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Annex:

EU – Australia MRA

Sectoral Annex on medicinal products, GMP inspection and batch certification

Operation of the Annex with respect to active pharmaceutical ingredients for medicinal products for human use

Joint Statement

The Mutual Recognition Agreement (MRA) between the European Union (EU) and Australia covers "*all medicinal products which are industrially manufactured in Australia and in the European Union, and to which Good Manufacturing Practice (GMP) requirements apply.*"[2]

According to the MRA, "'*Medicinal products' means all products regulated by the pharmaceutical legislation in the European Union and Australia referred to in Section I.*"[3]

Section I of the MRA refers to the Appendix, which lists Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

While, at the time of implementing the Sectoral Annex, only Australia had legal requirements for GMP for Active Pharmaceutical Ingredients (API) in place, with the adoption of Directives 2004/27/EC[4] and 2011/62/EU[5] amending Directive 2001/83/EC as regards GMP for API the EU explicitly includes API in the scope of Directive 2001/83/EC.[6]

Regarding the Australian legislation, the 'equivalence assessment' which was conducted by the European Commission in the context of Article 111b of Directive 2001/83/EC has confirmed that the Australian Therapeutic Goods Act has equivalent legal requirements for GMP for API in place.

It is therefore understood that API for medicinal products for human use are within the operational scope of the MRA between Australia and the EU.

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2 "Scope and Coverage", section 1, first paragraph.

3 "Scope and Coverage", section 1, fourth paragraph.

4 Directive 2004/7/EC of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 136, 30.4.2004, p. 34)

5 Directive 2011/62/EU of 8 June 2011 amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of falsified medicinal products (OJ L 174, 1.7.2011, p. 74).

6 See in particular Articles 2(3), 46(f) and 46b(1) of Directive 2001/83/EC.