Biosimilars data plan remains unclear

The Health Department says it is currently investigating potential opportunities to enhance data collection relating to PBS listed biosimilars but no clear plan has been formed.

An enhanced data collection regime "designed to collect specific data to monitor uptake and usage" is part of the $20 million Biosimilars Awareness Initiative announced by the government with the PBS Access and Sustainability Package last May.

The three-stage initiative is still at stage one the department said, noting that "to provide the flexibility necessary to meet the needs of the initiative, there are no set timeframes for each stage".

Funding, however, has been allocated over three years with $6.5 million in 2015-16, $6.7 million in 2016-17 and $7.1 million in 2017-18.

"A number of groups have been consulted on the approach to data collection," a departmental spokesperson said. "A meeting was held on 15 December 2015 with interested stakeholders to determine the availability of data and potential approaches. It was identified that future work on specific data needs will require further consultation across a range of groups. This will be progressed through the governance and consultation structures (Reference Group and Steering Committee) that were recently agreed by the Minister for Health," the spokesperson added.

However, the governance and consultation structures are still in their establishment phase with getting them up and running a priority for the beginning of this year along with conducting market research to establish an evidence-base on which to develop communications.

Last week the department issued an updated Biosimilar Awareness Implementation Framework, which noted that, with specific reference to **Inflectra** (infliximab), it was "currently in discussions with the Australian Rheumatology Association (ARA) to establish data collection ability in relation to the use of these medicines from rheumatologists, and build on their existing database of patient reported outcomes".

"The data collection is proposed to capture information such as biosimilar prescribing, adverse events, and reasons for switching agents, and link this to the patient reported outcomes data in the ARA database," the document said.

It added that the data "could be used in pharmacovigilance and to inform the communication activities of the Biosimilars Awareness Initiative".

Nick Lush, Pharma in focus 4th February 2016
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