

10th October 2019

ARTG excipients project
Scientific Operations Management Section
Scientific Evaluation Branch
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

Consultation: Increased online access to ingredient information

Dear Sir/Madam

Seqirus thanks the Therapeutic Goods Administration (TGA) for the opportunity to participate in the consultation "Increased online access to ingredient information". Our core values include patient focus, innovation and collaboration and we welcome this initiative which is aimed at helping consumers make more informed and safer choices about their medicines.

Please find attached our response to the TGA's consultation paper. Please feel free to contact me should you have any questions or require further information.

Yours sincerely,



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Response to TGA Consultation Paper Increased Online Access to Ingredient Information

October 2019

Seqirus thanks the TGA for the opportunity to provide feedback on the proposal to publish the names of excipient ingredients used in therapeutic goods in the public view of the Australian Register for Therapeutic Goods (ARTG).

Seqirus' response to the questions raised at the end of the consultation paper are provided below.

Q1. Which is your preferred option? Why?

Seqirus' preferred option is option 1B. This option provides online excipient information to consumers and brings the formulation information on the ARTG in line with the information currently available in both the approved Product Information and Consumer Medicine Information documents.

Q2. What are the risks and benefits (e.g. commercial, consumer safety, innovation) for each of the options proposed?

Although Seqirus' preferred option is 1B, the risks and benefits of all options were considered.

Option 1A

We acknowledge that Option 1A provides additional excipient information to consumers and therefore may increase the safety of the product. Seqirus supports all safety initiatives proposed by the TGA.

However, we note that the implementation of option 1A may be hindered by proprietary ingredient manufacturers. These manufacturers, who are often based outside Australia, can be reluctant to provide formulation information to Sponsors. Instead, it is common place for the necessary regulatory information to be sent directly to the TGA with only a letter of access provided to Sponsors.

A further example of the reluctance of some proprietary ingredient manufacturers to provide information to sponsors is the current practice for identifying potential allergenic excipients (i.e. those ingredients outlined in Schedule 1 to TGO 91/92). Sponsors may obtain information on potentially allergenic excipients via a declaration from proprietary ingredient manufacturers. This declaration is usually only provided on request and does not list the formulation of the product. The declaration only confirms whether their product contains any of the ingredients listed in Schedule 1 to TGO 91/92.

Should it become compulsory to list all ingredients on the ARTG, some proprietary ingredient suppliers may object to this, resulting in difficult negotiations, time delays and potentially the inability to register products in Australia.

Option 1B

Option 1B brings the formulation information on the ARTG into line with the information currently available in both the approved Product Information and Consumer Medicine Information documents.

Although full proprietary ingredient formulation details would not be listed under this option, if the proprietary ingredient did contain potential allergens listed in Schedule 1 of TGO 91/92 these would be listed directly on the product packaging thus providing clear allergen warning information to Consumers. We note, however, this current consultation does not cover other components which may be declared on product packaging (e.g. manufacturing impurities or residues such as Latex; ovalbumin is a processing impurity in some influenza vaccines and is declared on the packaging). In the interests of aligning information and enhancing patient safety, perhaps consideration could also be given to the inclusion of this type of information in the public view of the ARTG.

Option 1B is not viewed by Seqirus as having the potential commercial and regulatory risks associated with Option 1A.

Option 2

Seqirus has not identified any benefits to industry associated with Option 2. The primary risks identified with this option are that excipient information may be harder for consumers to find or, if using other non-TGA or Sponsor owned on-line sources, consumers may find incorrect information from overseas products or out of date information. The ARTG provides a reputable source for accurate and up to date information.

Q3. If Option 1A or 1B is implemented, are you interested in collaborating with us to help communicate this information to consumers?

Seqirus is unable to confirm our availability to assist with this project should Option 1A or 1B be implemented. We appreciate the efforts of the TGA to make additional information more easily accessible to consumers and for collaborating with Sponsors on this project.

