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PBS Post-Market
Department of Health and Ageing
MDP 900
GOP Box 9848
CANBERRA ACT 2601
Via email to: PBSpostmarket@health.gov.au

12 June 2014

Dear Sir/Madam

Re: Terms of Reference for the Post-market Review of Authority Required PBS Listings

Roche Products Pty Ltd (Roche) welcomes the opportunity to address the Terms of References for the above review, as listed on the Pharmaceutical Benefits Scheme (PBS) website 27 May 2014 and outlined below:

1. Review the criteria used by the Pharmaceutical Benefits Advisory Committee (PBAC) to determine if a medicine should be recommended as Authority Required or Authority Required (Streamlined) on the PBS.
2. Systematically review the current Authority Required listings according to the proposed criteria to ensure this is applied consistently to all PBS Authority listed medicines.

Authority Required Listings for Formulaty 1 Medicines

Roche endorses the need for a review of the medicines with Authority Required PBS listings, particularly those for treatment of patients with cancer and rheumatoid arthritis. Feedback received from rheumatologists and oncologists is that, as a consequence of the complexity of the forms for written authorities and the detailed requirements, they either have less time to consult with patients or the responsibility for completion is delegated to someone less familiar with the patient history. This can result in inadvertent errors and protracted engagement between the prescriber and Medicare, placing a burden on both parties and, most importantly, impacting patient care. Roche supports the need to ensure optimal use of these medicines in line with the PBS restrictions and believes that this can effectively be achieved with 'Authority Required –streamlined' listings, as evidenced by the experience gathered since implementation of this process for a broad range of medicines in 2007. A recent request to change the second and subsequent continuing treatment authorities for golimumab, infliximab, and ustekinumab for all of their PBS-reimbursed indications from complex written authority to telephone authority items serves as an example of how the process could be simplified for all bDMARDs.

Process for Restriction Changes for Formulary 2 Medicines

As patented medicines, it is more common that treatments listed in F1 have restrictions in the 'Authority Required' or 'Authority Required – streamlined' categories. However, there is a need to consider how the prescribing restrictions change over time and, additional to the above terms, the scope of the review should be broadened to include the criteria and process used by the PBAC when products are transitioned to less restrictive prescribing categories, being 'Restricted'and 'General' benefits, upon movement from Formulary 1 (F1) to Formulary 2 (F2) and introduction of price

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disclosure.

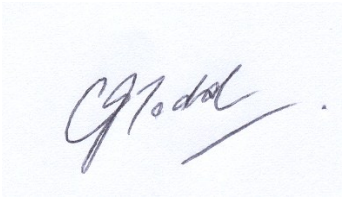
Roche believes that the transparency and consistency of this process need to be addressed. This is particularly true of the chemotherapy treatments currently listed in Section 100 of the PBS, where considerable inconsistencies exist in the restrictions applied to medicines that have transitioned from F1 to F2, as evidenced below:

While F2 chemotherapies *gemcitabine*, *oxaliplatin* and *irinotecan* are now listed without associated restrictions, *docetaxel* and *paclitaxel* still have an Authority Required (Streamlined) listing. This is despite all these treatments having taken significant price reductions through price disclosure. Similarly, it is unclear why the off-patent aromatase inhibitors are 'Restricted Benefit' whilst in contrast, genericised *temozolamide* remains an 'Authority Required' listing.

In addition, experience with chemotherapy agents commonly evolves over time (often rapidly), and as a consequence use in clinical practice is frequently broader than the approved TGA indications or PBS listings. This results in inconsistencies in what is considered standard treatment practice internationally and in the availability of reimbursed treatment for Australian cancer patients. For example, *capecitabine* is an alternative treatment option to infusional 5-*FU* for rectal cancer in NCCN Guidelines[1] and the NSW Cancer Institute treatment protocol[2]; but is neither TGA-registered or PBS-reimbursed for this indication. *Capecitabine* is now off-patent and likely to transition to F2 this year.

Roche believes once a cancer medicine is off-patent and subject to significant price reductions, a pragmatic approach to align PBS reimbursement with international best practice guidelines is to remove prescribing restrictions and afford these medicines a general listing. The criteria and process for doing so should therefore be reviewed and made transparent for all stakeholders as part of the Post-market Review of Authority Required Medicines. This will better enable both sponsors and the PBS to plan for a sustainable industry in the era of Price Disclosure. We trust that this view will be considered when deciding the final terms of this review.

Yours sincerely



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ROCHE PRODUCTS PTY LIMITED

References

1. National Comprehensive Cancer Network (NCCN). Rectal Cancer (Version 3.2014). Available at http://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf . Accessed 28 May 2014.
2. NSW Cancer Institute. eviQ Version 1.4.0. Avaliable at https://www.eviq.org.au/. Accessed 28 May 2014