

HISTORICAL DOCUMENT



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Draft Therapeutic Goods Order No. <to be allocated>
Standard for water for injection for parenteral medicines

I,, delegate of the Minister for Health and Ageing 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. DETERMINE that matters specified in this Order constitute a standard for water for injection:
 - a. for therapeutic use in a parenteral medicine; or
 - b. for use as an ingredient or component in the manufacture of a parenteral medicine other than for:
 - c. an export only medicine; or
 - d. a personal import as described under Item 1 of Schedule 5 of the Regulations.

Standard

Water for injection must comply with the relevant monograph for water in the British Pharmacopoeia or the European Pharmacopoeia.

Definitions

In this Order:

monograph means the requirements of, and definitions within, an individual or general monograph of the British Pharmacopoeia or the European Pharmacopoeia, read in conjunction with the General Notices contained in the same edition that are applicable to that monograph.

parenteral medicine means a sterile medicine intended for administration by injection, infusion or implantation into the body.

Commencement

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

Dated thisday of2009

.....

Delegate of the Minister for Health and Ageing