Improved Data Protection Scheme for AUST L(A) medicines

Therapeutic Goods Amendment (2020 Measures No. 2) Bill 2020

CMA is pleased to announce that Assistant Minister Trevor Evans has introduced the Therapeutic Goods Amendment (2020 Measures No. 2) Bill 2020. The Bill contains a number of amendments to the *Therapeutic Goods Act 1989* ('the Act') and contains an important measure to improve the flexibility of the Data Protection scheme for listed complementary medicines entering the TGA-assessed [AUST L(A)] pathway. Through 2020 CMA raised proposed amendments to the initially announced Data Protection scheme, to ensure increased confidence for industry and researchers undertaking clinical research. Numerous CMA members and affiliated academics have assisted in progressing critical parts of the amended scheme, another strength of the cooperation of our industry working together to advance Australian complementary medicines locally and globally.

Importantly, the new scheme enables researchers and sponsors to publish critically necessary aspects of their research in full, and five years earlier than previously permitted. This allows sponsors and researchers to publish important information about their research and gain public recognition of the efficacy of complementary medicines as soon as possible after market approval. Visible recognition of the evidence-base for complementary medicines including vitamins, minerals and herbal medicines will further help launch the recognition of the efficacy of these substances in the context of more recognisable and accessible therapeutic uses (restricted representations).

The new scheme also critically increases the flexibility and breadth of the scheme by expanding the eligibility of indications to ensure that a medicine with the same "intermediate" indication as another medicine but with different active ingredients, may also now access the scheme, to provide far greater certainty and be more effective in encouraging innovation into new therapeutic uses.

In summary, the operation of the new scheme will now permit medicines with the same indication as another protected medicine, but with different active ingredients, to access the Scheme.

It newly requires that applicants who wish to gain data protection for an AUST L(A) medicine must provide a clinical trial number which is included in a clinical trial registry. The trial needs to include an "intermediate level" indication that is assessable for the AUST L(A) pathway.

The recording of clinical trial numbers in a registry means that this process will now underpin the data protection scheme, significantly allowing researchers to more openly publish the efficacy data underpinning the trial, allowing better publication and scientific recognition of new evidence for complementary medicines.

Application for data protection as part of an AUST L(A) medicine remains entirely voluntary. Applicants may continue to use data that is unprotected, including data that is not eligible for protection, to apply for new AUST L(A) medicines. However, as before, applicants for new AUST L(A) medicines will not be able to utilise data whose clinical trial information is currently under protection for the 5 year period.

The data protection scheme, initially introduced to the Act in March by the Therapeutic Goods Amendment (2020 Measures No. 1) Act 2020, provides an opportunity for a business who has sponsored clinical research and subsequently received approval for market supply of that innovator medicine as a listed assessed or "AUST L(A)" medicine, to have protected use of that data for 5 years in the assessed listed pathway, allowing business cases to proceed into new clinical research. The scheme protects clinical trial results and preventing the Secretary from having regard to it in evaluating a subsequent application. This effectively prevents competitors from seeking market authorisation of generic forms of an assessed listed medicine – competitors will be unable to rely on data generated by the sponsor of the innovator medicine for 5 years after the listing of the innovator medicine.

By providing an opportunity to gain a return on investment for new research and product development, it stimulates new clinical trials and increasing research into complementary medicines.

Legislative result

Assuming no further changes through the Parliamentary process, after progression of the Bill and incorporation into the Act the amended scheme will read as follows, with the amended parts in blue:

> **26AF When the Secretary must not use restricted information in evaluating medicine for listing under section 26AE**
>
> (1) If an application is made under section 23 for the listing of a medicine under section 26AE, then, in evaluating the medicine under section 26AE, the Secretary must not use information about other medicine that is restricted information.
>
> (2) Information is ***restricted information*** if:
>
> (a) the information was given to the Secretary in relation to an application made under section 23 for the listing of a medicine (the ***existing medicine***) under section 26AE; and
>
> (b) the information is derived from a clinical trial in relation to an indication of the existing medicine, where:
>
> (i) the trial number of that trial is specified in the application for the listing of the existing medicine; and
>
> (ii) the Secretary is satisfied that the trial number of that trial is set out in a registry prescribed by the regulations for the purposes of this subparagraph; and
>
> (c) that indication is either:
>
> (i) a use of the existing medicine in preventing, curing or alleviating a disease, ailment, defect or injury in persons, other than a form of the disease, ailment, defect or injury that, under the Therapeutic Goods Advertising Code, is a serious form; or
>
> (ii) a use of the existing medicine in connection with alleviating a disease, ailment, defect or injury in persons, being a form of the disease, ailment, defect or

injury that, under the Therapeutic Goods Advertising Code, is a serious form; and

(d) at the time (the ***relevant time***) the application for the listing of the existing medicine was made:

(i) that indication was not covered by a determination under paragraph 26BF(1)(a); and

(ii) no other medicine with that indication, and with the same active ingredients as the existing medicine, was included in the Register under section 26AE; and

(da) no other medicine with that indication, and with the same active ingredients as the existing medicine, had been included in the Register under section 26AE at any time before the relevant time; and

(e) the existing medicine was listed under section 26AE on or after the commencement of this subsection; and

(f) 5 years have not passed since the day that listing commenced; and

(g) the person in relation to whom the existing medicine is listed has not given the Secretary permission in writing for the Secretary to use the information.

This replaces the previous (b), (c), and (d):

(b) the information is derived from a clinical trial in relation to an indication of the existing medicine, being an indication that is not covered by a determination under paragraph 26BF(1)(a); and

(c) the information is not available to the public; and

(d) at the time the application to list the existing medicine was made:

(i) no other medicine with that indication was included in the Register; and

(ii) no other medicine with that indication had been included in the Register at any time before that time; and

The Bill's description of the changes to data protection ('restricted information') included in Schedule 5 is reproduced in full in Attachment 1.

Complementary Medicines Australia has access to a draft copy of the Data Protection guidance by the TGA, for member comment as part of a targeted consultation. If you have not received a copy through participation on relevant CMA Committees, please email technical@cmaustralia.org.au to receive a copy for comment.

Resources

- Therapeutic Goods Amendment (2020 Measures No. 2) Bill 2020
- TGA website – Assessed Listed Medicines
- Indications for different kinds of complementary medicines including AUST L(A)
- AUST L(A) fact sheet
- Therapeutic Goods Act 1989
- Therapeutic Goods (Permissible Ingredients) Determination (No. 3) 2020

Attachment 1

Therapeutic Goods Act 1989

SCHEDULE 5—RESTRICTED INFORMATION

Summary

A data protection scheme for assessed listed medicines was introduced to the Act by the *Therapeutic Goods Amendment (2020 Measures No. 1) Act 2020*, to encourage and incentivise innovation in the complementary medicines industry by protecting clinical trial results and preventing the Secretary from having regard to it in evaluating a subsequent application. This effectively prevents competitors from seeking market authorisation of generic forms of an assessed listed medicine – competitors will be unable to rely on data generated by the sponsor of the innovator medicine for 5 years after the listing of the innovator medicine.

Since the scheme's introduction industry have raised a number of concerns in relation to the operation of the scheme, including that it does not reflect the range of products and the range of innovations that may relate to the products for which the assessed listed pathway may be used, and does not allow researchers or sponsors to publish certain information relating to their research.

This Schedule makes a number of amendments to the scheme to address some of these issues, in particular, to improve the flexibility and breadth of the scheme.

Item 1 – Paragraphs 26AF(2)(b), (c) and (d)

This item amends section 26AF of the Act to clarify a number of aspects of the meaning of 'restricted information' for the purposes of the data protection scheme for assessed listed medicines.

In particular, item 1 would substitute new subparagraphs 26AF(2)(b), (c), (d), and (da) for the current paragraphs 26AF(2)(b), (c) and (d), with the following main effects for an assessed listed medicine to be able to access the data protection scheme for such products:

- applications for listing in the Register of such a medicine must include the trial number of the clinical trial to which the information they are seeking data protection for relates;
- the Secretary must be satisfied that the trial number is included in a clinical trial registry prescribed for the purposes of new subparagraph 26AF(2)(b)(ii);
- the indication for the medicine must be of a kind that is appropriate for such products, and not an indication that would be made available for general use for all listed medicines – in practice such indications are referred to as "intermediate indications" and relate to preventing, curing or alleviating a disease, ailment, defect or injury other than one that, under the Therapeutic Goods Advertising Code (the Code) is a serious form; or to use in connection with alleviating a disease, ailment, defect or injury that would, under the Code, be a serious form (an example of the latter would be an indication relating to the use of a medicine to alleviate the symptoms or effects of a serious disease such as the alleviation of dehydration associated with gastroenteritis);
- ensuring that a person could not lose data protection through another person applying for the inclusion of the same indication in the Ministerial determination made under

paragraph 26BF(1)(a) of the Act which authorises the general use of indications for all listed and assessed listed medicines; and

- allowing medicines with the same indications, but different active ingredients, to access data protection.

Item 2 – After paragraph 26AF(2)(e)

Currently under section 26AF of the Act, for a sponsor to access the data protection scheme in relation to clinical trial information that relates to their assessed listed medicine, the information must not be available to the public.

This has the effect of precluding the publication of any such information, before or after the medicine is listed in the Register. Stakeholders have raised concerns that this is unduly restrictive, for both industry and researchers who may undertake clinical trial research on behalf of or in conjunction with sponsors seeking to innovate.

This item introduces paragraph (eb) in subsection 26AF(2) to address such concerns, principally by:

- focusing the time during which the information must not be available to the public to the period from the day the application for listing for the medicine was made to the end of the day before the medicine was listed in the Register – this limits the period in which the information must not be available to the public to the application and evaluation period for the medicine; and
- only requiring information other than information about the clinical trial that is included in a prescribed clinical trial registry to not be available to the public – this means that a subset of information about the research will be able to be made public through such a registry which is often required to undertake a clinical trial.

This item also introduces paragraph (ea) to require that for information relating to an assessed listed medicine to be restricted information under the scheme, it must have been relied upon by the Secretary in deciding to list the medicine. If the information was not relied upon (e.g. perhaps it did not provide sufficient evidence to support listing or was not relevant), then the information will not be restricted information.

Item 3 – At the end of section 26AF

This item introduces subsection (3) at the end of section 26AF, which would provide that a registry prescribed for the purpose of subparagraph 26AF(2)(b)(ii) may be a registry established within or outside Australia (i.e. it does not have to be an Australian registry) and must be a registry that is accessible by the public (i.e. a member of the public would be able to access the registry for free online).

Item 4 – Application provision

This item provides that the amendments in this Schedule apply to an application made on or after the commencement of this item, i.e. these amendments do not have retrospective effect.