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Mutual Recognition Agreement on Conformity Assessment in relation to Medicines Good Manufacturing Practice Inspection and Certification

Introduction

7.1 The *Mutual Recognition Agreement on Conformity Assessment in relation to Medicines Good Manufacturing Practice Inspection and Certification between the Government of Australia and the Government of Canada* (the Agreement) will provide for the mutual recognition of certification and for the acceptance of Certificates of Good Manufacturing Practice (GMP) of manufacturers of medicines between Canada and Australia.[1]

7.2 This means that Australia will recognise Canada's GMP certificates of manufacturers of medicines as acceptable forms of evidence in support of applications for entry on the Australian Register of Therapeutic Goods and Canada will recognise the Therapeutic Goods Administration's (TGA) GMP certifications.

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1 The term Good Manufacturing Practice (GMP) is used internationally to describe a set of principles and procedures which, when followed by manufacturers of therapeutic goods, helps ensure that the products manufactured will have the required quality and therefore be safe and reliable. Compliance with specified GMP requirements is used by most countries as the basis for licensing manufacturers of medicines.

Background

7.3 At present, information about manufacturers' GMP compliance, GMP inspections, acceptance of inspection reports and certificates is shared through membership of the Pharmaceutical Inspection Cooperation Scheme (PIC/S).[2] However, under the PIC/S regulatory authorities of respective countries are not legally obliged to supply information nor are any time frames imposed on providing information requested by another party.[3]

7.4 This is not viable in the long term, and one of the central advantages of concluding a treaty level agreement is the certainty it affords Australian exporters of medicinal products.[4] Canada currently requires that all imported batches of medicinal products be reanalysed before entry onto the market.[5] The proposed Agreement would eliminate uncertainty and any delays or costs associated with re-testing batches of medicines on import into Canada.[6]

7.5 In 2004, trade between Australia and Canada in regulated medicines for human use totalled $67 million, up from $44 million in 2000/2001.[7]

The Agreement

7.6 The Agreement is a single sector bilateral agreement that provides for the mutual recognition of the certification and acceptance of the certificates of GMP of manufacturers of medicines issued by the TGA and the Health Products and Food Branch of Health Canada.[8]

7.7 It will replace the current PIC/S arrangement with a formal government to government level treaty.[9] The Agreement will reduce time delays, increase certainty for manufacturers and is seen as an overall step towards greater market access through the reduction of barriers to trade.[10]

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2 National Interest Analysis (NIA), para. 6.
3 Regulation Impact Statement (RIS), p. 7.
4 RIS, p. 7.
5 RIS, p. 7.
6 RIS, p. 7.
7 NIA, para. 7.
8 Mr Terry Slater, *Transcript of Evidence*, 20 June 2005, p. 19.
9 Mr Terry Slater, *Transcript of Evidence*, 20 June 2005, p. 20 and see also the NIA, para. 6.
10 NIA, para. 5.

7.8 The central obligation of the Agreement is found in Article 4 which obliges Australia and Canada (the Parties) to accept the other's GMP Compliance Certification without re-control at import.

7.9 Article 2 limits the scope of the Agreement to the territories of each Party and only to medicines which are subject to a GMP Compliance Program. These include:

- human pharmaceuticals such as prescription and non-prescription medicines and medical gases
- human biologicals including vaccines, immunologicals and biotherapeutics
- human radiopharmaceuticals.

7.10 The Agreement does not apply to blood and blood components, tissues and organs of animal and human origin, official batch release of biologicals, stable medicines derived from human blood or plasmas, or veterinary pharmaceuticals, including sterile and non-sterile veterinary pharmaceuticals.[11] Nor does the Agreement apply to vitamins, minerals, herbal remedies and homeopathic medicines as Canada does not audit manufacturers of complementary medicines.[12]

7.11 Under the Agreement, the Parties are obliged to exchange information concerning their Mandatory GMP Requirements and GMP Compliance Programs, including any new technical guidance of inspection procedure.[13] Each Party must notify the other of any significant changes to the GMP Requirements and GMP Compliance Program within 60 days before the changes enter into force, unless health, safety and environmental protection considerations warrant a more urgent notification.[14]

7.12 A Joint Sectoral Group (JSG), to be responsible for the effective functioning of the Agreement, is established under Article 7. The JSG will function as an alert system in the case of batch recalls, quality defects or other problems with quality and will.[15]

7.13 Under Article 16 of the Agreement, the JSG is also responsible for the settlement of differences between the Parties. Where the JSG is unable

11 Article 2(4) of the Agreement.
12 Mr Terry Slater, *Transcript of Evidence*, 20 June 2005, p. 20.
13 Article 3(1) of the Agreement.
14 Article 3(2) of the Agreement.
15 Article 15 of the Agreement.

to resolve the differences, the Parties will settle them through direct bilateral discussions. The Queensland Government sought clarification on the way that 'direct bilateral discussions' will work, particularly with regard to the deciding authorities, participants and suggested process for the dispute settlement discussions.[16] The TGA advised the Committee that although the TGA and Health Products Food Branch (HPFB), Health Canada are yet to finalise the details of the arrangements for the bilateral discussions:

> It is envisaged that the direct bilateral discussions would be between senior representatives not included on the JSG from the Australian and Canadian Government, for example senior officials from the TGA, HPFB, the Department of Foreign Affairs and Trade, the Attorney-General's Department and the Canadian equivalent. Any decisions made at the bilateral discussions would be at the agreement of all participants.[17]

7.14 Parties are not obliged to disclose confidential proprietary information to the other unless it is necessary to demonstrate the competence of its Regulatory Authority to conduct GMP Inspection and GMP Compliance Program activities.[18]

7.15 Each Party retains the authority to interpret and implement its own mandatory requirements as well as to determine the level of protection it considers necessary with regard to health, safety and the environment.[19] Where a Party ascertains that products may not conform with its Mandatory GMP Requirements, it is able to take measures, such as withdrawing, recalling or prohibiting the importation of medicines.[20]

Implementation and costs

7.16 To implement the Agreement, the Minister is required to make a declaration under section 3B of the *Therapeutic Goods Act 1989* (Cth) to the effect that Canada is a country covered by a Mutual Recognition Agreement.[21] It is also necessary for the Secretary of the Department of Health and Ageing to approve in writing that Health Canada is a

16 Queensland Government, *Submission 5*, p. 2.

17 Department of Health and Ageing, Therapeutic Goods Administration, *Submission 8*, p. 1.

18 Article 8(1) of the Agreement.

19 Article 9(1) and (2) of the Agreement.

20 Article 9(3) of the Agreement.

21 NIA, para. 29, see also Mr Terry Slater, *Transcript of Evidence*, 20 June 2005, p. 20.

conformity assessment body that can issue attestations of conformity for the purposes of the Act.[22]

7.17 There is unlikely to be any extra costs as a result of the Agreement as it is replacing a pre-existing, voluntary PIC/S arrangement.[23] Costs associated with the JSG will be incorporated into other similar work undertaken by the TGA or met from TGA's existing budget.[24]

Consultation

7.18 State and Territory representatives, individual Premiers and Chief Ministers of all States and Territories and relevant industry associations, such as Medicines Australia (formerly the Australian Pharmaceutical Manufacturers Association), and the Australian Self Medication Industry, were consulted and all supported entering into the Agreement.[25]

7.19 The Complementary Healthcare Council of Australia raised concerns about the Agreement in relation to complementary medicines. As Canada does not require GMP certification for natural health products and Australia does, these products have been excluded from the scope of the Agreement.[26] However, Canada has indicated that natural health products will not require retesting at import so Australian manufacturers should not be disadvantaged by this exclusion.[27]

Conclusion and recommendation

7.20 The Committee supports a stronger health regulatory cooperation and trade relationship between Australia and Canada and believes that the Agreement will formalise current arrangements, improve market access and increase certainty for Australian manufacturers.

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22 Mr Terry Slater, *Transcript of Evidence*, 20 June 2005, pp. 20-21.
23 NIA, para. 31.
24 NIA, para. 32.
25 NIA, Consultation Annex, paras 1-2.
26 NIA, Consultation Annex, para. 3.
27 NIA, Consultation Annex, para. 3.

Recommendation 8

The Committee supports the *Mutual Recognition Agreement on Conformity Assessment in relation to Medicines Goods Manufacturing Practice Inspection and Certification between the Government of Australia and the Government of Canada* (Canberra 16 March 2005) and recommends that binding treaty action be taken.