Australian Government

Department of Health and Aged Care

Ministerial Submission – Standard
MS22-000608
Version (1)
Date sent to MO: 6 July 2022

To: Minister Butler

Subject: Collaboration between the Australian Government Department of Health (together with the Pharmaceutical Benefits Advisory Committee and the Medical Services Advisory Committee), Canadian and United Kingdom health technology assessment agencies

Critical date: 1 August 2022 to enable the collaboration arrangement to be entered into

Recommendation/s:

1. That you agree to the Secretary of the Department of Health and Aged Care signing the collaboration arrangement on behalf of the Department (Attachment A).

Agreed/Not agreed/Please discuss

Signature .....

Date: 13 / 7 / 22

Media Release required? YES/NO
Comments:

Contact Officer:	*Penny Shakespeare*	*Deputy Secretary, Health Resourcing Group*	Ph: (02) 6289 s22 Mobile: s22
Clearance Officer:	*Brendan Murphy*	*Secretary*	Ph: (02) 6289 s22 Mobile: s22

Issues:

- The Department, together with the Pharmaceutical Benefits Advisory Committee (PBAC) and the Medical Services Advisory Committee (MSAC) have been approached about joining a collaboration arrangement with like-minded health technology assessment (HTA) agencies in Canada and the United Kingdom.

- The international collaborating HTA agencies are:
    - National Institute for Health and Care Excellence (NICE) in England;
    - Canadian Agency for Drugs and Technologies in Health;
    - Health Improvement Scotland, including the Scottish Medicines Consortium and the Scottish Health Technologies Group.
    - Health Technology Wales, hosted by the Velindre University NHS Trust; and
    - All Wales Therapeutics and Toxicology Centre.
- The collaboration builds on, and places on a more formal footing, the collaborative engagement established between the partner organisations during the COVID-19 pandemic. The areas of collaboration have expanded to the mutual benefit of all partner organisations.
- The collaboration will facilitate capacity-building and the sharing of skills and experience between the partner organisations.
- Once implemented, work-sharing arrangements are likely to produce greater efficiencies for both PBAC/MSAC and industry by streamlining submission processes among the partner organisations. Such worksharing arrangements have been in place for a number of years for regulatory agencies and have delivered faster assessment times by the Therapeutic Goods Administration (TGA) when a product is jointly assessed with the FDA or Health Canada, for example.
- The collaboration arrangement sets out a framework for close and collaborative ways of working between the partner organisations, which will support strategic objectives and shared commitments to the following priority areas:
    - COVID-19 related intelligence sharing;
    - Future-proofing of HTA systems;
    - Collaborating with regulators;
    - Work-sharing and efficiency gains;
    - Digital and artificial intelligence.
- The collaboration complements the Memorandum of Understanding (MOU) in the field of health cooperation signed by the Department and Singapore's Ministry of Health in 2021. Under the MOU, the participants have agreed to cooperate on joint health assessment activities, with the object of improving evaluation throughput and potentially achieving costs savings for both countries and industry.
- The collaboration will build on the well-established and productive work-sharing arrangements between the TGA and its international counterparts in the United States, the United Kingdom, Canada, Singapore, Israel and Switzerland, among other countries.

- These arrangements can reduce the duplication of effort where assessment has already been conducted outside of Australia and expedite the evaluation and registration of medicines in Australia.

- These collaborations have operated to the mutual benefit of both the community and industry across the partner agencies home states.

Sensitivities

- Medicines Australia (MA) is aware of the development of this collaboration. The department is working with the other partner organisations to agree an approach to the publication of the collaboration arrangement once it has been finalised.

- MA and originator pharmaceutical companies will raise concerns about the potential sharing of confidential information with partner organisations under the collaboration. In essence, industry wants to prohibit international information to be shared about price and assumptions in the economic analyses, even if such transparency among two organisations agreeing to share the work on a particular medicine would lead to faster access for patients, and despite industry supporting the faster regulatory timeframes achieved on the back of worksharing arrangements.

- To allay industry's concerns and to enable the collaboration to proceed, even if it is on a more limited basis, the Department has no intention to disclose protected information. Clause 23 of the collaboration arrangement expressly states that the participation by partner organisations in the collaboration is subject to any laws, policies or other legal obligations of the partner organisation, including confidentiality obligations to third parties.

- The collaboration arrangement respects and preserves the governance arrangements and independence of each partner organisation.

Relationship with the HTA policy and methods review

- Increased international collaboration among HTA agencies is contemplated by clause 5.3.2 of the Strategic Agreement with MA, which requires the Reference Committee ('Committee') to examine, as part of the HTA policy and methods review, 'the feasibility of international work sharing for reimbursement submissions.'

- The collaboration arrangement does not anticipate the Committee's findings, but will inform, and be informed by, its analysis.

- The collaboration arrangement is not intended to impose legally-binding obligations on any organisation and, as such, does not commit the Commonwealth (or its Statutory Committees and Agencies) to undertake or engage in particular activities.

- The Strategic Agreement with MA does not include any commitment from the Commonwealth (or its Statutory Committees and Agencies) about its approach to international collaboration on HTA.

Next steps:

- NICE is co-ordinating the signing of the collaboration arrangement. To date, four partner organisations have signed the collaboration arrangement.
- The Department placed this process on hold during the caretaker period.
- We will notify NICE when the Department is ready to sign the collaboration arrangement. With your agreement, the Secretary will sign on behalf of the Department.

Consultations: Legal and Assurance Division, International Strategies Branch and the Department of Foreign Affairs and Trade.

Attachments:

A: Collaboration arrangement between the National Institute for Health and Care Excellence (UK), Canadian Agency for Drugs and Technologies in Health, Australian Government Department of Health, Healthcare Improvement Scotland, Health Technology Wales (Velindre University NHS Trust), and All Wales Therapeutics and Toxicology Centre.

ATTACHMENT A

NICE National Institute for Health and Care Excellence

Collaboration Arrangement between:

National Institute for Health and Care Excellence

Canadian Agency for Drugs and Technologies in Health

Australian Government Department of Health

Healthcare Improvement Scotland

Health Technology Wales (Velindre University NHS Trust)

All Wales Therapeutics & Toxicology Centre

Version dated: February 2022

Context and Shared Purpose

Purpose and scope

1. This Collaboration Arrangement sets out the nature of the Collaboration between the National Institute for Health and Care Excellence (NICE), the Canadian Agency for Drugs and Technologies in Health (CADTH), the Australian Government Department of Health (together with the Pharmaceutical Benefits Advisory Committee (PBAC) and the Medical Services Advisory Committee (MSAC)), Health Improvement Scotland (including the Scottish Medicines Consortium (SMC) and the Scottish Health Technologies Group (SHTG)), Health Technology Wales (HTW) (hosted by Velindre University NHS Trust) and the All Wales Therapeutics and Toxicology Centre (AWTTC) (hereafter referred to as "the Partner Organisations") over the term of this Arrangement.

2. This Arrangement provides an opportunity for the Partner Organisations to work together to draw on the strengths of their organisations and enhance the contribution that they each make for the benefit of the audiences and users we serve.

3. This Collaboration Arrangement sets out a framework for close and collaborative ways of working between the Partner Organisations that will support strategic objectives and shared commitments to the identified priority areas, set out in Appendix 1.

4. This Collaboration Arrangement is not intended to imply a legal commitment and is not intended to create or result in any legally binding rights or obligations; its purpose is to define the joint arrangement between the Partner Organisations and to indicate a common line of action. The Partner Organisations recognise that any information and proposed activities shared under this Collaboration Arrangement is on a confidential basis. The Partner Organisations will take appropriate steps to safeguard such information and proposed activities and seek permissions to share with others either internally or externally (unless there is written confirmation from the Partner Organisation introducing the confidential information that particular circumstances merit specific information or proposed activities being shared more widely).

5. Other arrangements (such as information sharing arrangements and service level arrangements) may be entered into separately to support the activities undertaken as part of this arrangement.

6. This Collaboration Arrangement does not create any financial arrangement between the Partner Organisations and each Partner Organisation will bear its own costs and expenses associated with its participation in the Arrangement. Nothing in this Arrangement authorises or is intended to obligate the Partner Organisations to enter into any contract, agreement, interagency agreement, or other financial obligation.

7. This Collaboration Arrangement will come into effect from the date of the final Partner Organisation signature and will be reviewed every two years.

Roles

NICE

8. NICE was established as a non-departmental public body in the Health and Social Care Act 2012. Our statutory role and responsibilities are set out in 2013 Regulations.

9. Since 1999, NICE has established itself as an international leader in technology evaluation, guideline development and evidence synthesis. Our work today spans three ecosystems (life sciences, guidelines, and information) that involve close working with partners to ensure patients have access to the latest technologies, advice and guidance.

10. In 2021, NICE published a new strategy that sets out our strategic priorities for the next five years with respect to:
    - *Rapid, robust, and responsive technology evaluation*: providing independent, world-leading assessments of new treatments at pace, quickening access for patients, and increasing uptake.
    - *Dynamic, living guideline recommendations*: creating and maintaining up-to-date guidance that integrates the latest evidence, practice, and technologies in a useful and useable format.

- *Effective guidance uptake to maximise our impact*: working with our strategic partners to increase the use of our guidance, monitor adoption and measure impact on health outcomes and health inequalities.
- *Leadership in data, research, and science*: becoming scientific leaders by driving the research agenda, using real world data to resolve gaps in knowledge and drive forward access to innovations for patients.

Australian Government Department of Health

11. The Office of Health Technology Assessment within the Australian Government Department of Health is the entity which supports the two independent advisory committees by which Australian HTA is best known internationally.

12. The Pharmaceutical Benefits Advisory Committee (PBAC) is an independent statutory committee comprising experts appointed by the Australian Minister for Health. Members include doctors, health professionals, health economists and consumer representatives.

13. Its primary role is to recommend new medicines for listing on the Pharmaceutical Benefits Schedule (PBS) or new vaccines for listing on the National Immunisation Program (NIP). No new medicine or new vaccine can be listed in these programs unless the committee makes a positive recommendation. The PBAC also considers amendments to and reviews of listed medicines and vaccines.

14. The Medical Services Advisory Committee (MSAC) is an independent non-statutory committee also comprising experts appointed by the Australian Minister for Health. Members include doctors, health professionals, health economists and consumer representatives.

15. MSAC appraises new medical services proposed for public funding and provides advice to Government on whether a new medical service should be publicly funded (and if so, its circumstances) on an assessment of its comparative safety, clinical effectiveness, cost-effectiveness, and total cost, using the best available evidence. MSAC considers a range of types of services funded on the Medical Benefits Schedule (MBS) including medical attendances, procedures, imaging, pathology, allied health and services funded via other programmes (for example,

blood products, high-cost therapies such as gene therapy and screening programmes). MSAC also considers amendments to and reviews of listed medical services.

Canadian Agency for Drugs and Technologies in Health

16. CADTH is an independent, not-for-profit agency that provides credible, impartial advice and evidence-based information about the effectiveness of drugs and other health technologies to Canadian federal, provincial and territorial governments.

Healthcare Improvement Scotland

17. Healthcare Improvement Scotland has specified functions, under the Public Services Reform (Scotland) Act, 2010, for the evaluation and provision of advice to the health service on the clinical and cost effectiveness of new and existing health technologies.

18. The Scottish Medicines Consortium (SMC) provides the specified function for medicines / pharmaceuticals. The purpose of SMC is to provide advice to NHS Scotland about the clinical and cost-effectiveness status of newly licensed medicines and new indications for established products. The advice is advisory not mandatory.

19. SHTG provides the specified function for health technologies that are not medicines / pharmaceuticals. SHTG's advice to NHS Scotland on the use of health technologies takes into account clinical effectiveness, safety and cost effectiveness, as well as expert stakeholder views. SHTG's work programme is determined via an open topic referral process, and SHTG's advice is provided across a variety of formats – from early research support to in-depth health technology assessments. SHTG advice is advisory not mandatory.

Health Technology Wales

20. Health Technology Wales (HTW) was established in 2017 and brings together NHS clinicians, healthcare professionals, academics, health economists, industry representatives and public partners to provide advice on strategic management

relating to the identification, appraisal and adoption of non-medicine technologies to the Welsh Government's Minister for Health and Social Care Services and Welsh health boards. All seven Welsh health boards are represented on the HTW Appraisal Panel. Health Technology Wales is hosted by Velindre University NHS Trust.

All Wales Therapeutics and Toxicology Centre (AWTTC)

21. The All Wales Therapeutics and Toxicology Centre (AWTTC) is an NHS Wales organisation, which provides a portfolio of services to NHS Wales. Each of the sections within AWTTC has a unique function and a different focus; medicines access and pathways, commercial arrangements for medicines, medicines optimisation and development of best practice guidance, pharmacovigilance and reporting of adverse drug reactions, analysis and monitoring of prescribing data and clinical toxicology services.

22. AWTTC provides expert clinical, scientific, technical, analytical, health economic and administrative support to Welsh Government's advisory committee on medicines and prescribing, the All Wales Medicines Strategy Group (AWMSG), for the purpose of assisting in creating a healthier, better informed Wales.

Principles

23. In implementing this Collaboration Arrangement, the Partner Organisations are aware of and mutually decide to uphold the following principles for the working relationship, subject to any laws, policies or other legal obligations of the Partner Organisations, including confidentiality obligations to third parties:
    - Mutually supportive, respecting the status and the independence of all Partner Organisations from each other.
    - Valued at the highest level of each Partner Organisation, with visible leadership, clear lines of accountability, and a coherent corporate approach.
    - Open and transparent, with all Partner Organisations sharing information to inform good decision-making and to minimise risk.

- Efficient, with business processes designed to deliver outputs quickly, facilitate rapid communication between the Partner Organisations and to enable the Collaboration to change and develop.
- Based on mutual recognition and acknowledgement of each Partner Organisation's contributions, joint working and collaboration, for example, through shared and mutually decided communications, conferences, workshops.
- Based on full adherence to any relevant legislation or governance standards of each Partner Organisation.

Joint priorities and areas of work

Joint work and objectives

24. Through major developments in the international healthcare landscape over the past decade, current HTA paradigms are increasingly challenged, and new solutions needed. Many of these challenges are common to HTA organisations internationally. This Collaboration Arrangement provides the basis for the Partner Organisations to work together to identify and characterise issues of common interest and to share and develop solutions. The Collaboration is expected to deliver incremental improvements to Partner Organisations' work through sharing best practice and "step change" solutions by collaborating on major challenges.

25. The specific areas expected to be of most importance for joint working over the term of this Arrangement are outlined in Appendix 1.

Communication

26. Where appropriate, the Partner Organisations will determine a joint communication approach to support this Collaboration Arrangement that will recognise the collaborative nature of the mutually determined joint priorities and areas of work.

Governance framework for publication of joint pieces of work

27. Where the Partner Organisations produce and intend to publish joint documents and outputs, the relevant documents should set out:
    - The intended audience

- The aims and purpose
- The scope of the document and what it is trying to achieve
- Any other relevant partners involved in producing the document
- Where the documents will be published and stored (online)
- The need and approach to updating the document, where appropriate, and who holds responsibility for doing so
- Clear joint labelling indicating joint ownership.

28. The documents should receive legal clearance from each participating Partner Organisation, where appropriate.

29. The documents should be formally approved and signed off by a relevant senior representative of each Partner Organisation.

30. The Partner Organisations intend to manage any intellectual property rights resulting from their joint efforts under this Arrangement through separate agreements, factoring in relevant and applicable legislation, if required.

Monitoring and arrangements for engagement

31. At a working level, the Partner Organisations will meet in working groups aligned to the priority areas in appendix 1. These groups will meet on a 3-monthly basis to review operational progress and discuss activities in their priority area. There will be an annual meeting of all Partner Organisations to review all activities and to realign where appropriate the developing areas of collaboration. The frequency of meetings may be re-evaluated once the work activities are established.

Arrangements

32. The Partner Organisations may amend any part of this Arrangement by mutual written consent. Any such amendment will be an integral part of this Arrangement and take effect on such date as may be decided by the Partner Organisations in writing.

33. Any amendment will not prejudice any specific understanding between the Partner Organisations arising from, or based on, this Arrangement (including, but

not limited to, any specific streams of work mutually determined between the Partner Organisations) before, or up to, the date of such amendment.

34. New organisations may be added as a Partner Organisation during the period of the Collaboration Arrangement, subject to the acceptance of all existing Partner Organisations. They will accept the principles and arrangements of this Collaboration and will become a Partner Organisation as of the date of their signature upon the updated Collaboration Arrangement.

35. Organisations may also stand down as a Partner Organisation with reasonable notice to all of the remaining Partner Organisations. When leaving, any shared information access accrued up to the date of termination and the commitments to grant access to information shared under and subject to clause 4 will continue in full effect. For the avoidance of doubt, if under clause 4 separate information sharing arrangements have been put in place, nothing in this arrangement will affect the rights and obligations of those separate arrangements.

36. If a Partner Organisation defaults and is required to leave the Collaboration due to the default then it will be required to continue to allow the Partner Organisations to hold and use its shared information under and subject to clause 4 but it must delete any and all copies of such information shared with it and not be permitted to use such shared information. This will occur immediately upon exit of the Collaboration.

37. If only one Partner Organisation remains, the Collaboration will cease to exist.

Signatures

Signed by, for and on behalf of the National Institute for Health and Care Excellence, Level 1 City Tower, Piccadilly Gardens, Manchester, M1 4BD, United Kingdom

Name:	Dr Sam Roberts
Position:	Chief Executive
Signature:	SIGNATURE
Date:	DD MONTH YYYY

Signed by, for and on behalf of the Canadian Agency for Drugs and Technologies in Health, 865 Carling Ave., Suite 600 Ottowa, ON Canada K1S 5S8

Name:	Suzanne McGurn
Position:	President and Chief Executive Officer
Signature:	SIGNATURE
Date:	DD MONTH YYYY

Signed by, for and on behalf of the Australian Government Department of Health, PO Box 9848, Canberra ACT 2601, Australia

Name:	Dr Brendan Murphy
Position:	Secretary
Signature:	SIGNATURE
Date:	DD MONTH YYYY

Signed by, for and on behalf of Healthcare Improvement Scotland (including the Scottish Medicines Consortium and the Scottish Health Technologies Group), Delta House, 50 West Nile Street, Glasgow, G1 2NP, Scotland

Name:	Dr Safia Qureshi
Position:	Director of Evidence
Signature:	SIGNATURE
Date:	DD MONTH YYYY

Signed by, for and behalf of Health Technology Wales (hosted by Velindre University NHS Trust), The Life Science Hub, 3 Assembly Square, Cardiff, CF10 4PL, United Kingdom

Name:	Steve Ham
Position:	Chief Executive, Velindre University NHS Trust
Signature:	SIGNATURE
Date:	DD MONTH YYYY

Signed by, for and behalf of the All Wales Therapeutics and Toxicology Centre, Cardiff & Vale University Health Board, University Hospital, Llandough, Penlan Road, Llandough, CF64 2XXUnited Kingdom

Name:	Dr James Coulson MD FRCP
Position:	Interim Clinical Director
Signature:	SIGNATURE
Date:	DD MONTH YYYY

Appendix 1: Priority areas for collaboration

1. The Partner Organisations have identified the following areas of substantive work for joint collaboration over the course of this Arrangement, which reflect the strategic priorities for our organisations.

The working level contacts (set out in Appendix 2) will have overall ownership for progress of the priority areas. Progress against the joint areas will be reviewed at frequent intervals.

Priority 1: COVID 19-related intelligence sharing

Partner Organisations to share experiences on

- working with regulators
- prioritisation of topics
- management of medicines with good evidence but no plans for obtaining marketing approval
- planning for HTAs
- approaches to modelling

to optimise approaches to the management of COVID 19 topics across agencies.

Priority 2: future-proofing of HTA systems

Partner Organisations to exchange ideas on processes to better anticipate technological and methodological challenges for HTA and to work in scientific and methodological areas to address challenges before they become issues. This could include exploring areas such as environmental sustainability and real-world evidence.

Priority 3: collaborating with regulators

Joint approach to engaging with the regulatory agencies in the UK, Canada and Australia to identify and progress opportunities to improve HTA and regulatory collaboration.

Priority 4: work-sharing and efficiency gains

Partner Organisations to capitalise on individual strengths, explore the feasibility of a mutual recognition system for already published information by a Partner Organisation, and explore running a pilot for a joint clinical assessment.

Priority 5: Digital and AI

Partner Organisations to share intelligence around developments in the evaluation of digital health technologies including technologies that involve AI. Explore areas such as approaches to evaluating adaptive algorithms, aligning with regulators, allowing for regular algorithmic updates, HTA evidence requirements and on-going data monitoring.

2. Work on the joint priority areas will be taken forward through dedicated working groups aligned to the priority areas. Further separate groups and sub-groups will be established as and when required.

Appendix 2: Working-level key contacts

For National Institute for Health and Care Excellence

Name	s47F
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For Canadian Agency for Drugs and Technologies in Health

Name	s47F
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For the Australian Government Department of Health

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For Scottish Medicines Consortium

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E mail address	s47F @nhs.scot

For Scottish Health Technologies Group

Name	s47F
Office Address	Delta House, 50 West Nile Street, Glasgow, G1 2NP
Telephone number	s47F
E mail address	s47F @nhs.scot

For Health Technology Wales

Name	s47F Director of Health Technology Wales (part of Velindre University NHS Trust)

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For All Wales Therapeutics & Toxicology Centre

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