**Proposed Amendments to the Therapeutic Goods Act**

In Australia drugs manufacturers can seek Provisional Approval for a drug ahead of submitting final clinical trial data.

Historically, clinical trials require about 7 years to complete (all trials) before an approval is granted. Whereas, a Provisional Approval can be granted in as little as 6 months after the start of clinical trials, with Safety and Efficacy data allowed to be submitted up to 6 years after the drug being administered.

Meanwhile, once Provisionally Approved (after only 6 months of testing), the Australian community can be falsely and dangerously assured the same drug is Safe and Effective, despite the complete absence of any conclusive data supporting such claims.

This fast-track Provisional Approval process benefits the drug manufacturers 100%, but when Risks are suspected or indeed unknown for up to 6 years, this requires the Australian Community to bear 100% of all the potential Risks, including the Risk of death.

Unquestionably this Provisional Approval process is flawed and dangerous to the Australian community, as evidenced by the Provisional Approval of the so-called Covid-19 vaccines, which were not vaccines by any traditional definition, rather a new class of drug entirely, namely gene-based therapy.

The piecemeal court-ordered release of Pfizer’s Covid-19 trial data in the United States has exposed a cover-up of serious deficits in safety and potential fraudulent exaggerations of efficacy. This is vital data that the US Food & Drug Administration (FDA), ***rather than acting upon***, ***petitioned the court to withhold*** such data from the public, the medical and scientific community, and governments ***until the year 2096***.

The unprecedented iatrogenic injuries and global failure in efficacy to stop Covid-19 that followed the fast-tracking and release of these gene-based vaccines into the global community, has evidenced an approval process deeply offensive to Pharmacovigilance duties, obligations and responsibilities such as the Precautionary Principle, which should have been the guiding light for the Australian Therapeutic Goods Administration.

In order to safeguard Australians from a repeat of the ongoing deaths, injuries, and devastation wrought by the decision to Provisionally Approve the Covid-19 gene-based drugs, *then fail to withdraw the Covid-19 gene-based drugs*, the following amendments to the [Therapeutic Goods Act](http://classic.austlii.edu.au/au/legis/cth/consol_act/tga1989191/) are imperative. Proposed amendments are coloured red.

**Current Provisional Approval Steps**

An applicant applies to the Secretary of Health for a [provisional determination](http://classic.austlii.edu.au/au/legis/cth/consol_act/tga1989191/s22c.html) under section 22C.

Once the application requirements are fulfilled under section 22C, the Secretary is then required to make or refuse to make a provisional determination under [section 22D](http://classic.austlii.edu.au/au/legis/cth/consol_act/tga1989191/s22d.html).

The current section 22D reads:

 **Provisional determinations**

(1)  If a person makes an application, in accordance with subsection 22C(2), for a provisional determination relating to a medicine, the Secretary must decide to make, or to refuse to make, the determination.

Criteria

(2)  The Secretary may make the determination if the Secretary is satisfied that the criteria prescribed by the regulations for the purposes of this subsection are met in relation to the medicine.

Content of determination

             (3)  The determination must specify:

                     (a)  the person to whom the determination relates; and

                     (b)  the medicine to which the determination relates; and

                     (c)  the indication of the medicine to which the determination relates; and

                     (d)  each active ingredient of the medicine to which the determination relates.

The determination may specify any other matters that the Secretary considers appropriate.

Notice of decision

             (4)  As soon as practicable after making the decision, the Secretary must:

                     (a)  give the person written notice of the decision; and

 (b)  if the Secretary refuses to make the determination--set out the reasons for the refusal in the notice.

***Proposed Amendments***

Add to subsections 22D(3) and (4), and insert new subsections 22D(5) and (6) to read as follows:

(3)  The determination must specify:

1. the person to whom the determination relates; and
2. the medicine to which the determination relates; and
3. the preliminary clinical data provided as prescribed by the regulations; and
4. the preliminary clinical data not provided as prescribed by the regulations; and
5. any requirements prescribed by the regulations; and
6. the indication of the medicine to which the determination relates; and
7. each active ingredient of the medicine to which the determination relates.

The determination may specify any other matters that the Secretary considers

appropriate.

Notice of decision

             (4)  As soon as practicable after making the decision, the Secretary must:

1. give the person written notice of the decision; and
2. make publicly available the full determination in (3) above; and
3. if the Secretary refuses to make the determination--set out the reasons for the refusal in the notice.

 **Prohibition on Representations**

(5) During any period a provisional determination remains in force:

(a) only the Secretary may publicly comment on or release public statements concerning the Safety or Efficacy of a medicine, provided each public comment or statement released includes precise

 information describing:

(i) the quality and reliability of the preliminary clinical data relied upon for the provisional determination; and

(ii) any item of preliminary clinical data not provided under the regulations for the purposes of the provisional determination.

(b) any public statutory body, public office holder, or elected government official who contravenes (5)(a) above commits an offence, where the maximum civil penalty is:

 (i) for an individual – 5,000 penalty units; and

 (ii) for a body corporate – 50,000 penalty units.

(c) a public statutory body, public office holder, or elected government official does not commit an offence of contravening (5)(a) in making a public comment or statement concerning the Safety or Efficacy of a medicine subject to a provisional determination, only where the public comment or statement reproduces without alterations, additions, or edits a public comment or statement by the Secretary made in accordance with (5)(a).

(d) the Secretary may not delegate the provision of public comments or statements under (5)(a).

 **Informed Consent & Public Discourse Exception**

 (6) The prohibition contained in (5) does not apply to:

(i) a person who is not a public statutory body or a public office holder or elected government official; or

(ii) a National Board under the ***Health Practitioner Regulation National Law*** (the National Law) that releases information on a medicine having followed the procedures under section 35(3) of the National Law [AS PROPOSED UNDER THE AMENDMENTS TO THE NATIONAL LAW]; or

(iii) a public health officer registered under the National Law; or

(iv) a health practitioner registered under the National Law.

**Current Criteria for Provisional Approval**

The criteria that must be satisfied for the Secretary to grant (or make) a provisional determination (or approval) are contained in [regulation 10L](http://classic.austlii.edu.au/au/legis/cth/consol_reg/tgr1990300/s10l.html) of the Therapeutic Goods Regulations 1990, which states:

 **Provisional determinations**

(1)  For the purposes of subsection 22D(2) of the Act, the criteria are all of the following:

(a)  an indication of the medicine is the treatment, prevention or diagnosis of a life-threatening or seriously debilitating condition;

                     (b)  either:

  (i)  no therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register (except in the part of the Register for goods known as provisionally registered goods); or

(ii)  if one or more therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register (except in the part of the Register for goods known as provisionally registered goods)--there is preliminary clinical data demonstrating that the medicine is likely to provide a significant improvement in the efficacy or safety of the treatment, prevention or diagnosis of the condition compared to those goods;

(c)  there is preliminary clinical data demonstrating that the medicine is likely to provide a major therapeutic advance;

(d)  the person who made the application under subsection 22C(1) of the Act has provided sufficient evidence of the person's plan to submit comprehensive clinical data on the safety and efficacy of the medicine before the end of the 6 years that would start on the day that provisional registration of the medicine would commence if the Secretary were to provisionally register the medicine.

             (2)  However, paragraphs (1)(b) and (c) do not apply if:

(a)  the application under subsection 22C(1) of the Act is made on or after the commencement of this subregulation; and

(b)  an indication of the medicine is the treatment or prevention of the disease known as coronavirus disease (COVID-19).

***Proposed Amendments***

Re-number current 10L(1)(b) as 10L(1)(c); Re-number current 10L(1)(c) as 10L(1)(d); Re-number current 10L(1)(d) as 10L(1)(e); Insert new 10L(1)(b); Re-number current 10L(1)(b)(ii) as 10L(1)(c)(iii); Insert a new 10L(1)(c)(ii); Delete current 10L(2) entirely; Insert a new 10L(2); Insert new 10L(3).

Regulation 10L to instead read:

 (1)  For the purposes of subsection 22D(2) of the Act, the criteria are all of the following:

(a)  an indication of the medicine is the treatment, prevention or diagnosis of a life-threatening or seriously debilitating condition;

(b) the medicine has not been available for sufficient time to conduct long term clinical trials and Pharmacovigilence but an urgent access need is apparent;

(c)  either:

(i)  no therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register (except in the part of the Register for goods known as provisionally registered goods); or

(ii) no therapeutic goods included in the Register have been shown in

off-label use, whether singularly or in combination, to demonstrate significant therapeutic outcomes in the treatment, prevention or diagnosis of the condition, while maintaining the safety and efficacy of the therapeutic goods when so used off-label; or

(iii) if one or more therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register (except in the part of the Register for goods known as provisionally registered goods)--there is preliminary clinical data demonstrating that the medicine is likely to provide a significant improvement in the efficacy or safety of the treatment, prevention or diagnosis of the condition compared to those goods;

(d)  there is preliminary clinical data demonstrating that the medicine is likely to provide a major therapeutic advance;

(e)  the person who made the application under subsection 22C(1) of the Act has provided sufficient evidence of the person's plan to submit comprehensive clinical data on the safety and efficacy of the medicine before the end of the 6 years that would start on the day that provisional registration of the medicine would commence if the Secretary were to provisionally register the medicine.

(f) if the medicine is a gene-based therapeutic involving a method of action requiring entry into human cells and involving synthetic or engineered mRNA or DNA, no provisional determination or approval can occur unless preliminary clinical data from high powered clinical trials shows:

(i) the medicine stops or significantly reduces transmission amongst humans of the target disease; and

(ii) the medicine stops or significantly reduces severe illness from the target disease in humans; and

(iii) the medicine does not or does not detrimentally bio-distribute throughout the human body; and

(iv) as compared to all other vaccines approved in Australia during the years 1975 to 2019, the medicine does not or does not in any statistically significant respect, cause death or serious adverse effects; and

(v) all preliminary clinical data in subsections (2)(i)-(xii) must be provided at the time the application is made under subsection 22C(1) of the Act; and

(g) if the medicine is a gene-based therapeutic involving a method of action requiring entry into human cells and involving synthetic or engineered mRNA or DNA, the medicine must pass assessment under the TGA Gene Therapy Checklist.

(2) Subject to (3) below, the ‘***preliminary clinical data***’ referred to in sub-regulations (1)(c)(iii) and 1(d) above must include and provide the following:

1. all clinical trial sites tasked with the collection of the preliminary clinical data must show proof of having been independently audited at least weekly during the period the preliminary data was collected; and
2. in accordance with ICH S2 (R1) full Genotoxicity studies; and
3. in accordance with ICH S1B full Carcinogenicity studies; and
4. in accordance with ICH S3B full Pharmacokinetics repeated dose tissue distribution studies; and
5. in accordance with ICH S3A full Toxicokinetics studies; and
6. in accordance with ICH S5 (R3) full reproductive toxicology studies; and
7. if the medicine is intended at some time in the future to treat, prevent or diagnose a life-threatening or seriously debilitating condition in pregnant or lactating women, all available in vivo pregnancy and lactation Safety and Efficacy studies; and
8. if the medicine is intended at some time in the future to treat, prevent or diagnose a life-threatening or seriously debilitating condition in persons aged 0-18, provision of ICH S11 test results together with all available in vivo paediatric and adolescent Safety and Efficacy studies; and
9. the method of manufacture of the dosage form of the clinical trial batches shall utilise the same methods and production equipment as for the production of commercial batches. The methods utilised in the manufacture of the product should be fully validated according to ICH Guideline Q11; and
10. stability studies conducted in accordance with ICH Guidelines showing the chemical, physical and microbial stability for the proposed shelf life of the product, for both clinical trial and production batches; and
11. a Drug Master File in accordance with ICH Guidelines; and
12. all documents and clinical data collected during all aspect of Phase I, II, or III trials undertaken for the preliminary clinical data must be made publicly available online from the date an application for a provisional determination is lodged under section 22C of the Act; and
13. documents and clinical data supplied under (xii) above must be complete and without redactions, except:
14. proprietary information which contains a chemical formula or information which would enable a competitor to reproduce the drug or produce a competing drug, may be redacted;
15. personnel, personal, and personally identifying information may be redacted.
16. complete and unredacted copies of documents or clinical data for which redactions are sought under (xiii) above must be provided to the Secretary when submitting preliminary clinical data for the purposes of section 22C of the Act.

(3) Should any item of ‘***preliminary clinical data***’ in (2) above not be provided to the Secretary when an application is made under section 22C of the Act, except for a therapeutic falling under (1)(f) above, the Secretary may allow the absence of the item of preliminary clinical data when making a provisional determination under section 22D, provided that:

1. the provisional determination specifies the item of preliminary clinical data absent when making a determination under section 22D; and
2. the provisional determination specifies a requirement the person making the application under section 22C must provide the item of preliminary clinical data to the Secretary as soon as practicably possible; and
3. once the preliminary clinical data is provided to the Secretary under (3)(b) above, make that data available pursuant to (2)(xii) above; and
4. for so long as preliminary clinical data is not supplied to the Secretary under (3)(b), all Product Information and Patient Prescribing Information for the medicine is required to:
5. contain an opening section clearly titled ‘**WARNING**’ in BOLD UPPER case in a font 2 times larger than the standard font; and
6. under the ‘**WARNING**’ title clearly state each item of preliminary clinical data not supplied pursuant to sub-regulation 10L(2); and
7. clearly state the types of information the missing preliminary clinical data would have provided to a patient; and
8. clearly state all potential risks to a patient due to the preliminary clinical data not being available; and
9. the ‘**WARNING**’ section must conclude with the following statement in BOLD UPPER case in a font 2 times larger than the standard font:

‘**THIS IS AN EXPERIMENTAL DRUG FOR WHICH THERE IS NO MEDIUM OR LONG-TERM SAFETY OF EFFICACY DATA**’

(4) No provisional determination or approval can be made under section 22D of the Act until a PDSMB is established in respect of the therapeutic with the following structure and powers:

(i) formation of a fully independent Pharmacoviligence Data Safety Monitoring Board (PDSMB);

(ii) the PDSMB shall comprise 6 members each with at least 20 years experience conducting human clinical trials;

(iii) members of the PDSMB must have no history of direct employment with the Therapeutic Goods Administration;

(iv) members of the PDSMB must have no Conflicts of Interest as determined by reference to the Damocles Charter;

(v) the PDSMB shall be granted unrestricted access to the TGA DAEN system in respect of all reports suspecting the therapeutic;

(vi) the PDSMB shall be granted unrestricted access to all proprietary and commercially sensitive information contained within the application for provisional determination;

(vii) the PDSMB shall be granted unrestricted access to all data and analysis associated with the Risk Management Plan formalised with the applicant in respect of the therapeutic;

(viii) the PDSMB shall concurrent with the TGA receive all Periodic Safety Update Reports from the applicant in respect of the therapeutic;

(ix) the PDSMB shall meet at least weekly with a quorum being 4 members;

(x) 3 members of the PDSMB may elect a new member should a seat on the PDSMB be vacated;

(xi) all meetings of the PDSMB shall be video recorded in full, and made publicly available within 24 hours;

(xii) when during a meeting of the PSDMB 3 members agree the therapeutic harms recipients, and this harm outweighs any benefit from the therapeutic, the PSDMB must as soon as practicable inform and recommend the Secretary revoke the provisional determination;

(xiii) when during a meeting of the PSDMB 4 or more members agree the therapeutic harms recipients, and this harm outweighs any benefit from the therapeutic, the PSDMB must as soon as practicable inform the Secretary the PSDMB is revoking the provisional determination pursuant to section 22F(1)(a) of the Act;

(xiv) the PDSMB shall commence operations from the date a provisional approval is granted under section 22D of the Act;

(xv) the PDSMB may make a recommendation under (xii) above at any time after commencing operations, but must refrain from revoking a provisional determination under (xiii) above for a period of three (3) months from the date a provisional determination is granted under section 22D;

(xvi) the PDSMB may make publicly available non-proprietary de-identified data, findings, and determinations during and subsequent to any meeting of the PDSMB;

(xvii) the PDSMB must make publicly available non-proprietary de-identified data, findings, and reasons when a determination is made to make a recommendation under (xii) above, or to revoke under (xiii) above.

**Current Power to Revoke a Provisional Approval**

The relevant [section is 22F](http://classic.austlii.edu.au/au/legis/cth/consol_act/tga1989191/s22f.html) reads as follows:

 **Revocation of provisional determination**

Revocation on Secretary's own initiative

(1)  The Secretary may revoke a provisional determination under section 22D relating to a person and a medicine if the Secretary is satisfied that the criteria prescribed by the regulations for the purposes of subsection 22D(2) are no longer met in relation to the medicine.

Revocation on request

(2)  The Secretary must revoke a provisional determination under section 22D relating to a person and a medicine if the person requests the Secretary, in writing, to do so.

Notice of revocation

             (3)  As soon as practicable after making a revocation under this section, the Secretary must:

                     (a)  give the person written notice of the revocation; and

                     (b)  for a revocation under subsection (1)--set out the reasons for the revocation in the notice.

Day revocation takes effect

(4)  A revocation under this section takes effect on the day on which the Secretary gives the person notice of the revocation.

***Proposed Amendments***

Insert new subsection (1)(a); Re-number current subsections (3) and (4), as (4) and (5) respectively; insert a new subsection (3).

Section 22F to instead read:

**Revocation of provisional determination**

(1)  The Secretary may revoke a provisional determination under section 22D relating to a person and a medicine if the Secretary is satisfied that the criteria prescribed by the regulations for the purposes of subsection 22D(2) are no longer met in relation to the medicine, or:

(a) a PSDMB established under the regulations for the purposes of subsection 22D(2) must revoke a provisional determination when the criteria for revocation has been met.

Revocation on request

(2)  The Secretary must revoke a provisional determination under section 22D relating to a person and a medicine if the person requests the Secretary, in writing, to do so.

**Precautionary Principle Revocation**

(3) The Secretary must revoke a provisional determination under section 22D relating to a person and a medicine when:

1. final and conclusive Phase III clinical data evidencing the long term Safety of the medicine for all persons has not been provided to the Secretary; and
2. an Australian State or Territory government proposes to mandate or require or compel the administration of the medicine in any manner whatsoever.

(4)  As soon as practicable after making a revocation under this section, the Secretary must:

(a)  give the person written notice of the revocation; and

(b)  for a revocation under subsection (1)--set out the reasons for the revocation in the notice.

Day revocation takes effect

(5)  A revocation under this section takes effect on the day on which the Secretary gives the person notice of the revocation.

**Current Power to Suspend a Drug**

[Section 29D](http://classic.austlii.edu.au/au/legis/cth/consol_act/tga1989191/s29d.html) which reads in part:

 **Suspension of registration or listing**

(1)  The Secretary may, by written notice given to a person in relation to whom therapeutic goods are included in the Register, suspend the registration or listing of the goods if:

                     (a)  the Secretary is satisfied that:

(i)  there is a potential risk of death, serious illness or serious injury if the therapeutic goods continue to be included in the Register; and

(ii)  it is likely that the person will, within the period of the suspension, be able to take the action necessary to ensure that the therapeutic goods would not cause a potential risk of death, serious illness or serious injury if the therapeutic goods were to continue to be included in the Register; or

(b)  the Secretary is satisfied that it is likely that there are grounds for cancelling the registration or listing of the goods under paragraph 30(1)(da), (e), (ea), (f), (fa), (fb) or (g) or subsection 30(1A), (1C), (1D) or (2).

***Proposed Amendments***

Delete ‘may’ and replace with ‘must’ in the opening to subsection 29D(1), and insert ‘(a)’, ‘(c)’, and ‘(d)’ in subsection 29D(1)(b).

 Section 29D(1) to instead read:

1. The Secretary must, by written notice given to a person in relation to whom therapeutic goods are included in the Register, suspend the registration or listing of the goods if:

                     (a)  the Secretary is satisfied that:

(i)  there is a potential risk of death, serious illness or serious injury if the therapeutic goods continue to be included in the Register; and

(ii)  it is likely that the person will, within the period of the suspension, be able to take the action necessary to ensure that the therapeutic goods would not cause a potential risk of death, serious illness or serious injury if the therapeutic goods were to continue to be included in the Register; or

(b)  the Secretary is satisfied that it is likely that there are grounds for cancelling the registration or listing of the goods under paragraph 30(1)(a), (c), (d), (da), (e), (ea), (f), (fa), (fb) or (g) or subsection 30(1A), (1C), (1D) or (2).

**Current Power to Cancel a Drug**

[Section 30](http://classic.austlii.edu.au/au/legis/cth/consol_act/tga1989191/s30.html) which reads in part:

 **Cancellation of registration or listing**

(1)  The Secretary may, by notice in writing given to a person in relation to whom therapeutic goods are included in the Register, cancel the registration or listing of the goods if:

(a)  it appears to the Secretary that failure to cancel the registration or listing would create an imminent risk of death, serious illness or serious injury; or

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(2)  Subject to subsection (3), the Secretary may, by notice in writing given to a person in relation to whom therapeutic goods are included in the Register, cancel the registration or listing of the goods if:

(a)  it appears to the Secretary that the quality, safety or efficacy of the goods is unacceptable; or

***Proposed Amendments***

Delete ‘may’ and replace with ‘must’ in the opening to subsection 30(1); amend subsection 30(1)(a); in subsection 30(2) delete ‘may’ and replace with ‘must’; amend subsection 30(2)(a).

Section 30 to instead read:

(1)  The Secretary must, by notice in writing given to a person in relation to whom therapeutic goods are included in the Register, cancel the registration or listing of the goods if:

1. any sources of verified information evidence that the registration or listing has causally resulted in death, serious illness or serious injury, or failure to cancel the registration or listing would create an imminent risk of death, serious illness or serious injury; or

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(2)  Subject to subsection (3), the Secretary must, by notice in writing given to a person in relation to whom therapeutic goods are included in the Register, cancel the registration or listing of the goods if:

1. any sources of verified information evidence that the quality, safety or efficacy of the goods is unacceptable or significantly less than originally claimed in any preliminary clinical data used as the basis for a provisional determination made under section 22D; or