AUSTRALIA AND EUROPEAN COMMUNITY
MUTUAL RECOGNITION AGREEMENT
OF
CONFORMITY ASSESSMENT, CERTIFICATES AND MARKINGS

SECTORAL ANNEX
MEDICINAL PRODUCTS GMP INSPECTION
AND BATCH CERTIFICATION

Report
13 June 2001

Report at the Completion of the Transitional Arrangements for Veterinary Medicinal Products and Operational Provisions for the Entire Annex from EC AND AUSTRALIA to the JOINT COMMITTEE
EXECUTIVE SUMMARY

The European Community and Australia have completed the transitional period for veterinary medicinal products foreseen within the framework of the Sectoral Annex on medicinal products, GMP inspection and batch certification to the EC-Australia Mutual Recognition Agreement (MRA). Based on the work completed in the two-year transitional period, the EC and Australia agree to recommend to the Joint Committee for the MRA to conclude the transitional arrangements for veterinary medicinal products.

Documentation and procedures for the operation of the Sectoral Annex have also been agreed.

The EC and Australia request the Joint Committee to endorse these findings and start the operational arrangements for veterinary medicinal products with a recommended commencement date of 1 July 2001.

1. INTRODUCTION

The European Community and Australia signed a Mutual Recognition Agreement (MRA) in 1998 that included a Sectoral Annex on medicinal products, GMP inspection and batch certification pertaining to medicinal products. In accordance with Article 14 of the MRA, the agreement came into force in 1 January 1999.

According to Section 1 of the Scope and Coverage, the provisions of the Sectoral Annex cover all medicinal products which are industrially manufactured in Australia and the EC, and to which Good Manufacturing Practice (GMP) requirements apply. For medicinal products covered by the Sectoral Annex, each Party shall recognise the conclusions of inspections of manufacturers carried out by the relevant inspection services of the other party and the relevant manufacturing authorisations granted by the Competent Authorities of the other Party. In addition, the manufacturer’s certification of conformity of each batch to its specifications shall be recognised by the other Party without re-control at import.

Two year transitional arrangements for veterinary medicinal products came into force upon execution of the Agreement. The transitional arrangements are detailed in section IV of the Sectoral Annex.

This report summarises the evaluation of the results by the EC and Australia and recommends the arrangements needed for the full operation of the Sectoral Annex on GMP and proposes a date for the end of the transitional arrangements for veterinary products.

2. TRANSITIONAL ARRANGEMENTS

During the transition period for veterinary products the EC has performed a documentation review, evaluation of processes and procedures, including on-site evaluation and decision making on the results of the findings.

Two visits were made to Australia to carry out on-site verification of the GMP inspection programme, which included conduct and observation of GMP inspections. The objective was to observe the preparation, executing and reporting of veterinary medicinal products good manufacturing practice inspection carried out by the Therapeutic Goods Administration (TGA) on behalf of the National Registration Authority for Agricultural and Veterinary Chemicals (NRA). This included an immunological veterinary inspection. The results of the evaluation work were referred to the corresponding responsible people at the NRA for comment and clarification and were then reported separately.

Inspection reports have not been routinely exchanged between the Parties, as it was not felt necessary.

Australia has taken the opportunity during the transition period to also assess EC legislative requirements and inspections. This assessment was based on the assumption that the EC ensures and assures consistency of interpretation and application of its Directives by each of the EU Member States. On that basis assessment has been limited by Australia to an evaluation of the EC legislation (in the
form of checklists) provided by the EMEA and observation of two GMP inspections of veterinary vaccine manufacturers undertaken by inspectors from the EC.

3. RESULTS

- The GMP legislation of the EC and Australia for veterinary medicinal products is considered to be equivalent.
- GMP inspections carried out by inspectors from the TGA under the provisions of the MRA are considered equivalent to EC GMP inspections.
- Product Coverage: Some discussion has taken place on better defining the products that fall within the scope of the MRA and the legislation of the respective Parties. Guidance will be developed for human and veterinary medicinal products for information purposes.

4. OPERATIONAL PROVISIONS

The agreement foresees in Section III exchange of documents and information and joint activities. For this a number of documents have been drafted and agreed.

**Joint Sectoral Group**
Establishment of a Joint Sectoral Group is recommended with the proposed Terms of Reference detailed in Attachment 1.

**Information Exchange**
A maintenance programme has been developed. The programme will cover both human and veterinary medicinal products and includes provision for information exchange, inspectors’ training and joint inspections.

**Alert System**
- The EC uses the EC procedure ENTR/6266/00 for notifying Rapid Alerts and Recalls arising from Quality Defects.
- Australian authorities are using the same classification and criteria of the EC’s procedure in their own recall procedures.

**Batch and GMP Compliance Certificates**
Standard formats for Certificate of GMP Compliance of Manufacturer and Batch Certificate have been developed to facilitate operation of the Agreement.

The Certificate of GMP Compliance of Manufacturer is a proposed revision of the ‘Certificate of Pharmaceutical Manufacturer’ included in Appendix 2 of the Agreement. The Certificate of GMP Compliance of Manufacturer is submitted as Attachment 2 for consideration and endorsement by the Joint Committee.

**Guide to the Medicinal Annex of the EC-Australia MRA**
A guide to the Medicinal Product Annex of the Agreement is being prepared to facilitate its understanding by industry and regulators.

**Official Batch Release**
The parties have not been able to reach an understanding on whether the official batch release provisions of Section III, paragraph 8 of the Annex apply to both human and veterinary immunological medicinal products (vaccines) and blood derivatives. The Joint Committee is requested to clarify whether these provisions apply to veterinary immunological medicinal products.
5. CONCLUSIONS AND RECOMMENDATIONS

The EC and Australia recommend that the Joint Committee accepts this report and in so doing endorses the conclusions and the following recommendations:

– that the operational phase for veterinary medicinal products commence on 1 July 2001;
– establishment of a Joint Sectoral Group and the proposed Terms of Reference (Attachment 1);
– endorse the revised Certificate of GMP Compliance of Manufacturer (Attachment 2);
– provide clarification on whether the Official Batch Release provisions of the Agreement apply to veterinary immunological medicinal products (vaccines) and blood derivatives.

For the European Community:

Katrin Nodop
EMEA

Emer Cooke
DG Enterprise

For Australia:

Fatima Beattie
National Registration Authority for Agricultural and Veterinary Chemicals

Robert Tribe
Therapeutic Goods Administration