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A healthy decision

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Sandoz PTY Ltd

Submission to Oncology Taskforce: Response to Deloitte Access Economics Report: Access to Cancer Medicines in Australia (July 2013)

Sandoz, a Novartis company, welcomes the opportunity to submit a response to the Deloitte Access Economics report: *Access to Cancer Medicines in Australia.*

The issue of the increasing healthcare burden is not unique to Australia. Cancer represents a significant and growing burden on all healthcare systems. During the last decade or so, patient outcomes have improved radically with the introduction of newer and more targeted therapies, including biologics. However, they do come at a cost which is now threatening the accessibility and financial sustainability of healthcare systems. In 2000, only one of the top 10 drugs globally was a biologic. By 2008 half of the top 10 drugs were biologics[1]. Biological sales in 2010 accounted for US134billion in Australia, Canada, EU and Japan[1]. In Australia, 5 of the top 10 drugs are biologics accounting for AU$909m of PBS spend, which represents 8.2% of the budget[2].

The report highlights that there are currently 981 cancer medicines and vaccines in clinical development, which will represent a challenge to both regulatory and reimbursement systems as financial constraints on healthcare systems will only are increase.

However, the opportunity that pending patent expiries on major biological therapies used in oncology and other therapeutic areas is not discussed. The current value of biologics where patent expiries and biosimilar entry is expected over the next 5 years is AU$1.2b[2] (August IMS, 2013: ranibizumab, adalimumab, rituximab, etanercept, trastuzamab, pegfilgrastim, infliximab, darbopoetin alfa, bevacizumab).

It is generally accepted that due to the costs associated with the stringent development, manufacturing and licensing requirements of biosimilars versus small molecules, the cost savings will likely be 15-10% versus 80% with conventional generics[3]. However, given the high prices of biological medicines, even small relative price reductions might lead to substantial savings. In Australia, a 20% saving on these biologics alone represents cost savings of AU$245m[2].

As a global market leader of biosimilars, Sandoz believes that in order to create a sustainable health environment, the role of biosimilars, which are proven to be a safe and effective alternative to the originator biologic therapies, needs to be addressed. Biosimilars represent a potentially significant savings to payers. The increased affordability of biosimilars, could enable earlier and expanded access to treatment, fund new innovative treatments or allow the release of funding to be used elsewhere in clinical care.

The first patents on biologics expired in 2001. The first biosimilar medicines were approved by EMA in April 2006 and launched in May 2007. Three classes have entered and are being used safely in the European market: recombinant human erythropoietins (epoetin alpha and epoetin zeta), G-CSFs (filgrastim), and human growth hormones

(somatropin). The biosimilar volume has grown, the non-referenced product volume has declined. Reference products have maintained volume but value has declined[4].

Within the EU, there is documented evidence of cost savings through the adoption of biosimilars. In the Aapro paper[3], the cost savings are clearly outlined:

1. Biosimilar epoetins saved Euros 60 million in Germany during their first year of availability—a figure that is projected to rise to Euros 8 billion by 2020 (IGES 2010).
2. US$188 million would be saved per annum assuming a 100% switch to a biosimilar epoetin (at 2010 prices) across seven European countries (France, Germany, Italy, Romania, Spain, The Netherlands and UK)
3. Savings that could be made by increasing use of biosimilar epoetin, filgrastim and monoclonal antibodies in eight European countries—France, Germany, Italy, Poland, Romania, Spain, Sweden and UK, ranged from from Euros 11.8 to Euros 33.4 billion by 2020, depending on the model used. This represents 5.2% to 14.6% of total therapy expenditure. The bulk of these savings are expected to be made in France, Germany and UK—the countries that currently spend the most on biological drugs.

There is a clear incentive to ensure a competitive and sustainable environment for biosimilars.

However, uptake of biosimilars and the extent of cost savings to be realised is impacted by differences in healthcare systems, structures and processes across the EU. The differences outlined by the consensus paper are:

Physician perception of biosimilars
Patient perception of biosimilars
Local pricing and reimbursement regulations
Procurement, policies and terms.

In Australia, the second year post launch the biosimilar volume market shares in Australia, were only 1.4%% for epoetin and 4.8% for daily GCSF[2]. For both biosimilars this uptake is low compared to European markets. The uptake of epoetin has been further impaired by the different ABN Novartis were required to adopt- epoetin lambda.

The recent proposed naming convention by the TGA requiring non-proprietary names for biosimilars different from those of their reference products, will further compound the issue. Aside from the confusion this may cause with clinicians and prescribers, different ABNs also have implications for the current reimbursement structure for products which move from F1 to F2 in the event of competitor entry.

In order to create a sustainable healthcare system and free money to fund new innovative medicines, there should no barriers put into place to hinder the adoption of biosimilars. The current naming convention will lead to the initial 16% price reduction (perhaps), and then further price reductions through price disclosure will be reduced by the lower uptake of biosimilars. This ultimately creates an unattractive, non-competitive market for biosimilar competition, keeping prices for biologics high and potentially impairing patient access in the future.

Cornes P. in his article: The Economic Pressure for Biosimilar Drug Use in Cancer Medicine[5], recognises Germany, as the country that has set the benchmark for early adoption of biosimilars in the EU. As early as 2008, 55% of epoetins and 31% of GCSF prescriptions were for biosimilars.

It is generally recognised that centralised healthcare systems, and those with a strong tradition of generic medicine use, biosimilar use will rise with predictions of more than 80% of some biologic drugs within one year of entry in the USA[5].

With the appropriate regulation and monitoring in place, increasing adoption of biosimilars represents a key approach in creating a sustainable healthcare budget and improving patient access to important therapies.

For example, if Australia was to follow the lead of many healthcare systems in the EU and "restrict" access to pegylated filgrastim due to the affordability of biosimilar daily GCSF, at a 50% discount off the daily GCSF reference product, AU$64m would be realised by the healthcare system.

Individual physicians and hospitals can save on established treatment programs with a policy of biologic drug equivalent substitution as experienced in the EU. However, with the current regulatory and reimbursement structure, firstly the "incentive" to adopt a biosimilar is not present at a prescriber level, as these drugs are high cost drugs funded federally and not by local health bodies. Thus, where prescribing changes have been driven by tenders, these cost savings are not automatically passed onto the Pharmaceutical Benefits Advisory Committee (PBAC) or taxpayers due to the S100 reimbursement system.

An added complication is how to maximise cost savings when the majority of prescriptions go through the retail pharmacy channel, not the hospital pharmacy setting - where substitution of biosimilars is not allowed, e.g. 140k, which is 99% of etanercept sales are currently recorded as going through the retail pharmacy channel[2].

It is the recommendation of Sandoz that a comprehensive overview beyond the scope of the current recommendations is undertaken to look at further driving the adoption of biosimilars to increase patient access, either by broadening access to existing classes or by creating significant and timely savings for the PBS to fund new novel therapies.

We welcome the opportunity of being invited to participate in the working group and being involved in stakeholder consultations in the future.

References:

1. Labry et al. *Biosimilars in the European market.* Generics and Biosimilars Initiative Journal (GaBI Journal). 2013;2 (1):30-5.
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3. Aapro S. *Biosimilars in oncology: current and future perspectives.* Generics and Biosimilars Initiative Journal (GaBI Journal). 2013;2(2). Epub ahead of print. **DOI:** 10.5639/gabij.2013.0202.023
4. EU Consensus Information Paper 2013*. What you need to know about Biosimilar Medicinal Products*
5. Cornes P. *The Economic Pressures for Biosimilar Drug Use in Cancer Medicine*. Targeted Oncology 2012:49