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 and Aged Care

Healthcare Improvement Scotland

Health Technology Wales (Velindre University NHS Trust)

All Wales Therapeutics & Toxicology Centre

Institut national d'excellence en santé et en services sociaux
(joined July 2023)

Pharmac
(joined July 2023)

Version dated: July 2023

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 and Aged Care (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), the All Wales Therapeutics and Toxicology Centre (AWTTC), the Institut national d'excellence en santé et en services sociaux (INESSS) and Pharmac (hereafter referred to as "the Partner Organisations") over the term of this Arrangement.

2. This Collaboration 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 Collaboration 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 and Aged Care

11. The Office of Health Technology Assessment within the Australian Government Department of Health and Aged Care 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.

Institut national d'excellence en santé et en services sociaux (INESSS)

23. INESSS is the independent not-for-profit health technology assessment organization for the province of Québec (Canada) and it reports to the Québec Minister of Health and Social Services. Health is a provincial jurisdiction in Canada and each province has its own distinct health system.

24. Succeeding to the Conseil du médicament (Drug Council) and the Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS, Agency for the evaluation of technologies and intervention modes in health), it

was created in 2011 following the adoption of a new legislation in the province.

25. It assesses the value of medicines, medical devices, health interventions and social services and it produces evaluations for reimbursement purposes, as well as guidelines and standards (e.g., optimal use).

26. The Institut aims at being an essential reference to better support decision-making, improve practices, and add value in the Quebec health care, as well as in social services.

27. The mission of the Institut is to promote clinical excellence and the efficient use of resources in the health and social services sector, in accordance with the values of excellence, independence, openness, scientific rigour, transparency, probity, and fairness towards those who use health services and social services and with due regard for its resources.

28. To carry out its work, INESSS mobilizes patients, users, citizens, as well as experts from the clinical and scientific communities.

29. Priorities of the INESSS 2021-2024 strategic plan include accelerating access to innovation, supporting the optimization of care and service pathways using the most up-to-date data, strengthening the response to evaluation needs in social services and mental health, supporting the achievement of measurable outcomes through our recommendations, and engaging staff and collaborators in the rigorous and agile application of value assessment principles.

Pharmac

30. Pharmac was established in 1993 by the four health funding agencies in New Zealand at that time, aiming to negotiate better prices with pharmaceutical companies and thus make medicines more affordable. It became a crown entity in 2001 under the Public Health and Disability Act, assigned the responsibility to secure the best health outcomes within its fixed budget.

31. Today, Pharmac's statutory role and responsibilities are articulated under the

Pae Ora (Healthy Futures) Act 2022. The legislative objective remains to secure the best health outcomes that are reasonably achievable from pharmaceutical treatment and within the amount of funding provided for eligible people in need of pharmaceuticals.

32. Pharmac is unique among HTA agencies, as it not only decides which pharmaceuticals to fund but also has the responsibility of managing a fixed budget for these pharmaceuticals. Its decisions are guided by input from a comprehensive expert advisory network. Over time, Pharmac has broadened its mandate: it initially focused on community medicines, but incorporated the national immunisation schedule into its responsibilities in 2012, and added hospital medicines and hospital medical device contracts in 2013.

33. Pharmac is now moving towards broadening its model to encompass hospital medical devices. Pharmac has laid a solid foundation for strategic management of hospital medical devices by negotiating national contracts for devices currently in use in public hospitals. The next phase involves conducting health technology assessment and price negotiation of medical devices, in a manner similar to its existing approach for medicines and vaccines.

Principles

34. 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

35. 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.

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

Communication

37. 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

38. 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.

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

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

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

Monitoring and arrangements for engagement

42. 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

43. 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.

44. 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.

45. 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.

46. 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.

47. 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.

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

Appendix 1: Priority areas for collaboration

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.

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.