

Aspen's Response to the Consultation: Whether the TGA should publish that a prescription medicine is under evaluation

Q1: Please specify your preference in terms of information that should be included in a potential published list (e.g. active ingredient, trade name, therapeutic area versus indication, sponsor name)?

Response

active ingredient and therapeutic area

Option 1: maintain TGA's current publication arrangements

Response

Aspen supports this option. For commercial reasons, Aspen prefers to retain control over when its product registrations become public.

Option 2: list all applications accepted for evaluation

Response

Aspen does not support this option. Aspen regards this as commercially sensitive information, and prefers to be in control of when information regarding its pipeline is publically available. In addition, there are many uncertainties at the time the application is accepted for evaluation, including whether the product will be approved for registration, when it will be approved, and whether and when it will be marketed. Publication while these uncertainties exist is likely to lead to confusion and require additional resources. Furthermore, as Aspen licences and registers International products, it is concerned that the publication of such products on the TGA website prior to registration may reduce those originator's interest in registering in the Australian market, and thereby reduce patient access to these medications.

Option 3: list all applications at two different time points

Response

Aspen does not support this option for the reasons specified above.

Option 4: list applications of innovator medicines of highest public interest, but not generic or biosimilar medicines

Response

Aspen does not support this option for the reasons specified above.