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AMA submission – TGA proposals regarding nomenclature of biological medicines

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The AMA acknowledges that there are benefits in introducing measures to better differentiate between biological and biosimilar medicines.

However, on balance, the AMA considers it would be sensible to support option 1 in the consultation paper for the time being, that is, to maintain the status quo by continuing to identify the active ingredient in biological medicines using its Approved Biological Name, allocated Australian registration number, proprietary trade name and batch numbers when available.

The current system is sufficiently robust for Australia to continue with the status quo until international bodies and regulators such as WHO, FDA and the EMA have determined which option they will adopt and have commenced implementation. This will allow Australia to learn from international experience and see more clearly the costs/benefits of each system, what mistakes to avoid, and what would best suit Australian conditions.

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