Member Alert

- **Improved Data Protection Scheme for Assessed Listed Complementary Medicines enters the Therapeutic Goods Act**
- **Modern Manufacturing Strategy Update**

Data Protection for Assessed Listed Complementary Medicines

CMA is pleased to announce that the *Therapeutic Goods Amendment (2020 Measures No. 2) Bill 2020* was passed in both houses of Parliament without amendment on 18 February 2021. This Bill introduces a 5-year data protection regime for clinical trial information used to support the TGA efficacy-assessed listed medicines, known as 'Assessed Listed' or AUST L(A) complementary medicines.

The data protection will, in effect, mean that competitors will be unable to rely on the data generated by the sponsor of the innovator medicine for 5 years after the listing of the sponsor's AUST L(A) medicine, thus preventing generic 'copy' AUST L(A) versions of the approved medicine from being marketed, and ensuring that the investment into clinical research reliably generates a commercial return for the sponsoring company.

This has been an important element of the Medicine and Medical Device Reforms (MMDR) for complementary medicines advocated for by CMA, with the goal of better incentivising clinical research and public recognition of the efficacy of complementary medicines. Globally, it represents a step forward on data protection of complementary medicines in regulation, as retaining intellectual property has been one of the biggest challenges of an industry using naturally derived substances as distinct from patentable "Novel Chemical Entities" often used in registered and prescription medicines.

Greater confidence in investing in research and receiving return from clinical research can help to grow the scientific evidence base for complementary medicines, to the advantage of the complementary medicines sector and its consumer base.

Visible recognition of the evidence-base for complementary medicines including vitamins, minerals and herbal medicines will further help launch public policy and scientific recognition of the efficacy of these substances in the context of more impactful therapeutic uses (such as relief of symptoms associated with higher level indications known as restricted representations).

How does the Scheme work?

In summary, the updated Data Protection Scheme enables the sponsor of a clinical trial which is included on a prescribed clinical trial registry to apply for data protection when applying for the medicine to be evaluated as a "Listed Assessed" medicine. The indication must be an 'intermediate' level indication and must not have previously been approved for another Listed Assessed medicine

with the same active ingredients. The TGA will record the trial registry number and not use that trial to assess other L(A) applications for a 5 year period. The data protection does not apply if the sponsor provides express permission for the information to be used by other sponsors in generic applications (eg as may occur as part of a private licensing arrangement).

Therefore, during those 5 years, the sponsor (and any licensees) are the only entities who will be able to market a medicine for that indication with that combination of active ingredient(s), and the medicine will be eligible to include the positive claimer of efficacy 'TGA Assessed'.

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. Applicants for new AUST L(A) medicines will not be able to utilise data whose clinical trial information is currently under 5 year protection.
The TGA will publish guidelines shortly which will help further clarify operational aspects.

What has changed?

This Bill contains a number of amendments to the *Therapeutic Goods Act 1989* ('the Act') to improve the flexibility of the Data Protection scheme for listed complementary medicines entering the TGA assessed [AUST L(A)] pathway in comparison to the scheme that was originally announced. Through 2020 CMA raised proposed amendments to the original 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 domestically and globally.

The scheme formerly required that certain data was not published in order to receive protection, whereas the new scheme instead requires applicants who wish to gain data protection for an AUST L(A) medicine to provide a clinical trial number which is included in a clinical trial registry, which forms the basis of the protected data. The new scheme enables researchers and sponsors to publish critically necessary aspects of their research in full, five years earlier than previously permitted, generally once the medicine has gained TGA market approval. 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.

The operation of the new scheme will now permit medicines with the same indication as another protected AUST L(A) medicine, but with *different* active ingredients. This enables greater confidence in embarking on new research projects, considering that different complementary medicine formulations may have similar therapeutic goals (such as relief of insomnia). This increases the flexibility and breadth of the scheme to encourage innovation into new therapeutic uses.

Legislative result

Amended parts of section 26AF of the Act are included in Attachment 1 and highlighted in blue, along with and the Bill's description of the changes to data protection ('restricted information').

Resources

- *Therapeutic Goods Amendment (2020 Measures No. 2) Bill 2020* and Explanatory Statement
- TGA website – Assessed Listed Medicines and AUST L(A) fact sheet
- Indications for different kinds of complementary medicines including AUST L(A)

Modern Manufacturing Strategy Update

The Modern Manufacturing Initiative (MMI) is the centrepiece of the Australian Government's Modern Manufacturing Strategy (MMS). The MMI will help manufacturers to scale up and create jobs to lift manufacturing capability, drive collaboration, and identify new opportunities to access domestic and global supply chains.

The Modern Manufacturing Initiative (MMI) is now open, providing co-funding for manufacturing projects across two streams:

- **Manufacturing Translation Stream:** this stream helps Australian manufacturers translate high quality research and ideas into commercial outcomes and support businesses to scale-up and become more competitive and resilient.
- **Manufacturing Integration Stream:** this stream helps Australian manufacturers to access domestic and international value chains, propelling their goods and services into new markets and fostering Australia's reputation as a modern manufacturing leader.

Australian Government funding will be provided on a co-investment basis and will cover up to 50% of eligible project expenditure.

The first round of the MMI Translation and Integrations streams is for the Space National Manufacturing Priority however, funding rounds for the other National Manufacturing Priorities (including medical products) will open in the coming weeks.

Information Sessions

The Department of Industry, Science, Energy and Resources are hosting information sessions that will provide an overview of the Manufacturing Translation and Integration streams, including eligibility requirements and key points from the assessment criteria. General tips for presenting a strong application will also be provided. The session will be held on Wednesday 24 Feb from 2pm - 3:30pm AEDT and will be recorded and uploaded to business.gov.au.

Please also see the "Make it Happen" booklet for a comprehensive overview of the strategy.

You can also subscribe for updates on the strategy by completing the linked form.

Attachment 1

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

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.

Therapeutic Goods Act 1989

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.