



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

***Therapeutic Goods Act 1989***

**THERAPEUTIC GOODS ORDER No. 70C**

**Standards for Export Only Medicine**

I, Larry Kelly, delegate of the Minister for Health for the purposes of section 10 of the *Therapeutic Goods Act 1989* (the Act) and acting under that section, having consulted with the Therapeutic Goods Committee in accordance with subsection 10(4) of the Act, HEREBY:

1. REVOKE Therapeutic Goods Order No.70B "Amendment to Therapeutic Goods Order No. 70 - Standards for Export Only Medicine", made on 26 February 2007; and
2. DETERMINE that the matters specified in a relevant monograph of each of the publications listed in column 1 below constitute alternative standards for medicine manufactured in Australia, or imported into Australia, for export only, subject to the requirements (if any) set out in column 2 below:

<b>Column 1</b>	<b>Column 2</b>
British Pharmacopoeia, United States Pharmacopoeia and European Pharmacopoeia (as each are defined in subsection 3(1) of the Act)	i) if the medicine is regulated other than as a medicine in the country to which it is to be exported, it meets the regulatory requirements of that country for such products.
Japanese Pharmacopoeia (16th edition including English language translation of	i) the exporter is to hold evidence that a relevant authority of the country to which the medicine is to be exported has confirmed its willingness to accept medicine which complies with this Order, or confirmed that it would have no objection to accepting such medicine, except where the

Supplement 1 of April  
2013 and partial  
revision of Supplement  
1 of May 2013)

country to which the medicine is to be exported is a country  
where the medicine is regulated other than as a medicine;  
and  
ii) if the medicine is regulated other than as a medicine in  
the country to which it is to be exported, it meets the  
regulatory requirements of that country for such products.

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This Order commences on the day after the day it is registered on the Federal Register  
of Legislative Instruments.

Dated this 16<sup>th</sup> day of May 2014

(Signed by)

Dr Larry Kelly  
Delegate of the Minister for Health