Regional Comprehensive Economic Partnership – General Review 2026

Introduction

Medicines Australia (MA) is the peak body representing the research-based medicines industry in Australia. Our members bring new medicines and vaccines to Australian patients, invest heavily in local research and development, and export to the region. MA welcomes the opportunity to contribute to the General Review of RCEP. Our comments are limited to intellectual property (IP), where our members have a direct interest. We have not commented on other areas of the review, which fall largely outside our remit.

Medicines Australia position is that a strong, stable and predictable IP framework underpins investment in medicines development, which is costly, high-risk and long. MA welcomes that RCEP's IP chapter is consistent with the TRIPS Agreement and has not eroded existing protections. The chapter does not, however, address the exclusivity settings that matter most to innovative medicines. It sets no minimum period of regulatory data protection (RDP) and does not provide for patent term restoration. Protection therefore differs significantly across RCEP markets, and that influences where companies choose to invest, register and launch new medicines.

MA asks that the review preserve existing protections and explore the three measures set out below.

Regulatory data protection

MA asks the review to explore, with partners, a minimum period of RDP for new medicines. International benchmarks point to at least eight years in Japan and ten in the European Union, with an additional year for new indications. MA's position is that Australia's own five-year period should be aligned with at least the EU standard.

Patent term restoration

The effective patent life of medicines in Australia averages 11 to 12 years, well short of the 15 years that patent term extension is intended to deliver. MA asks the review to consider mechanisms that restore term lost to development and regulatory approval, and to resist any weakening of existing arrangements.

Patent notification and resolution of disputes

MA supports effective patent notification and enforcement arrangements across the region, so that disputes can be resolved early and without disrupting market entry.

Conclusion

MA supports RCEP's role in strengthening trade and investment in the region. Greater consistency in the exclusivity protections available to innovative medicines would improve predictability for innovators and strengthen the region's attractiveness for research, investment and patient access to new medicines.

MA would welcome the opportunity to discuss these points with DFAT as the review progresses. Please contact Apoorvi Mishra, Policy and Research Officer at apoorvi.mishra@medicinesaustralia.com.au should you wish to discuss this submission.