



**Medicines Australia Limited –
application for revocation of authorisations A91316-A91320 and
substitution of new authorisations A91436-A91440
Interim authorisation decision
4 December 2014**

Decision

The Australian Competition and Consumer Commission (the ACCC) has granted interim authorisation in respect of the application for authorisation lodged by Medicines Australia Limited (Medicines Australia) on 2 July 2014.

Interim authorisation is granted to enable Medicines Australia to continue to give effect to edition 17 of its Code of Conduct while the ACCC is finalising its consideration of edition 18 of the Code.

Interim authorisation commences on 10 January 2015 and remains in place until it is revoked or the date the ACCC's final determination comes into effect.

The application for authorisation

Medicines Australia has sought revocation of the current authorisation granted in respect of edition 17 of the Code and its substitution with a new authorisation of edition 18 of the Code (re-authorisation). Medicines Australia's Code of Conduct is a voluntary industry code for the prescription medicines industry in Australia.

The ACCC initially granted authorisation to edition 17 of Medicines Australia's Code until 11 January 2015.

Medicines Australia is seeking interim authorisation because it is unlikely that the ACCC will make a final decision on the application for re-authorisation before the current authorisation expires.

The authorisation process

Authorisation provides protection from legal action for conduct that may otherwise breach the competition provisions of the *Competition and Consumer Act 2010* (the Act). Broadly, the ACCC may grant authorisation if it is satisfied that the benefit to the public from the conduct outweighs any public detriment, including from a lessening of competition. The ACCC conducts a public consultation process to assist it to determine whether a proposed arrangement results in a net public benefit.

Interim authorisation

Section 91 of the Act allows the ACCC to grant interim authorisation where the ACCC considers it appropriate to do so for the purposes of enabling the ACCC to give due consideration to the substantive application for authorisation.

In the case of an application for re-authorisation the ACCC may suspend the operation of the authorisation sought to be revoked and grant an authorisation that is expressed to be an interim authorisation in substitution for the authorisation suspended.

Medicines Australia requested interim authorisation on the basis that:

- it required additional time to consult further with member companies and reach a concluded position in relation to the ACCC's draft determination
- it and its member companies require time to consider any third party submissions provided to the ACCC, which were due on 21 November 2014
- it and its member companies may seek to provide further submissions to the ACCC following the pre-decision conference held on 28 November 2014
- the ACCC's review process will likely coincide with the Christmas closure period.

Consultation

The ACCC sought submissions from a number of interested parties potentially affected by this application, including pharmaceutical companies, industry associations, Government departments, consumer groups and individuals. A summary of the public submissions received from Medicines Australia and interested parties follows.

Medicines Australia submits that interim authorisation should be for edition 18 (as drafted), noting:

- the new transparency requirements outlined in edition 18 do not commence until 1 October 2015 and thus there will be little difference to the current position under edition 17
- the numerous public benefits associated with edition 18 of the Code.

Dr Ken Harvey, the Australian Medical Association and the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists support Medicines Australia's request for interim authorisation.

Further information in relation to the application for authorisation, including any public submissions received by the ACCC as this matter progresses, may be obtained from the ACCC's website www.accc.gov.au/authorisations.

Reasons for decision

The ACCC has decided to suspend the operation of authorisations A91316-A91320 and grant interim authorisation in substitution, consistent with section 91(2)(f) of the Act. The interim authorisation is for the Code in terms of edition 17. This has the effect of maintaining the status quo while the ACCC finalises its decision regarding the authorisation of edition 18 of the Code.

In granting interim authorisation for the Code in terms of edition 17, the ACCC notes that:

- the ACCC will not be able to make a final determination before the existing authorisation expires on 11 January 2015, noting that the deadline for submissions from the applicant and interested parties was extended until 21 November 2014 (at the request of Medicines Australia) and a pre-decision conference was held on 28 November 2014
- interim authorisation will maintain the status quo, including the associated benefits and detriments
- interim authorisation will avoid the uncertainty that may arise if the existing authorisation is allowed to lapse
- edition 18 of the Code introduces a regime which requires reporting of individual transfers of value made to healthcare professionals, except where the healthcare professional has not consented to the disclosure. In a draft determination issued on 17 October 2014 the ACCC proposed changes to the regime by way of a condition that would ensure that all relevant transfers of value by pharmaceutical member companies to individual healthcare professionals are reported. The ACCC is also considering requiring ongoing hospitality reporting. Interim authorisation will enable the ACCC to continue the consultation process following the draft determination, including on any conditions of authorisation
- The ACCC anticipates releasing a final determination on this matter in the first quarter of 2015 and so the interim authorisation will be in place for only a limited time.

Reconsideration of interim authorisation

The ACCC may review the interim authorisation at any time. The ACCC's decision in relation to the interim authorisation should not be taken to be indicative of whether or not the final authorisation will be granted.