SUMMARY OF REGULATIONS TO SUPPORT THE 2017 CHANGES TO THE THERAPEUTIC GOODS ACT (ENACTED AND PROPOSED)

A number of regulation changes are planned for late 2017 to support key elements of the Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017 and related amendments to the *Therapeutic Goods (Charges) Act 1989*, and of the *Therapeutic Goods Amendment (2016 Measures No.1) Act 2017* that was enacted earlier this year.

Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017

This Bill, planned for introduction in September 2017, is the second tranche of principal legislation that amends the *Therapeutic Goods Act 1989* to implement the Australian Government's Response to the recommendations of the Expert Panel Review of Medicines and Medical Devices Regulation.

A number of Review measures in this Bill require supporting regulations – particularly to:

- list the kinds of medicines for which sponsors may apply for a provisional determination, and the criteria for qualifying for a provisional determination (qualifying for a determination will enable a sponsor to then apply for provisional registration); and
- make consequential regulation changes, for example to remove references to the Complaints Resolution Panel and requirements relating to advertisements for which approval is needed (to reflect that this Bill removes pre-approval for advertisements).

The below table summarises the main aspects of the proposed regulations supporting this Bill:

Bill measure	**Main elements of supporting regulations**
Provisional registration of medicines	· the kinds of medicines which can be a provisionally registered medicine – principally, these will be prescription medicines that have early clinical data but which show strong evidence of potential for a substantial benefit to Australian patients if made available earlier than they otherwise would; · the criteria for qualifying for a provisional determination – principally, these will relate to having highly promising early clinical data on efficacy and safety, and addressing an unmet clinical need; and · the fee for applying for a provisional determination, and the fee for applying for an extension of a determination.
Establishing a permitted indications list for listed complementary medicines	· the fee for applying for a variation to the permitted indications legislative instrument; and · consequential amendments to make it clear that for medicines listed under section 26A of the Act, compliance

Bill measure	Main elements of supporting regulations
	with the new permitted indications instrument is part of being eligible for listing in the Register.
Establishing a new pathway for listed complementary medicines seeking to use indications other than those in the above instrument	· the application and evaluation fees for applications relating to this new pathway; and · amendments to ensure that medicines that are listed under this new pathway are eligible for listing.
Legislated timeframes for complementary medicine pre-market assessments	· amendments to provide for application procedures for complementary medicines and evaluation of new ingredients, including 'stop clocks' and timeframes within which applications must be decided; and · application and evaluation fees relating to applications for new ingredients and registered complementary medicines.
Reforms relating to advertising of therapeutic goods	· consequential amendments to remove references to the Complaints Resolution Panel (and related regulation 9 orders) and the Therapeutic Goods Advertising Code Council, and consequential amendments to reflect the Bill's removal of the requirement for advertisements for therapeutic goods to be approved.
Broadening the current range of investigation and enforcement powers	· consequential amendments to remove references to infringement notices, to reflect that revised arrangements for such notices are to be introduced to the TG Act by this Bill.

Amendments to the Charges Act

The Therapeutic Goods (Charges) Amendment Bill 2017 will amend the *Therapeutic Goods (Charges) Act 1989* to make it clear an annual charge is payable for a conformity assessment body determination that is in force.

Regulations will be made later this year to support this by setting out what such charge or charges will be (different charges may apply depending on the scope of an Australian conformity assessment body's certification-related activities). Regulations will also be made setting out what such charge or charges will be in relation to provisionally registered goods.

Therapeutic Goods Amendment (2016 Measures No.1) Act 2017

This Act, which received Royal Assent in June 2017, was the first tranche of principal legislation relating to the Review reforms, and the TGA's regulations program includes amendments to complete two important measures from this Act:

· the arrangements for the making of conformity assessment body determinations (while the second Bill above further recognises the role of these bodies, most of the powers to set out matters relating to the bodies in regulations were introduced by this Act); and

- the arrangements for the priority approval pathway for medical devices.

The below table summarises the main aspects of the expected regulations for these measures:

Act measure	**Main elements of supporting regulations**
Enabling Australian conformity assessment bodies to undertake conformity assessments	· enable Australian corporations to apply for a conformity assessment body determination, in the approved form and manner and noting the required supporting information; · the application fee for such applications; · the requirements for becoming an Australian conformity assessment body, including for example: o organisational and general requirements (e.g. legal status, liability insurance and impartiality); o quality management requirements (e.g. having a quality manual and procedures for taking preventative and corrective actions e.g. complaint handling); and o resource requirements (e.g. qualifications and training for staff, subcontractors and external experts, and having adequate facilities). · the fee for assessing such applications; and · the conditions applying to conformity assessment determinations, including for example: o allowing inspections by authorised persons; o notifying manufacturers if a body's determination is suspended or revoked; and o notifying the Secretary of having suspended or revoked a certificate issued to a manufacturer within 10 working days.
Priority approval for medical devices to enable quicker access for patients	· enabling persons to apply for a medical devices (priority applicant) determination, in the approved form and manner and noting the required supporting information; · the application fee for such applications; · the eligibility criteria to be satisfied for the Secretary to make a determination – these will relate to where: o the kind of device is intended for the treatment, prevention or diagnosis of a life-threatening or seriously debilitating disease or condition; o the kind of device addresses an unmet clinical need; o there is evidence the kind of device represents a breakthrough technology or offers a major clinical advantage over existing alternatives in the Register or (for in vitro diagnostic medical devices only) early availability with result in a major public health benefit.

Act measure	Main elements of supporting regulations
	· the duration of such a determination; and · when a determination may be revoked by the Secretary (principally, where the holder of a determination has not applied for marketing approval and the Secretary is satisfied the device no longer meets the eligibility criteria.

Regulation amendments are also expected in October 2017 to support alignment with the European medical device regulatory framework in relation to the up-classification of surgical mesh and patient implant cards, and later in 2017 to amend the existing pathway for applications for prescription medicines associated with a shortened processing time (175 days). This pathway currently requires the submission of two overseas regulator reports, with specific conditions, which will be reduced to only require one overseas regulator report. These amendments will also include prescribing notifiable variations for registered medicines and biologicals that sponsors may make without pre-approval.

It is anticipated that other regulations (and/or legislative instruments) to support implementation of other review reforms will be made in early 2018.

Depending on the results of current consultations and policy decisions by Government, these may relate to:

- details of the advertising of therapeutic goods (including advertising of pharmacist – only medicines);
- arrangements for the regulation of low-risk therapeutic goods;
- other changes required to align with the European medical device regulatory framework; and
- a broader range of evidence sources for the assessment of the quality of new ingredients for complementary medicines.