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June 13, 2013

Management and Co-ordination Section
Office of Product Review
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

30 May 2013

Dear Sir/ Madam,

Consultation:
Evaluating the feasibility of a new-to-market risk communication scheme for therapeutic goods

CSL thanks-you for the opportunity to provide feedback on the aforementioned proposal paper, currently under consultation.

Please note that CSL Limited recently restructured the organisation so that the previous entity CSL Biotherapies is now separate business entities named bioCSL Pty Ltd [ABN: 26 160 735 035] and CSL Behring (Aust) Pty Ltd [ABN: 48 160 734 761]. The enclosed comments to this consultation represent the combined feedback of bioCSL and CSL Behring (Aust) [referred to collectively as CSL].

CSL supports initiatives such as a new-to-market risk communication scheme, which promote the quality use of therapeutic goods and improve public understanding and consumer confidence in the healthcare sector.

As stated in the proposal paper, CSL agrees that a new-to-market risk communication scheme should be designed to signal to people that a particular therapeutic product is new, or is newly available for a particular use and that the scheme is not intended to alert people to specific known or suspected risks associated with a product.

Keeping the intent of the scheme in mind, CSL's feedback and suggestions of a possible model for a new-to-market risk communication scheme are provided in the table enclosed with this cover letter.

If any further information is required, please contact me by phone: 03 9389 1363, fax: 03 9388 2351 or e-mail: Anastasia.Moisidis@biocsl.com.au . Please direct any written correspondence to Dr Jane Leong, Vice President of Scientific Affairs, bioCSL.

Sincerely,

Anastasia Moisidis
Manager, Regulatory Affairs
bioCSL Pty Ltd

Marie Theodorou
Senior Regulatory Affairs Associate
CSL Behring (Aust) Pty Ltd

cc
Dr Jane Leong, Vice President of Scientific Affairs, bioCSL (Aust) Pty Ltd
Ms Neama Baho, Acting Director of Regulatory Affairs, CSL Behring (Aust) Pty Ltd

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How might a new-to-market risk communication scheme work in Australia?

Item No.	Section, page number	Comments
1	**Selection of products for inclusions in the scheme, p.15**	
1.1	**Criteria for inclusion of medicines in the scheme, p.15**	With regards to inclusion of previously registered active ingredients for which registration is sought for a new dose form, CSL suggests that this should be assessed on a case-by-case basis as some changes to dose form would have limited impact to the safety profile, for example, a change from 'powder for injection' to 'solution for injection' dose form. CSL seeks clarification of the proposed criterion "*after registration, the sponsor is required to submit a risk management plan that includes additional pharmacovigilance activities*". CSL has concerns with this proposed criterion because TGA can request a risk management plan at any stage of a registered products lifecycle. CSL would not support the inclusion of established medicines for which new safety concerns have arisen in the new-to-market risk communication scheme because the scheme is not intended to alert people to specific known or suspected risks associated with a product. TGA has other existing mechanisms for addressing newly identified concerns relating to product safety as listed on page 9 of the proposal document under the heading "Addressing new information about a therapeutic product". CSL requests that seasonal products such as influenza vaccines, where the viral strain composition may change annually, be exempted from this scheme.
2.	**Communication to health professionals and consumers, p.15**	
2.1	**Sources of communication, p.16**	CSL is in support the use of a symbol next to the name of the product in sources such as: • PI and CMI for medicines • IFU for medical devices

		• Prescribing and dispensing software • Promotional and educational materials produced by the sponsor • Information sources commonly used by health professionals (such as MIMS, Australian Medicines Handbook, NPS information) • The Australian Register of Therapeutic Goods • The National Product Catalogue Additionally CSL recommends that the requirement is integrated in the Code of Conduct of relevant industry bodies, such as Medicines Australia. In light of the various abovementioned sources of communication CSL believes it is unnecessary to include the requirement on product packaging. The inclusion of the symbol with the product trade name would result in wastage of packaging materials and a cost burden to sponsors when the product is removed from the scheme.
3	**Removal of products from the scheme, p.16**	
3.1	**Automatic removal from the scheme, p.16**	CSL proposes that products are automatically removed from the scheme after a two year period to maintain the integrity of the scheme and to avoid both administrative and cost burden to both the TGA and sponsors. If a sponsor submission and TGA evaluation are required to remove products from the scheme, the number of products on the scheme will grow over time, diluting the impact of the scheme. This in turn could affect a desired outcome of the scheme, being better targeting of adverse event reporting for newly registered medicines and devices.

3.2	**TGA consideration for removal from the scheme, p.16**	CSL suggests that taking the number of people that had used the product into consideration would be problematic for certain medicinal products such as orphan drugs, emergency medicines and some vaccines. For these groups of medicines, the number of patients using the medicine can be limited and could result in the products being on the scheme for a very long time. In addition, accurate estimation of numbers of patients that have used these types of products is difficult.
3.3	**Communications about a scheme**	CSL agrees that for the scheme to be successful it is imperative that additional activities are undertaken by Government to raise public awareness and understanding of the scheme. It is critical that the community understands that inclusion of products in the scheme is automatic for all new products and inclusion in the scheme is not an alert for specific known or suspected risks associated with a product.
3.4	**Evaluation of a scheme**	If implemented, CSL supports the evaluation the new-to-market communication scheme. Considering the industry investment required in implementing the scheme, CSL believes it is important that the Department of Health and Ageing undertakes an effectiveness review of the scheme to ascertain whether the desired outcomes of the scheme have been achieved.