

# Medicines Australia

*Senate Economics Legislation Committee*

*Inquiry into the National Health Amendment (Pharmaceutical Benefits) Bill 2015*

- Total savings from the package of reforms are \$6.6bn, over \$4bn of which will come from the innovative pharmaceutical industry
- This will have a considerable impact on the industry locally in terms of jobs, investment, research & development, exports and availability of medicines
- Medicines Australia signed a Letter of Intent with the Government to deliver the savings in return for a five year period of stability
- This followed a very challenging and time-limited process of discussions
- As per the Letter of Intent, Medicines Australia is now seeking to negotiate a Strategic Agreement with the Government – this process is ongoing
- MA has been working constructively with the Government to ameliorate the impact of the savings measures (in a short timeframe) given the magnitude of impact and to seek to ensure a viable industry going forward
- Our priority is to ensure that the PBS will ensure access to new innovative medicines consistent with the National Medicines Policy
- Industry's primary concern is the issue of substitution of biosimilar medicines at the pharmacy level
- Medicines Australia represents the strong majority of biosimilars companies both locally and globally – our members want to see an effective, safe and successful entry of biosimilars into the Australian market
- The legislation proposes to enable the switching of biosimilar medicines at the pharmacy-level
- It appears it will be based on advice by PBAC with no explicit role for the TGA to assess any evidence for the safe switching of biologics with a biosimilar.
- This position is out of step with comparable international regulators
- MA is particularly concerned that the legislation in relation to biosimilars does not ensure the fundamental principle of patient safety
- MA supports clinician led substitution of biosimilar medicines
- MA would support pharmacy level substitution, only based on a transparent, decision-making process, supported by appropriate evidence, not absence of evidence to the contrary