Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

CONSULTATION SUBMISSION COVER SHEET

This form accompanies a submission on:

Amendments to the Therapeutic Goods Regulations 1990 for the implementation of the Biologicals Framework	
Name and designation:	Dr Anna Lavelle, CEO
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☐ Yes ☒ No	I would like the comments I have provided to be kept confidential: *(Please give reasons and identify specific sections of response if applicable)*
☐ Yes ☒ No	I would like my name to be removed from all documents prior to publication and not be included within the list of submissions on the TGA website.

It would help in the analysis of stakeholder comments if you provide the information requested below.

I am, or I represent, a: (*tick all that apply*)

Business in the therapeutics industry (please tick sector):

☒ Prescription Medicines ☐ OTC Medicines

☐ Complementary Medicines ☒ Medical Devices

☐ Blood/Tissues ☐ Other

☐ Sole trader ☐ Business with ☐ employee(s)

☐ Importer ☐ Manufacturer ☐ Supplier ☒ Industry organisation

☐ Government ☐ Researcher ☐ Professional body

☐ Consumer Organisation ☐ Institution *(eg. University, hospital)*

☐ Reg. Affairs Consultant ☐ Laboratory Professional

☐ Healthcare Practitioner - please indicate type of practice

☐ Other (please specify):

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AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

3 December 2010

Administration Officer
Biological Science Section
Office of Scientific Evaluation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Administration Officer,

Biologicals Framework Consultation – Amendments to the Therapeutic Goods Regulations 1990

Thank you for the documentation and recent information session which outline the proposed amendments to the Regulations for the implementation of the Biologicals Framework. AusBiotech recognises the work done to arrive at this consultation phase since the possibility of a national framework was first proposed in 2006 and welcomes the opportunity make this submission for your consideration.

1. AusBiotech believes that the proposed definition of 'biological', while very specific, is a significant variation from what is commonly understood by scientists and those in the medical and veterinary professions and that this may result in a great deal of unintended confusion as sponsors seek to understand what is captured by the Biologicals Framework. The sound medical and scientific rationales of the Framework must be supported by the legislation and there should be no risk of unintended consequences arising from inappropriate legalistic drafting.

2. AusBiotech suggests that clear guidelines are developed to minimise any uncertainty that might arise from real or perceived overlaps between the Biologicals Framework and other regulatory codes eg, cGMP, ARTG, CTX, CTN

3. In relation to the Classification Rules, AusBiotech is highly concerned that

a) basing the level of regulation of a product (ie, Class 1 -4) on the extent of manipulation applied makes little or no scientific or medical sense particularly in light of the stated goal of the framework 'to minimise the risk of infectious disease transmission.' For instance, AusBiotech contends that there are many separation techniques (eg, filtration) that are not only minimal forms of manipulation but are specifically designed to eliminate bioburden. AusBiotech believes that the envisaged distinction between Class 2 & 3 Biologicals should be reconsidered as a matter of importance and possibly even removed.

b) the proposed fees and charges applicable to biologicals, particularly the quantum of fee proposed for the evaluation of dossiers for Class 3 and 4 products, will place an unacceptably high financial burden on biotechnology companies that may detrimentally impact the output of Australian innovators. All biotechnology companies would benefit from timely discussions with the TGA on the regulatory pathway most suitable for a product

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in order to inform the decision-making process in relation to the product's development pathway and budget.

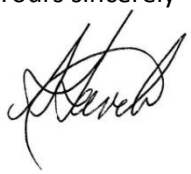
4. For the purposes of selecting the most appropriate classification for a product within the Biologicals Framework, AusBiotech believes there could be confusion about when the sponsor is also the 'principal manufacturer' and recommends that this be clarified and exemplified.

5. AusBiotech is concerned that a completely new application would be required whenever a sponsor wished to make a change to a registered product, for example, a change in container type. As currently proposed, this would result in an unacceptable cost burden on the sponsor which could not possibly be justified by the TGA on the basis of safety when the entire dossier had already been evaluated and approved.

6. AusBiotech suggests that some examples be provided to exemplify circumstances that might result in medical practitioner exemptions from registering a Biological under the proposed Framework.

AusBiotech asks the Office of Scientific Evaluation to consider unintended and potentially damaging consequences, prior to finalising the legislation to incorporate a new regulatory framework for biologicals.

Yours sincerely



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