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Agreement between Australia and the European Union Amending the Agreement on Mutual Recognition in relation to Conformity Assessment (MRA), Certificates and Markings between the European Community and Australia done at Brussels on 23 February 2012

Introduction

4.1 On 28 February 2012, the *Agreement between Australia and the European Union Amending the Agreement on Mutual Recognition in relation to Conformity Assessment (MRA), Certificates and Markings between the European Community and Australia done at Brussels on 23 February 2012* was tabled in the Commonwealth Parliament.

Background

4.2 The proposed treaty is to bring into force the Agreement between Australia and the European Union (EU) amending the Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings between the European Community and Australia, done at Brussels on 23 February 2012 (the proposed Amending Agreement). The Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings between the European Community and

Australia ('the MRA') was signed in Canberra on 24 June 1998 and entered into force on 1 January 1999.[1]

Overview and national interest summary

4.3 The MRA's underlying principle is that Australia and the European Union recognise and accept the technical competence of each other's conformity assessment bodies (CABs) to test and certify specified products for compliance with the standards and regulatory requirements of the other Party.[2] The goal is to largely eliminate the need for duplicative testing or re-certification of traded goods.[3] The MRA provides for the conformity assessment of products to be undertaken in the exporting Party rather than in the importing Party.[4]

4.4 The proposed amendments simplify the MRA's administrative arrangements, introduce greater flexibility, remove the rule of origin restriction from the MRA, accord less-than-treaty status to the Sectoral Annexes, and extend the role of the joint committee administering the agreement (the Joint Committee) to amend the Sectoral Annexes in response to regulatory and industry developments.[5] The proposed amendments will also enable the timely maintenance of the sectoral annexes and allow Australian export businesses in the designated product areas, as well as CABs, to benefit more readily from the MRA's operation.[6]

4.5 The Department of Industry, Innovation, Science, Research and Tertiary Education provided further explanation:

> The MRA does not require harmonisation of each party's technical regulations nor does it involve recognition of the standards that apply to the other party. The MRA's scope is limited to products which are subject to regulation by government authorities and they are outlined in sectoral annexes. The products covered by the

1 This includes 'European Community' being replaced by 'European Union' in the proposed Amending Agreement, as requested by the European Union.

2 National Interest Analysis [2012] ATNIA 7 with attachment on consultation Agreement between Australia and the European Union Amending the Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings between the European Community and Australia, done at Brussels on 23 February 2012, (Hereafter referred to as 'NIA') para 3.

3 For a discussion of the advantages of consistent international standards, see: Egan, M, "Setting Standards: Strategic Advantages in International Trade" <bsr.london.edu/files/1293/1467-8616.00202.pdf > accessed 10 April 2012.

4 NIA, para 4.

5 NIA, para 5

6 NIA, para 6.

agreement include medicinal products to which good manufacturing practice requirements apply, medical devices, telecommunications terminal equipment, electromagnetic compatibility, pressure equipment, machinery, low-voltage electrical equipment and automotive products.[7]

4.6 This type of agreement is not unique. Australia currently has a similar agreement with Singapore. Within APEC there are also mutual recognition agreements in relation to electrical or electronic products as well as telecommunications equipment. Australia also has a higher-level agreement with New Zealand.[8]

Reasons for Australia to take the proposed treaty action

4.7 Since the MRA's entry into force in 1999, certain administrative aspects have proved unwieldy, particularly the requirement that Sectoral Annexes changes undergo the domestic treaty amendment process in both Parties. Many of the Sectoral Annexes are now out of date and do not reflect current Australian or EU requirements, particularly in terms of applicable technical and regulatory arrangements.[9]

4.8 Further, the inclusion of the rule of origin provision in Article 4 which specifies that the products covered by the MRA must originate in the Parties, has limited the opportunities for Australian manufacturers and testing bodies to utilise the MRA, and has potentially restricted where our businesses can source their inputs and the markets where Australian CABs can compete for conformity assessment work.[10]

4.9 It is likely that failure to remove the rule of origin provision and to streamline the administrative aspects of the MRA to enable the Joint Committee to maintain and update the Sectoral Annexes would result in the MRA remaining under-utilised as EU Directives and Australian legislation change over time.[11]

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7 Mr Brian Phillips, Manager, Standards and Conformance Policy Section, Trade and International Branch, Enterprise Connect Division, Department of Industry, Innovation, Science, Research and Tertiary Education, *Committee Hansard*, 7 May 2012, p. 1.

8 Mr Brian Phillips, Manager, Standards and Conformance Policy Section, Trade and International Branch, Enterprise Connect Division, Department of Industry, Innovation, Science, Research and Tertiary Education, *Committee Hansard*, 7 May 2012, p. 2.

9 NIA, para 7.

10 NIA, para 8.

11 NIA, para 9.

Removal of the Rule of Origin Restriction

4.10 The current rule of origin in Article 4 of the MRA limits the coverage of the MRA to products originating in the Parties according to non-preferential rules of origin. Products covered by the MRA include: medicinal products to which good manufacturing practice (GMP) requirements apply; medical devices; telecommunications equipment; those requiring electromagnetic compatibility; automotive products; pressure equipment; machinery; and low voltage equipment.[12]

4.11 The Amending Agreement will remove the rule of origin restriction of Article 4. However, the restriction in the Sectoral Annex on GMP Inspection and Batch Certification for medicinal products will be retained and a similar restriction inserted into the Sectoral Annex on Medical Devices. The retention of these restrictions will help protect the high quality assurance and safety requirements for high-risk medical products.[13]

Simplification of the MRA

4.12 The amendments are designed to simplify the MRA and make it more efficient. They include clarifying and extending the powers of the Joint Committee to include amending the Sectoral Annexes and according less-than-treaty status to the Sectoral Annexes to enable the Joint Committee to update these annexes in a timely manner.[14]

4.13 Bringing the proposed Amending Agreement into force would also assist in meeting expectations arising out of the less-than-treaty-status Australia-EU Partnership Framework, which was first established in October 2008 and which has as one of its action items the finalisation of the proposed Amending Agreement.[15]

Obligations

4.14 The proposed Amending Agreement does not significantly alter Australia's core obligations,[16] but will affect the operation and scope of the

12 NIA, para 10.

13 NIA, para 11.

14 NIA, para 12.

15 NIA, para 13.

16 These obligations require Australian regulators in agreed product areas to accept attestations of conformity - including test reports, certificates and authorisations and, where appropriate, marks of conformity - issued in accordance with Australian requirements by specifically designated CABs in the EU.

MRA obligations as they relate to the Sectoral Annexes.[17] The proposed amendments are set out in Article 1 of the proposed Amending Agreement. The key amendments are outlined below.[18]

Overarching Framework Agreement

Removal of the Rule of Origin Restriction

4.15 The proposed amendment to Article 4 removes the rule of origin restriction and replaces it with a more general 'Scope and Coverage' provision which states that the MRA shall apply to the conformity assessment of products specified in the statement of scope and coverage in each Sectoral Annex.[19]

Simplification of the MRA

4.16 Article 3(2)(c) has been removed and the Sectoral Annexes no longer require a CAB list. Both Parties will now retain and update their own lists (revised Article 9(1)).[20]

4.17 Proposed amendments to Articles 6(1 & 2), which refer to the powers of the Parties' designating authorities, remove inconsistencies in the language between the two Articles and reflect the inclusion of processes in relation to the suspension of a CAB, previously outlined in Article 6(3) of the MRA which has now been removed.[21]

4.18 Article 8(6) is amended so that unless decided otherwise by the Joint Committee, the suspension of a CAB now occurs from the time its competence or compliance is challenged by a Party rather than when suspension has been agreed by the Joint Committee. The suspension runs from this time until either agreement has been reached in the Joint Committee or the challenging Party notifies the other Party and the Joint Committee that it is satisfied with the relevant CAB's competency.[22]

4.19 Article 9 provides for the exchange of information between the Parties on the implementation of, or changes to, legislative, regulatory and administrative provisions identified in the Sectoral Annexes, as well as the imposition of urgent measures warranted to protect safety, health or the

17 NIA, para 14.
18 NIA, para 15.
19 NIA, para 16.
20 NIA, para 17.
21 NIA, para 18.
22 NIA, para 19.

environment. The proposed amendment expands Article 9(1) to ensure that the Parties maintain an accurate list of CABs. Proposed changes to Article 9(2) and the inclusion of a new Article 9(3) now more clearly reflect the Parties' existing obligations under the World Trade Organization Agreement on Technical Barriers to Trade to provide time to comment where a Party intends to make changes to the legislative, regulatory and administrative provisions relating to the MRA's subject matter.[23]

4.20 Article 12 establishes the Joint Committee and provides for its powers and responsibilities. The proposed amendments expand the powers of the Joint Committee, granting it the ability to amend the Sectoral Annexes and to adopt new Sectoral Annexes in accordance with the MRA. The proposed amendments provide processes for the designation of a CAB by a Party and the procedure for objecting to a CAB designated by the other Party. It also gives the Joint Committee power to verify the technical competence of a contested CAB.[24]

4.21 Amendments to Article 15(1) establish that the Sectoral Annexes have less-than-treaty status. Amendments to Articles 15(3 & 4) allow the Joint Committee to adopt new and amend existing Sectoral Annexes respectively. While the Sectoral Annexes do not have treaty status, changes to them will affect the MRA's scope. [25]

Sectoral Annex on Medicinal Products GMP Inspection and Batch Certification

4.22 The proposed amendments to the 'Scope and Coverage' section of the Sectoral Annex on Medicinal Products GMP are mainly language changes to ensure consistency following the proposed amendments to the MRA. They do not provide for any new obligations. [26]

4.23 Section II of this Sectoral Annex has been amended so that the Parties must now maintain their respective lists of official inspection services. Further, a Party may request that the other Party provide the latest lists of official inspection services and this request must be complied with within 30 days of the receipt of the request.[27]

4.24 Paragraph 7 of Section III covers the ongoing exchange of information between authorities necessary for the ongoing mutual recognition of inspections. This has been amended to include the right of a Party to

23 NIA, para 20.
24 NIA, para 21.
25 NIA, para 22.
26 NIA, para 23.
27 NIA, para 24.

request additional specific information about the capability of official inspection services or their programs where significant changes to regulatory systems have occurred. This is to ensure that these services are sufficiently competent to carry out conformance assessment in accordance with the other Party's regulatory requirements.[28]

4.25 Section IV provides that the Parties may be required to provide information to verify programs for the mutual recognition of inspections, for the entry of a new official inspection service or for significant changes to an existing official inspection service.[29]

Sectoral Annex on Medical Devices

4.26 The 'Scope and Coverage' section of the Sectoral Annex on Medical Devices provides that it will apply to medical devices exported to Australia only if they are 'made in the EU'. As mentioned above, this is a more restrictive rule given the high risk nature of the products involved and will provide confidence that only EU bodies with quality assured and monitored manufacturing practices will fall within the MRA's scope.[30]

4.27 Amendments to paragraph 1 of Section V updating and strengthening confidence-building measures help to ensure that CABs can demonstrate their experience in assessing conformance to Australian requirements. The confidence-building period will be reviewed after two years of the amended Sectoral Annex's operation.[31]

4.28 Paragraph 5 of Section V provides that the Sectoral Annex shall not constrain a Party from implementing measures necessary to protect public health and safety.[32]

Implementation

4.29 No changes to Australian legislation are required by this agreement. State and Territory Governments are responsible for regulating the low voltage equipment, machinery and pressure equipment sectors covered by the MRA. The 1998 Inter-Governmental Cooperation Agreement (IGCA) between the Commonwealth and the States and Territories commits the

28 NIA, para 25.
29 NIA, para 26.
30 NIA, para 27.
31 NIA, para 28.
32 NIA, para 29.

States and Territories to the terms of the MRA. The proposed Amending Agreement does not affect the inter-governmental agreement.[33]

Costs

4.30 There will be minimal financial costs associated with bringing the proposed Amending Agreement into force.[34] Administrative costs under the MRA, including meetings of the Joint Committee, are covered within the normal appropriations for the Department of Industry, Innovation, Science, Research and Tertiary Education, the lead agency for the MRA and the Australian member of the Joint Committee.[35]

4.31 Removing the rule of origin restriction clause for all but two of the Sectoral Annexes will allow Australian firms greater flexibility potentially in sourcing inputs more competitively and give Australian testing and certification bodies greater scope to compete on world markets in relation to products from third countries. The proposed amendments to the MRA can result in potential cost-savings in terms of 'time to market' and fees for testing, inspection and certification. The MRA is designed to ensure, through its procedures for the designation and monitoring of CABs, that these bodies are sufficiently competent to provide the necessary quality of testing, particularly where products are sourced from third countries.[36]

4.32 In the case of the Sectoral Annexes on good manufacturing practice for Medicinal Products and Medical Devices, for Australian importers using overseas manufacturing sites in MRA countries, there will be a significant reduction in regulation and the regulatory cost burden, largely associated with the cost of on-site inspections by the Therapeutic Goods Administration.[37] The Therapeutic Goods Administration has advised that, as the proposed amendments to the MRA are largely mechanical, it does not anticipate any additional costs associated with Medicinal Product GMP inspections. [38]

4.33 The Australian Pesticides and Veterinary Medicines Authority (APVMA) has advised that the savings to industry from the amended MRA will be partly offset by the cost of confidence-building and confidence-maintaining measures associated with the proposed Amending

33 NIA, para 30.
34 NIA, para 31.
35 NIA, para 36.
36 NIA, para 32.
37 NIA, para 33.
38 NIA, para 34.

Agreement. However, ongoing maintenance activities have increased the effectiveness of the APVMA's regulatory activities and led to efficiencies and cost-savings.[39]

Alternative processes for goods assessment

4.34 The Committee notes that the MRA is not the only avenue through which goods can receive approval for entry into the Australian market. This was highlighted by two cases whereby medical goods that were ultimately deemed as sub-standard entered Australia. These were the ASR metal-on-metal hip replacement devices and PIP breast implants. Neither company used the MRA pathway to access the Australian market and the processes that applied to them were not covered by the former agreement and would not necessarily be changed by the current amendments.[40]

4.35 The Therapeutic Goods Administration (TGA) explained what processes were used:

> Both the ASR hip [replacement] under our new arrangements and PIP breast implants under our current arrangements are class III high-risk medical devices and would not be covered by this. But a large number of products come on to the market without using the MRA pathway to access the market... Both pathways have scrutiny. They are different pathways.
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> Level of risk is one defining feature [that determines which pathway is chosen]. Australian regulation has classes of products based on a risk assessment which we make at the TGA and that risk assessment determines the way in which that product will come on to the market if it is approved to come on to the market.[41]

4.36 Specifically, on the PIP implants, the issue was that of fraud, which is difficult to regulate for:

> PIP breast implants, they were allowed into the Australian market based on a full Australian TGA conformity assessment process. It was not based on any assessment by overseas notified bodies. The

39 NIA, para 35.

40 Ms Jenny Hefford, Chief Regulatory Officer, Therapeutic Goods Administration, *Committee Hansard*, 7 May 2012, p. 3.

41 Ms Jenny Hefford, Chief Regulatory Officer, Therapeutic Goods Administration, *Committee Hansard*, 7 May 2012, p. 3.

> difficulty with the PIP case was that it was out-and-out fraud that led to the faulty implants. That is something that is very difficult to regulate for, but that was a process that underwent full TGA scrutiny.[42]

4.37 The metal hip replacements also went through a different process than to that of the MRA:

> The ASR [hip replacements] [were] assessed by a European notified body... They issued a certificate in Europe. Under our legislation, that certificate is a way into the Australian marketplace, provided that Australia agrees with that particular assessment—when we get their certificate, we do a check to see that that certificate was issued appropriately. What we do not do, and we did not do with ASR and we do not do for the vast majority of medical devices, is that we do not review the prime evidence or the clinical evidence—the manufacturing data. That responsibility is done by the European regulatory system.[43]

4.38 This is not necessarily a negative, as going through other avenues will still invite scrutiny from other agencies such as the TGA:

> The difference between an MRA process and another European process is that both get assessed by a European conformity assessment body. In the case of an MRA, TGA plays no further role in the assessment. We have five days to allow that product into the Australian marketplace if it uses the MRA process. If it uses European assessment process but non-MRA, TGA then intervenes to assess the suitability of the assessment undertaken by the notified body. As we go forward we are proposing to reclassify the ASR hip implant up to class III, which is the highest-risk classification. From 1 July, if this amendment goes through, those particular devices will be excluded from the MRA. All class IIIs, the highest risk devices, will be excluded until there has been confidence building between the Australian government and the relevant European regulators.[44]

4.39 When it became known that there were potential problems with the hip replacements, Australian authorities acted to make them unavailable:

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42 Dr Larry Kelly, Group Coordinator, Monitoring and Compliance Group, Therapeutic Goods Administration, *Committee Hansard*, 7 May 2012, pp. 3-4.

43 Dr Larry Kelly, Group Coordinator, Monitoring and Compliance Group, Therapeutic Goods Administration, *Committee Hansard*, 7 May 2012, pp. 4.

44 Dr Larry Kelly, Group Coordinator, Monitoring and Compliance Group, Therapeutic Goods Administration, *Committee Hansard*, 7 May 2012, pp. 3-4.

> ...in 2009 when we started to collect the solid evidence from the joint registry that showed it was performing worse than devices of the same type that regulatory action was taken. That was nine months before any other country in the world took action against that particular device.[45]
>
> **...** Australia was the first country to take regulatory action against the ASR. We were the first country to remove the ASR hip from the supply, ahead of European countries.[46]

Conclusion

4.40 The Committee supports the proposed amendments to simplify the MRA's administrative arrangements. Greater flexibility within the arrangements and extending the role of the Joint Committee to amend the Sectoral Annexes in response to regulatory and industry developments is a positive change to the agreement.

4.41 The Committee notes, however, that not all goods go through the MRA process and that they can enter the Australian market place through other mechanisms. The examples given here – poor quality hip replacements and fraudulent breast implants – show that even with such agreements, vigilance must be maintained by the relevant Australian public authorities to ensure that Australian consumers do not receive sub-standard and dangerous products.

Recommendation 3

The Committee supports the *Agreement between Australia and the European Union Amending the Agreement on Mutual Recognition in relation to Conformity Assessment (MRA), Certificates and Markings between the European Community and Australia done at Brussels on 23 February 2012* and recommends that binding treaty action be taken.

45 Dr Larry Kelly, Group Coordinator, Monitoring and Compliance Group, Therapeutic Goods Administration, *Committee Hansard*, 7 May 2012, p. 4.

46 Dr Larry Kelly, Group Coordinator, Monitoring and Compliance Group, Therapeutic Goods Administration, *Committee Hansard*, 7 May 2012, p. 4.