



*Generic Medicines Industry  
Association Pty Ltd*

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Joint Standing Committee on Treaties  
PO Box 6021  
Parliament House  
CANBERRA ACT 2600  
AUSTRALIA  
[jsct@aph.gov.au](mailto:jsct@aph.gov.au)

Dear Sirs

**The Generic Medicines Industry Association's submission to the inquiry into the Anti-Counterfeiting Trade Agreement**

The Generic Medicines Industry Association

The Generic Medicines Industry Association ("GMiA") is a representative body of generic medicine suppliers in Australia. Its members ensure that all Australians are offered the highest quality generic medicines in the world whilst providing affordable community health outcomes that benefit all Australians.

The generic medicines industry is a high value-add sector, delivering significant health and economic benefits to the Australian public in the context of an ageing population. This includes the provision of affordable medicines, the generation of substantial savings to the PBS, the creation of highly skilled jobs and the export of medicines.

GMiA members believe in achieving an appropriate balance between the rights of patent owners and the provision of affordable medicines to all Australians.

Pharmaceuticals are Australia's leading export of manufactured goods. Generating \$3.74 billion in 2011, pharmaceutical exports are more significant to the economy than the exports of cars (\$2.5 billion in 2011) or wine (\$2.0 billion in 2011).

The GMiA supports the general principles of ACTA. GMiA is, however, concerned that the wording of ACTA allows for the implementation of an over-reaching and onerous system of Intellectual Property enforcement. GMiA understands that in the government's opinion the wording of ACTA does not require it.

GMiA makes the following recommendations to ensure ACTA achieves its objectives and to ensure no unintended consequences.

We endorse the Joint Standing Committee on Treaties' review of ACTA and request that the Australian Government instigates an independent and transparent assessment of the final text of ACTA and that it presents the report to the Australian Parliament.

**Recommendations:**

1. GMiA acknowledges that ACTA expressly allows parties to exclude Patents and Confidential Information from the remedies provided in Chapter 2, Section 2 (Civil Enforcement). GMiA supports balanced Intellectual Property rights in the pharmaceutical sector and recommends that the Australian Government does so.

However, GMiA remains concerned that in ratifying ACTA, the parliament leaves it open for another Australian government, either because it has a different policy on IP infringement or because it is forced to by international agreement in the future, to remove this exclusion

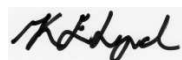
GMiA recommends that the Australian Government also issues a public statement that is incorporated into Hansard to the effect that the word 'counterfeit' in ACTA is not to include generic medicines entered or eligible for entry on the Australian Register of Therapeutic Goods.

2. The potential implementation of ACTA reinforces the urgency surrounding an unresolved issue currently threatening the generic medicines industry. This issue concerns copyright infringement in the production of product information documents, which accompany generic medicines. The Australian Government has recently introduced legislation which attempts to ensure that generic manufacturers will not be at risk of copyright infringement when complying with their obligations, imposed by the Therapeutic Goods Administration, to provide product information that is substantially identical to the originator's medicine.

However, this legislation is defective in a number of respects. Importantly (amongst other things), this legislation does not deal with potential infringements that occurred before the introduction of this legislation and does not appear to cover Consumer Medicines Information leaflets. This issue is currently before the Full Federal Court in *Apotex Pty Ltd v Sanofi- Aventis Australia Pty Ltd & Ors* NSD 2133 of 2011. However, GMiA believes that this issue requires legislative intervention in order to ensure that generic manufacturers are adequately protected.

Given that the seizure provisions of ACTA apply to goods that infringe copyright, failure to resolve this pre-existing copyright issue may result in the seizure of generic drugs at Australian borders. Accordingly, GMiA recommends that the Australian Government addresses this vital copyright issue in conjunction with its consideration of ACTA.

Kind regards,



**Kate Lynch**  
**Chief Executive Officer**  
**Generic Medicines Industry Association Pty Ltd**