Question:

a) Is the Government considering allowing the TGA to rely on a single trusted overseas regulator to make the decision that a biosimilar is substitutable as opposed to requiring the TGA to independently make that decision?
b) Is there currently a universally accepted regulatory framework for biosimilars across the world?
c) Do the European Medicine Agency, the WHO and the FDA all use the same regulatory approaches/definitions in regards to biosimilars?
d) Is there any country in the world that currently allows the automatic substitution of a biosimilar at pharmacy level for a biosimilar referenced to its biologic?
e) IS TGAs position that biosimilars should only be switched under the supervision of the treating GP?
f) Is it the case that the TGA is currently reviewing its guidelines in regards to the substitution of biologics at the pharmacy level?
g) What would be the savings to Government of substitution of biosimilars?
h) In the April PBAC outcome statement in regards to biosimilars PBAC stated, "where a biosimilar could not be 'a' flagged at the time of PBS listing, data should be collected to support 'a' flagging at later point". What type of data would this be? In regards to a 'later point' is this a reference to months or years?
i) If a biosimilars is substituted at the pharmacy level, and the treating GP has not authorised its substitution, but due to the biosimilar being 'a' flagged, the pharmacist offers the alternative biosimilar, who is liable in the case of a patient having a serious adverse event? The pharmacist, GP or anybody else?
j) Will the pharmacist be required to inform the patients GP that the biosimilar they have prescribed and stated on the prescription should not be substituted, but is substituted by the pharmacist anyway as it has been 'a' flagged, have to inform the treating GP that it has been substituted?
k) Is there any concern that pharmacists will consider biosimilar and generic as one and the same when it comes to 'a' flagging?
l) Can you confirm the evidence given at Senate Estimates that Quebec allows pharmacy-level substitution of biosimilars?

Answer:

a) The Therapeutic Goods Administration (TGA) assesses biosimilar products for safety, quality and efficacy, regulating them as prescription medicines under the Therapeutic Goods Act 1989. The question of the use of trusted overseas regulators by the TGA was reviewed through the Independent *Review of Medicines and Devices Regulation*. The Government is considering this review report. Substitutability at the pharmacy level is a matter for the Pharmaceutical Benefits Advisory Committee (PBAC).

b) & c) No – there is not at this time a universally accepted regulatory framework for biosimilars across the world.

d) International experiences with biosimilars vary. Several reviews undertaken in Europe, including a recent assessment by the European Commission, have concluded that availability of biosimilar drugs has not resulted in any spike in apparent safety issues such as immunogenicity.

Other examples are as follows:

- France - when prescribing a biological, physicians are required to specify whether this is the first time the biological is prescribed. If this is the case the pharmacist is allowed to substitute a biosimilar in the following circumstances:
    - The biosimilar belongs to the same "similar biologic group" as the prescribed product. Similar biologic groups consist of the reference biologic and its authorised biosimilars - these lists must still be drafted by the French regulator ANSM (Agence Nationale de Sécurité du Médicament)
    - The prescribing physician has not explicitly marked the prescription as non-substitutable.
    - If the pharmacist substitutes a biosimilar, they must write the name of the dispensed product on the prescription and inform the prescribing physician.
    - If the treatment is continued and the prescription is renewed, the same (substituted) medicine should be dispensed.

- Germany – with the highest use of biosimilars in Europe (around 50% volume uptake), Germany has 17 "physician based regions", the majority of which have implemented biosimilar quotas for Epoetin (EPO). They have an active role of prescription utilisation management to track physicians' budgets. Payer education activities address potential safety concerns and reinforce the concept of biosimilarity. Biosimilar EPO uptake is around 60%, with cumulative savings to Germany between 2007-2011 estimated to be €551m (around $A807m). Germany, amongst other European countries, is also considering tendering some biosimilars because of the existence of parallel traders in Europe.

- United States of America - although few biosimilars are yet on the market in North America, some private health insurance companies charge patients lesser copayment amounts for choosing a biosimilar over the originator biologic.

- Canada – there is no designation of interchangeability or substitution between biologic and biosimilars, however each province has the authority to decide whether it will allow substitution in its provincial reimbursement plans or allow pharmacists to substitute for patients with private insurance.

e) and f) The TGA's role is to assess biosimilar products for safety, quality and efficacy, as it would any other biological medicines. Biosimilar product's assessment also focuses on comparability with innovator products. PBAC provides advice to the Minister for Health in

relation to interchangeability and substitutability. If as part of its assessment TGA had evidence that a product was not substitutable, then TGA would draw the attention of the PBAC to this.

g) The use of biosimilars is expected to deliver estimated efficiencies of $880 million over five years (2015-16 to 2019-20).

h) At its April 2015 meeting, the PBAC considered that where a biosimilar product could not be "a" flagged at the time of PBS listing, data should be collected to support "a" flagging at a later point. Consideration of the appropriate evidence required would be made on a case-by-case basis as previously stated by the PBAC, taking into account the evidence presented in each submission to list a biosimilar product.

(i) Good pharmacy practice in Australia requires that the pharmacist consults with the patient and obtains their consent in deciding whether to substitute. Brand substitution for PBS medicines has been in place since 1994, and the obligations of pharmacists will not change with the introduction of biosimilars.

(j) A pharmacist cannot substitute if the GP has marked the prescription "not for substitution". To do so would be illegal under subsection 103(2A) of the *National Health Act 1953*.

(k) Pharmacists are trained health professionals who can be expected to understand the differences between biological and small molecule medicines.

l) At the request of a pharmaceutical company, the Department met with representatives from within the Canadian Health System in March 2015. This discussion focused on biologics and biosimilars in Canada, specifically the model used in Quebec. The Quebec system is different to Australia's, but it does require the pharmacist to dispense the cheapest brand, regardless of the brand the consumer is currently on, unless the prescriber selects no substitution as it is in Australia. Equivalent measures are in place in countries such as Germany, Finland and Norway to encourage use of the cheaper product in place of the branded biological and so reduce the financial burden on payers.