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Australia Calls For Companion Testing Plans For Drugs Requiring A CDx

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An updated guide from the Therapeutic Goods Administration proposes that sponsors of marketing applications for drugs that require companion diagnostics should provide reassurance that Australian patients will have access to at least one IVD that is adequate for companion testing.

Australia's Therapeutic Goods Administration is inviting stakeholder feedback on a *proposal* to update its guidance on IVD companion diagnostics (CDx) to introduce, among other things, the concept of a "companion testing plan" that must be provided in marketing applications for medicine or biological indications that require CDx testing.

The purpose of the companion testing plan is to "provide reassurance that there is access to at least one adequate IVD for companion testing and ensure the Australian patients can be treated for that indication safely and effectively," the draft guidance says. "All applications for registration of a new medicine or biological indication that require CDx testing must include a companion testing plan."

The draft guidance says that the testing plan only needs to identify one IVD that the TGA considers adequate and is "not meant to be a comprehensive description of all possible companion tests that are available in Australia at the time of medicine indication registration (or over subsequent time)."

It adds that ideally, a CDx should be developed and an application for inclusion in the Australian Register of Therapeutic Goods (ARTG) should be submitted to the TGA for each corresponding indication for use of a medicine or biological that requires CDx testing. However, "this may not necessarily be possible within the same timeframe (or ever, if CDx testing is performed overseas)," it notes.

Moreover, CDx testing may also rely on the use of in-house CDx IVDs. All these factors may make it difficult to submit concurrent applications for a CDx and the relevant indication for use of a corresponding medicine or biological. "Therefore, whilst it is strongly encouraged, concurrent submission and assessment of these applications is not mandated under the Australian legislation," the guideline explains.

The companion testing plan provides a mechanism for the TGA to evaluate the performance and validity of IVDs intended for companion testing, even when there is no concurrent application for inclusion of a CDx in the ARTG (or notification of an in-house CDx IVD).

This approach recognizes that there may be barriers to bringing a CDx to the Australian market for local supply, and that Australian samples may have to be sent for testing internationally. "While this is not preferred, the companion testing plan provides a mechanism for the TGA to appraise such testing and for a medicine or biological sponsor to take responsibility for it, until the registration or notification of a local testing option is possible," it adds.

The guideline clarifies that a medicine or biological indication that requires CDx testing can be approved without a corresponding CDx test being on the ARTG (or notified to the TGA as an in-house IVD), as long as an adequate companion testing plan is in place. However, a commercial CDx must be included in the ARTG (or an in-house CDx must be notified to the TGA) before the device can be legally supplied in Australia.

With respect to post-approval actions, the guideline states that if the TGA becomes aware that all existing (approved and notified) CDxs for a given medicine or biological indication have become unavailable in Australia, the sponsor of the medicine or biological may be asked to provide a new companion testing plan for evaluation, and a new condition of registration regarding substantial changes to the testing plan may be added.

Other proposed changes in the revised guideline include:

- The introduction of a CDx testing identification guide to assist sponsors in identifying whether their medicine or biological indication requires companion testing.
- Improved clarity on clinical and analytical performance requirements for CDx.
- The addition of case studies to assist sponsors of medicines and medical devices on the regulatory process and the technical documentation required for an IVD CDx.

Comments on the TGA's proposals will be accepted until 17 June. The draft guideline, when finalized, will replace the *current guidance* on regulatory requirements for IVD CDx, which has

been in effect since October 2022.