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Department of Health
Therapeutic Goods Administration

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Consultation submission

This form accompanies a submission on Criteria for Comparable Overseas Regulators (CORs) consultation

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MEDICINES Australia
BETTER HEALTH THROUGH RESEARCH AND INNOVATION

MMDR consultation: Criteria for Comparable Overseas Regulators
Reform Coordination and Support
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

19 December 2016

Dear Sir/Madam

Thank you for the opportunity to respond on behalf of the innovative, research-driven pharmaceutical industry in Australia, to the Therapeutic Goods Administration's paper *Consultation: Criteria for Comparable Overseas Regulators* (Version 1.0, October 2016).

Our submission has been prepared with the expert input of Medicines Australia's Regulatory Affairs Working Group (RAWG). Members of RAWG are selected for their regulatory experience and industry knowledge, and bring a whole-of-industry perspective to the consideration of regulatory issues that stand to impact to our sector.

RAWG members, and members of Medicines Australia, appreciate the opportunity to have attended two targeted consultation meetings with the TGA already, on 14 October 2016 and 28 November 2016, regarding the implementation of Medicines and Medical Devices Review (MMDR). Our industry strongly supports the MMDR and looks forward to ongoing consultation on its many aspects to help shape its successful implementation.

Overall, industry agrees with the approach taken by the TGA to the criteria for comparable overseas regulators (CORs) as presented in the paper, however, the two-step process should be reconsidered to reflect a key underlying principle of the Review, being to reduce red tape through the existence of a COR mechanism. Clarification on a number of points is also necessary, in particular, the application of criteria labelled 'desirable'. Whilst we would expect that the sponsor would be permitted to offer a rationale for not meeting a 'desirable' criterion in a specific case, it is not clear how flexible the TGA would be in accepting an application where the 'desirable' criterion was not fully met. Guidance on this point would be very helpful. In addition, we note that access to, sharing of, and reference to, un-redacted reports, is not possible in all cases, and will require joint efforts by all parties.

Our detailed feedback is attached. We stand ready to discuss our approach and look forward to further refinements being considered and consulted upon by the TGA.

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We note that our member companies may make submissions in their own right to this paper, reflecting their own experiences and expertise, and that these should also be given due and proper consideration.

Finally, we acknowledge the extension granted by the TGA to respond to this paper.

Yours sincerely

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Stage 1: Identification of a comparable overseas regulator

Stage 1 criteria describe how closely the overseas agency's regulatory framework aligns with that of the TGA.

CRITERION	COR report process	Work-sharing
1. The COR's regulatory framework should be similar to that of the TGA in terms of what must/must not be taken into account in making regulatory decisions.	Required	Required

CRITERION	COR report process	Work-sharing
2. The TGA must have established a formal and robust framework for cooperation with the COR.	Desirable	Required

CRITERION	COR report process	Work-sharing
3. The COR must use similar international guidelines and standards to the TGA.	Required	Required

CRITERION	COR report process	Work-sharing
4. The COR should be able to conduct their business and release reports in English.	Required	Required

Stage 2: Application-specific considerations

Stage 2 criteria focus on the specifics of a particular application. Once an overseas regulator has been identified as either a source of assessment reports or a work-sharing partner, the following considerations will be applied to determine whether proposed use of the COR reports or work-sharing can proceed.

For both processes the following factors will be crucial:

- comparability of the medicines and
- the nature of the assessment process undertaken by each agency.

All relevant criteria would need to be addressed to allow COR reports to be utilised or work-sharing activities to be initiated with a COR.

Comparability of the medicines

CRITERION	COR report process	Work-sharing
5. Identical indications are proposed for the medicines (including dosage regimen and route of administration).	Desirable	Required

CRITERION	COR report process	Work-sharing
6. The medicine for which Australian registration is sought is identical to that approved by, or submitted to, the COR (i.e. dosage form, strength, formulation and manufacture).	Desirable	Required

Nature of the assessment reports

CRITERION	COR report process	Work-sharing
7. Assessment reports should be prepared using methodology, guidelines and standards consistent with those used by the TGA.	Required	Required

CRITERION	COR report process	Work-sharing
8. Assessment reports must be un-redacted and complete.	Required	Required

CRITERION	COR report process	Work-sharing
9. The TGA must be able to use assessment reports and any supplementary information generated during the evaluation process as part of Australian Public Assessment Reports.	Required	Required

Questions Presented in the Paper and Medicines Australia's Responses

- **Is the proposed two-step process for identifying suitable opportunities for collaboration appropriate?**

  The proposed two-step process may not be necessary in most cases and there is an opportunity to avoid potential red tape, consistent with the principles underlying the MMDR recommendations. Step 1 of the process i.e. identifying comparable overseas regulator, can be completed independently of Step 2. We suggest the TGA consider publicly providing list of overseas regulators deemed as being comparable, this way if a sponsor chooses to use one from the list, then Step 1 will not be necessary.

  To avoid any ambiguity, we wish to suggest the TGA include reference to guidelines that outline TGA's framework.

- **Are the individual criteria under Stages 1 and 2 appropriate?**

  Comments on some of the individual criteria are provided below:

  Criterion #2: *The TGA must have established a formal and robust framework for cooperation with the COR.*

  - It is unclear what form a "formal and robust framework" means. Is it a Memorandum of Understanding (MoU), Mutual Recognition Agreement (MRA) or some other agreement?
  - As suggested above, will the COR 'list' be made public?

  Criterion #5: *Identical indications are proposed for the medicines (including dosage regimen and route of administration).*

  Criterion #6: *The medicine for which Australian registration is sought is identical to that approved by, or submitted to, the COR (i.e. dosage form, strength, formulation and manufacture).*

  - Criteria 5&6 are described as "desirable" for the COR process. It is unclear whether that means that the dossier may or may not have to be 'identical'.

Criterion #7: *Assessment reports should be prepared using methodology, guidelines and standards consistent with those used by the TGA.*

- Methodologies used by regulators to prepare assessment reports may not be accessible to sponsors; therefore it would be almost impossible for sponsors to ensure the methodologies are consistent with those used by the TGA.

Criterion #9: *The TGA must be able to use assessment reports and any supplementary information generated during the evaluation process as part of Australian Public Assessment Reports.*

- There could be some areas of concern when overseas assessment reports are used as part of Australian Public Assessment Reports (AusPARs), especially if reference is made to un-redacted portions of reports. The TGA may need to work with the COR as well as the local sponsor for consensus on what sections could be used in AusPARs.