Medicines Australia response to the Department of Industry, Science and Resources consultation: 'Possible association to Horizon Europe: request for information'

Medicines Australia (MA), leads the research-based pharmaceutical industry in Australia. Our members discover, develop, and deliver innovative medicines, biotherapeutic products, and vaccines that improve health outcomes for Australians and globally. MA strongly supports consideration of association with Horizon Europe (HE) as association would provide significant benefits not only for our sector but also for Australia's broader health and medical research ecosystem.

Medicines Australia recommends the Australian Government to pursue association with HE to:

1. Unlock substantial collaborative R&D funding and global innovation opportunities.
2. Strengthen regulatory and policy alignment with the European Union, particularly in health technology assessment (HTA), clinical trials, and manufacturing standards.
3. Enhance intellectual property and data exclusivity protections to attract greater investment in health R&D and clinical trials.
4. Align HE participation with national health priorities and strengthen collaboration with European observatories and HTA networks to enhance innovation and evidence-based decision-making.
5. Establish domestic support mechanisms including co-funding schemes and administrative assistance to enable effective participation, especially for SMEs.

Association with HE is not only about funding; it enables Australia to align with EU standards in areas such as HTA and clinical trials where appropriate to do so. Alignment has the potential to reduce regulatory fragmentation and provides global certainty for investors, strengthening Australia's position in international R&D networks.

Benefits of association with Horizon Europe

Association with HE would open substantial new funding opportunities for collaborative research and development, particularly benefiting Australian researchers and small and medium enterprises (SMEs) developing new therapeutics. HE has a total budget of €95.5 billion for 2021–2027 (Horizon Europe, 2025).

As an associate member, Australian participants would be able to access this competitive funding pool on conditions equivalent to EU entities (subject to any work-programme or call-specific limitations), including eligibility to participate fully in consortia and, where allowed by call rules, to lead consortia — a key limitation under third-country status (European Fund Management Consulting, 2025).

Participation would give Australian innovators the opportunity to integrate into world-class networks across biotechnology, clinical research, digital health, and advanced manufacturing. For SMEs, this could mean earlier access to translational funding, regulatory-science collaborations, and exposure to global value chains that accelerate commercialisation. HE includes dedicated instruments such as the EIC Accelerator, which offers grants up to €2.5 million and equity investments up to €10 million for high-risk, high impact innovations (Epium, 2025). Additionally, 70% of certain program budgets are allocated for SMEs, reflecting their strategic importance (Horizon Europe NI, 2025).

Participating in HE can strengthen the EU-Australia Free Trade Agreement (FTA) by deepening strategic, economic, and innovation ties between the two regions (Group of Eight, 2025). Exploratory talks between the EU and Australia have highlighted that association would enable Australian researchers to lead projects and access funding directly, reinforcing bilateral cooperation in health, digital, and industrial competitiveness (European Commission, 2025e).

The establishment of the Health Innovation Observatory – Australia (HIO-A) through NHMRC funding presents a valuable opportunity to expand Australia's horizon-scanning capabilities for emerging health technologies.

Collaborating with internationally recognised centres such as the UK's NIHR Innovation Observatory (NIHR-IO)—a leader in data-driven health and care innovation scanning that supports NICE technology assessments—could enhance the Observatory's impact and methodological rigour.

Where formal partnerships are established, association would make it easier to build links to European observatory networks and HTA intelligence units, such as the European Observatory on Health Systems and Policies and the EUnetHTA network, which facilitate evidence-based decision-making and joint clinical assessments across Europe.

Strengthening regulatory and policy alignment

Association would also strengthen Australia's connections with the European Union, both scientifically and regulatorily. Australia already engages in international regulatory cooperation and has adopted or referenced numerous international scientific guidelines, including ICH/GxP-type guidance, in TGA documents (Australian Clinical Trials Alliance, 2025; Therapeutic Goods Administration, 2025a). The TGA also maintains international Memorandums of Understanding (MOUs), mutual recognition arrangements (MRAs), and uses reliance/recognition mechanisms where appropriate, underpinning practical alignment in areas such as Good Manufacturing Practice (GMP), pharmacovigilance, and clinical trial guidance (Therapeutic Goods Administration, 2025b).

The EU Health Technology Assessment Regulation (Regulation (EU) 2021/2282) establishes an EU framework for Joint Clinical Assessments (JCAs), providing scientific analysis of clinical evidence that member states can use in national HTA processes (European Commission, 2025c). Closer engagement through HE and related EU HTA initiatives could support Australia's HTA modernisation by facilitating methodological exchange, data-sharing agreements, and early scientific advice mechanisms (Alvarez Gomez, 2025).

Closer alignment with Europe on health R&D policies would also strengthen Australia's innovation environment. Medicines Australia advocates alignment on scientific and regulatory standards and on policies that incentivise investment in health R&D investment—particularly intellectual property (IP) and data protection (Medicines Australia, 2025). The EU/EMA definition of data exclusivity—eight years during which clinical and other data cannot be relied upon by subsequent applicants—is a key benchmark (J A KEMP, 2023; PPRI, 2025). Australia currently provides five years of data exclusivity, which is less competitive than the EU standard.

Stronger data exclusivity protection makes Australia more attractive for R&D investment and early-phase clinical trials, especially relevant given Minister Butler's recent comments on the National One Stop Shop (NOSS) initiative, stating reforms "will help to make Australia a leading destination for more clinical trials (Australian Government DoHDA, 2025)". Note: EU discussions in 2023–2025 on pharmaceutical incentives and exclusivity periods show active reform proposals, including reducing baseline regulatory data protection from 8 years to 6-7.5 years with conditional extensions, and changes to market protection periods (van den Bos et al., 2025). This is a live policy area and should be monitored if Australia seeks alignment.

In the longer term, improved regulatory, HTA, and IP alignment could reduce duplication, promote faster access to new medicines, and make Australia a preferred launch destination for innovative therapeutics — though outcomes depend on many factors such as market size, pricing, reimbursement, and company commercial strategy.

Quantifying and assessing the benefits

The potential benefits of association can be assessed across three dimensions:

Direct financial gains: association provides increased access to HE funding for collaborative R&D. Early practical experience from countries that recently associated is informative. For example, New Zealand's association (provisionally applied from mid-2023) enabled researchers to join and lead consortia under Pillar II, which has a budget of €53.5 billion (New Zealand Foreign Affairs & Trade, 2024). The "Twelve Months On" report by New

Zealand's Ministry of Foreign Affairs and Trade documents initial participation levels and early engagement, including 18 NZ partners in 13 successful projects and a ~24% success rate.

Leverage and investment effects: international partnerships established through HE attracts additional private-sector R&D spending and strengthen translational research capacity by connecting researchers and industry to larger consortia and investors. The Biennial Monitoring Report (2024) shows that HE partnerships have leveraged €40 billion in additional investment from partners, complementing €24.9 billion in EU funding (European Commission, 2024b). Evaluations also indicate that every euro invested through instruments like European Innovation Council (EIC) attracts over three euros from private investors, demonstrating strong multiplier effects (European Commission, 2025d).

Intangible impacts: association enhances national innovation capacity, global visibility, and talent exchange, particularly valuable for SMEs and research teams in precision medicine, AI-driven diagnostics, and advanced therapies. HE fosters networking, knowledge exchange, and alignment with European research standards, boosting credibility and competitiveness for participants (van Leeuwen, 2023). It also supports skills mobility and collaboration across world-class networks, which strengthens innovation ecosystems and accelerates technology adoption (European Commission, 2025a).

Lessons from other countries and implementation recommendations

Association could directly advance Australia's health and medical research priorities listed under national strategies and programs. HE's "Health" cluster (under Pillar II) covers areas that align with Australian priorities — infectious disease preparedness, cancer, brain health, rare diseases, and digital health (EUcalls, 2025). Increased participation would complement domestic instruments such as the Medical Research Future Fund (MRFF) and NHMRC by providing additional collaborative funding streams and international coordination.

Experiences from other associated countries — including New Zealand, Canada, and South Korea — demonstrate the value of strong domestic coordination mechanisms and targeted support for SMEs.

- New Zealand: The "Twelve Month On" report shows early engagement after association, with NZ researchers joining HE consortia under Pillar II and initial success in health and digital clusters (New Zealand Foreign Affairs & Trade, 2024).
- Canada: Association in 2024 enabled Canadian entities to participate on equal terms, with government guidance emphasising co-funding and administrative support for applicants (European Commission, 2024a).
- South Korea: Became the first Asian country to associate in 2025, highlighting the importance of transitional arrangements and national coordination teams to facilitate participation (Korea-EU Research Centre, 2025).

Best practice domestic measures observed or recommended in literature and government reports include:

- Targeted cofounding schemes to cover overheads and incentivise participation (e.g., NZ's MBIE top-up funding) (Ministry of Business Innovation and Employment, 2025).
- Administrative support for SMEs and research organisations, including proposal development and compliance assistance (European Commission, 2025b; UK Research Office, 2023).
- Mechanisms to ensure national priorities are reflected in project selection, such as NHMRC's targeted HE grant topics aligned with Australian health priorities (NHMRC, 2025).

Medicines Australia thanks the Department of Industry, Science and Resources (DISR) for the opportunity to provide input into the consultation on a possible association with Horizon Europe and looks forward to continued engagement on this important initiative.

References

Alvarez Gomez, S. (2025). Impact of the New Regulations on the Health Technologies Evaluation. *HealthManagement*, *25*(2). https://healthmanagement.org/c/healthmanagement/IssueArticle/impact-of-the-new-regulations-on-the-health-technologies-evaluation

Australian Clinical Trials Alliance. (2025, April 2). *Webinar recording: ICH GCP E6 (R3) guidelines: What's new, what's changed, what's next!* https://clinicaltrialsalliance.org.au/resource/ich-gcp-e6-r3-guidelines-whats-new-whats-changed-whats-next/

Australian Government DoHDA. (2025). *$13.6 million to cement Australia's status in world-class clinical trials*. https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/136-million-to-cement-australias-status-in-world-class-clinical-trials

Epium. (2025, October 3). *EIC Accelerator propels startups and SMEs with major funding under Horizon Europe*. https://epium.com/news/eic-accelerator-propels-startups-and-smes-with-major-funding-under-horizon-europe/

EUcalls. (2025, June 13). *Horizon Europe Guide - Part 2: Health Cluster Opportunities in 2025*. https://eucalls.net/blog/cluster1-horizon-europe-programme

European Commission. (2024a, July 3). *International cooperation with Canada in research and innovation*. https://research-and-innovation.ec.europa.eu/strategy/strategy-research-and-innovation/europe-world/international-cooperation/association-horizon-europe/canada_en

European Commission. (2024b, September 19). *New report shows impact of partnerships under Horizon Europe*. https://research-and-innovation.ec.europa.eu/news/all-research-and-innovation-news/new-report-shows-impact-partnerships-under-horizon-europe-2024-09-19_en

European Commission. (2025a). *Association to Horizon Europe*. https://research-and-innovation.ec.europa.eu/strategy/strategy-research-and-innovation/europe-world/international-cooperation/association-horizon-europe_en?utm_source=chatgpt.com

European Commission. (2025b). *How to build a successful consortium for a Horizon Europe project*. https://rea.ec.europa.eu/how-build-successful-consortium-horizon-europe-project_en

European Commission. (2025c). *Joint Clinical Assessments - Health Technology Assessment. Public Health*. https://health.ec.europa.eu/health-technology-assessment/implementation-regulation-health-technology-assessment/joint-clinical-assessments_en

European Commission. (2025d, April 30). *Horizon Europe programme analysis*. https://research-and-innovation.ec.europa.eu/strategy/support-policy-making/shaping-eu-research-and-innovation-policy/evaluation-impact-assessment-and-monitoring/horizon-europe-programme-analysis_en

European Commission. (2025e, September 10). *EU and Australia open exploratory talks on association to Horizon Europe*. https://research-and-innovation.ec.europa.eu/news/all-research-and-innovation-news/eu-and-australia-open-exploratory-talks-association-horizon-europe-2025-09-10_en

European Fund Management Consulting. (2025, April 22). *Associated countries vs associated partners & countries with co-funding mechanism*. https://efmc.eu/associated-countries-vs-associated-partners-countries-with-co-funding-mechanism/

Group of Eight. (2025, June 4). *Joint Industry Statement: EU-Australia FTA "Time to get this done."* https://go8.edu.au/joint-industry-statement-eu-australia-fta-time-to-get-this-done

Horizon Europe. (2025). *Horizon Europe - Cliffnotes*. https://horizon-eu.eu/

Horizon Europe NI. (2025). *Small to Medium Sized Enterprises*. https://www.horizoneuropeni.com/small-medium-sized-enterprises

J A KEMP. (2023, September 5). *Data exclusivity and market protection in the EU / EEA and UK*. https://www.jakemp.com/knowledge-hub/data-exclusivity-and-market-protection-in-the-eu-eea-and-uk/

Korea-EU Research Centre. (2025, July 17). *South Korea signs Horizon Europe Association Agreement with the EU*. https://k-erc.eu/2025/07/news-activities/27961/

Medicines Australia. (2025). *Intellectual property - Issues Brief*. https://www.medicinesaustralia.com.au/publications/issues-briefs/intellectual-property/

Ministry of Business Innovation and Employment. (2025). *Horizon Europe Research Fund. New Zealand Government*. https://www.mbie.govt.nz/science-and-technology/science-and-innovation/international-opportunities/horizon-europe-research-fund

New Zealand Foreign Affairs & Trade. (2024). *New Zealand's Association to Horizon Europe: Twelve Months On*. https://www.mfat.govt.nz/en/trade/mfat-market-reports/new-zealands-association-to-horizon-europe-twelve-months-on-march-2024

NHMRC. (2025). *NHMRC-Horizon Europe 2025: EU Collaborative Research Grant Scheme*. https://www.nhmrc.gov.au/funding/find-funding/nhmrc-eu-collaborative-research-grant-scheme-2025

PPRI. (2025, May 20). *Data exclusivity*. https://ppri.goeg.at/data_exclusivity

Therapeutic Goods Administration. (2025a). *International scientific guidelines adopted in Australia*. https://www.tga.gov.au/resources/resource/international-scientific-guidelines

Therapeutic Goods Administration. (2025b, May 21). *International agreements and arrangements for GMP clearance*. https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medicine/good-manufacturing-practice-gmp/international-agreements-and-arrangements-gmp-clearance

UK Research Office. (2023). *Horizon Europe-Building a Consortium Work with those you know and trust*.

van den Bos, H., Mischie, J., & Tuijp, M. (2025, June 10). EU Pharma Law Package: Council Position on Reduction of Regulatory Exclusivity Rights. *Hogan Lovells*. https://www.hoganlovells.com/en/publications/eu-pharma-law-package-council-position-on-reduction-of-regulatory-exclusivity-rights-

van Leeuwen, B. (2023, October 19). *Associated Countries are crucial for Horizon Europe*. https://www.pnoinnovation.com/insights/associated-countries-are-crucial-for-horizon-europe/