

# **Generic Medicines Working Group (GMWG) sub-groups – work plan summary**

## **Pricing Policy, Supply and Viability**

This sub-group will be led by GBMA.

The Pricing Policy, Supply and Viability sub-group will gather information from both industry and Government to consider the impact of pricing policy and commercial decisions that may lead to issues with the supply of important medicines and may impact the viability of the generic medicines sector.

The subgroup is focused on concerns at the industry level, more than company-specific concerns, and may collect and analyse relevant data provided by industry members. The subgroup will undertake this work with reference to the central objectives of the National Medicines Policy.

## **Uptake Drivers for Generic and Biosimilar Medicines**

This sub-group will be led by GBMA.

The Uptake Drivers sub-group will investigate the uptake of both generic small molecule and biosimilar medicines in Australia. The group will gather and analyse data to fully understand the Australian system, consider advice from GBMA members on perceived barriers to uptake in Australia, as well as considering approaches used in comparable overseas markets. Based on these investigations, the sub-group will discuss possible approaches to address these barriers, for consideration by GMWG.

## **Biosimilar Policy**

This sub-group will be led by the Department of Health.

The sub-group will look into ways to support the awareness and uptake of biosimilar medicines in Australia. The group will identify and devise practical ways to do this, including through research on international practice. The sub-group may identify current and future barriers for market entry for biosimilar medicines, and discuss possible approaches to overcome these barriers, for consideration by GMWG.

The work will occur alongside the Government's Biosimilar Awareness Initiative.

## **Transparency**

This sub-group will be led by the Department of Health.

The sub-group will investigate ways to increase the transparency of PBS processes, including ways to increase the information available to all stakeholders, with a particular focus on information for consumers. The work will give consideration to transparency activities in other jurisdictions, and the group may consider options such as developing guidelines for redaction/release of clinical evidence contained in submissions, considering the information that is released by Government regarding listing decisions, and developing processes to improve consumer engagement regarding the consideration of submissions.

Any potential initiatives would need to be developed into an actionable plan for consideration by the GMWG, with proposed implementation in collaboration with relevant stakeholders considered.

This will complement the work being undertaken by the Access to Medicines Working Group sub-group, but there will be a focus on the potential for information and evidence around biosimilar medicines to improve public confidence and knowledge around biosimilar medicines.