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Australia to finalize a policy on naming biosimilars

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Singapore: In July 2013, Therapeutics Goods Administration, Australia, had published a guidance on biosimlar naming based on the combination of a WHO Program on International Nonproprietary Names (INN) issued biosimilar identifier with the Australian biological name (ABN).

The regulator, however has decided that it will not be continuing with the previously proposed naming convention for biosimilars as another policy published by the WHO-INN superseeded the previous INN position upon which the TGA policy was based. A review of the policy has been undertaken.

WHO's new draft policy, Biological Qualifier - An INN Proposal, revized the previously proposed naming convention for biosimilars. The draft policy now states that a biological qualifier will be applied "prospectively and retrospectively" to all biological substances given INNs. The biological qualifier will now consist of four letters.

Meanwhile, biosimilars in Australia will use the Australian biological name without a specific biosimilar identifier suffix, for example a biosimilar to the reference product Neupogen filgrastim would be named "TRADENAME" filgrastim, the TGA said in a statement.

WHO had earlier cautioned that without international consensus on a naming convention for biosimilars, a situation could emerge where the same biosimilar product could be given different non-proprietary names in different jurisdictions.