Application Entry, Support and Export Section
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Sir/Madam

Consultation on Export of Medicines from Australia & Export Certification for Medical Devices

Medicines Australia welcomes the opportunity to provide comment on the Therapeutic Goods Administration (TGA) draft guidance relating to export of Medicines and Devices from Australia.

Our submission has been prepared with the expert input of Medicines Australia's Regulatory Affairs Working Group (RAWG). Members are selected for their regulatory and pharmacovigilance experience and industry knowledge. They bring a whole-of-industry perspective to the consideration of regulatory issues that impact our sector. Answers to the specific questions included in the consultation paper have been based on consideration of the following:

- Is the guidance sufficiently clear and easy to follow for its intended purpose of assisting Sponsors understand their responsibilities?
- Are there any aspects that are not currently covered in the guidance?
- Are there any other issues that may affect the usability of the guidance?
- Are there any major issues relating to the content of the guidance that are likely to affect Industry?

We would be happy to discuss or provide further comment on any aspect of our response and we appreciate being kept up to date on further developments. Please feel free to contact Betsy Anderson- Smith if you would like further clarification on any aspect of our submission (bandersonsmith@medaus.com.au).

Sincerely

Dr Vicki Gardiner
Director of Policy and Research
Medicines Australia

Questions:

Is it of benefit to allow submission of electronic schedules to accompany a Certificate of Pharmaceutical Product (CPP) or a Certificate of Listed Product (CLP) application?

- We currently require all export documents to be provided in hard copy to the TGA, as this was a requirement of importing countries over 15 years ago

Medicines Australia has no objection to the submission of electronic schedules. This will benefit Sponsors and reflects standard working practices for other applications that utilise the electronic submission of application data.

Is it of benefit for the TGA to provide traceable post for all hard copy certificates?

- This may incur an appropriate fee increase

Medicines Australia has no objection to using traceable post to ensure the delivery of certificates.