Hunt ignored biosim concerns

Posted 23 July 2018

Health Minister Greg Hunt ignored doctor concerns and pushed ahead with changes to the prescriber authority system to make it easier to access a biosimilar over the reference drug, new evidence has revealed.

The Australian Rheumatology Association (ARA) wrote to the minister late last year after the department of health sought submissions to a proposal to change the authority requirements for biosimilars.

Saying the change suggested a different safety profile between a biosimilar and its reference drug and that it would also encourage patients to be switched to biosimilars "for non-clinical reasons", the ARA put in a submission objecting to the change in authority and wrote to the minister expressing its concerns.

However, the minister informed them the change would go ahead as outlined.

As a result, the authority level required for biosimilars was changed to ''streamlined'' from 1 July while the biological equivalents continued to require written authority.

The change provided for "a simpler and faster approval process for prescribing biosimilar brands (e.g. streamlined authority) while maintaining an existing higher level authority requirement for the reference biological brand (e.g. written authority)", the department said.

"The ARA does not support the uptake driver differential (lower) authority levels for biosimilars," Biosimilars Working Group co-chair Mona Marabani said.

"The ARA wrote to the Health Minister Greg Hunt earlier this year voicing our concerns around the direction of biosimilar policy and uptake drivers but was informed that there would be no change to this policy direction."

As a result, the ARA has "reminded our members that substitution can be prevented by ticking the ''brand substitution not permitted box'' on prescriptions if they so wish".

"The ARA believes all biologics should have the same streamlined authority for subsequent prescriptions," Dr Marabani said.

"All medicines which are deemed to have a similar safety and cost profile should be subject to the same authority level. To do otherwise risks sending a message to prescribers that the originator and the biosimilar/s have different safety and efficacy profiles."

The change in authority level is applied not on initial script but only on subsequent prescriptions, a change which the ARA says "will encourage patients to be switched from the originator medicine to a biosimilar for a non-clinical reason".

"A patient who has been stabilised on a medicine should not be switched unless there is a medical reason to do so," Dr Marabani said.

"To do otherwise may put the patient at risk for no clinical benefit."

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