

Information Brief MB21-002349 Version (1) Date sent to MO:24/06/21

·To:

DEPARTMENT INITIATED INFORMATION BRIEF - MEMORANDUM OF Subject: UNDERSTANDING BETWEEN AUSTRALIA AND SINGAPORE IN THE FIELD OF HEALTH COOPERATION

| Greg Hunt Signed | | D | 10: (U 7 1201) |
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Key Issues:

- The Department and the Singapore Ministry of Health (the Participants) have been engaged in negotilations to develop a Memorandum of Understanding in the Field of Health Cooperation (MoU).
- 2. These negotiations have progressed to a point where the Participants have resolved outstanding differences and have finalised and signed the MoU.
- 3. The MoU was signed by the Secretary, Dr Brendan Murphy, and the Permanent Secretary of the Singapore Ministry of Health, Mr Chan Yeng Kit on 9 June 2021 (Attachment A).
- 4. The MoU is considered to have commenced on signature and is not intended to be legally-binding.
- 5. The signing of the MoU was included in a Joint Statement issued by the Prime Minister of Australia, the Hon Scott Morrison MP, and the Prime Minister of Singapore, Mr Lee Hsien Loong, during Prime Minister Morrison's visit to Singapore on 10 June 2021.
- 6. The MoU will be included in the Australia-Singapore Comprehensive Strategic Partnership Roadmap.

Background:

- In November 2019, members of the Department and the Singapore Ministry of Health met to discuss a potential 'work-sharing alliance' in health technology assessment evaluation.
- In February 2020, the Department and Singapore Ministry of Health began negotiations to formalise this alliance in a Memorandum of Understanding.
- The MoU was drafted with reference to existing memoranda of understanding between
 - the Therapeutic Goods Administration and the Health Sciences Authority of Singapore; and
 - o the Department and the United Kingdom Department of Health and Social Care.
- While the COVID-19 pandemic has made engagement more difficult due to shifting priorities, the Participants have been able to work together to finalise the MoU.
- The Participants identified areas of mutual priority, and have formalised these in the MoU, which seeks to enhance cooperation and collaboration in the following fields of co-operation:

 - co-operation:

 Genomics and precision medicine

 Gene therapies

 Cancer treatments

 Joint health technology assessment activities

 Drug utilisation review

 Medicine shortages

 Capability building on health technology assessment and related skills (e.g. negotiating risk share arrangements). negotiating risk share arrangements)
 - o Educating stakeholders and the public about health technology assessment
 - Consumer engagement and education as part of the health technology assessment process
 - Diagnostics
 - Anti-microbial resistance
 - National medicines policy (e.g. quality use of medicines)
 - Any other emerging health technologies as determined by the Participants.
- The Participants will endeavour to fulfil these objects through effective communication and exchange of knowledge and expertise in the areas of:
 - Health technology assessment
 - Pricing negotiations (subject to confidentiality obligations to third parties) and relevant strategies, including risk-sharing arrangements
 - Other collaborative activities involving medicines, medical devices and any other health technologies.

Sensitivities:

Medicines Australia and originator pharmaceutical companies may raise concerns about the sharing of confidential information with Singapore under the MoU. Talking points in a question and answer format, addressing potential lines of enquiry, are provided at Attachment B.

Consultations:

In accordance with the Department of Foreign Affairs and Trade's *Guidance Note:*

<u>Australia's Practice for Concluding Less-Than-Treaty Status Instruments</u>, the draft MoU was reviewed by DFAT's International Law: Advising and Treaties Section, which has confirmed that the draft MoU is drafted in language appropriate for a less-than-treaty status instrument.

- The draft MoU was also reviewed by the Legal and Assurance Division, and incorporates revisions recommended by them and agreed to by the Singapore Ministry of Health.
- The International Strategies Branch and the Pharmaceutical Benefits Advisory Committee were also consulted during negotiations.

Attachments:

- **A:** Memorandum of Understanding between the Ministry of Health of the Government of Singapore and the Government of Australia as represented by the Department of Health in the Field of Health Cooperation.
- **B:** Talking points.

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Cover Page for Ministers' Offices

| Minister | Minister Hunt |
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| PDR Number | MB21-002349 |
| Subject | Department Initiated Information Brief - Memorandum of Understanding between Australia and Singapore in the field of health cooperation |
| Due Date | 02 July 2021 |
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MEMORANDUM OF UNDERSTANDING

BETWEEN

The Ministry of Health of the Government of Singapore

The Street

Government of Australia as represented by the Department of Health

IN

The Field of Health Cooperation

The Ministry of Health of the Republic of Singapore and the Government of Australia represented by the Department of Health (hereinafter jointly referred to as the "Participants" and in the singular as a "Participant"):

DESIRING to consolidate and strengthen the friendly ties and reciprocal understanding between the Participants;

DESIRING to promote mutual knowledge, experience and understanding of their respective human and development needs in the fields covered by this Memorandum of Understanding ("MOU");

CONSIDERING that the Participants wish to enhance bilateral cooperation in respect of public health outcomes and healthcare policy; and

RECOGNISING the mutual interest of the Participants in the exchange of programmes to enhance technical skills and share best practices.

HAVE REACHED THE FOLLOWING UNDERSTANDING:

PARAGRAPH 1
OBJECTIVES

The objectives of this MOU are:

- to enhance cooperation and collaboration in the fields of health care and health technologies;
- b) to strengthen friendly cooperation and collaboration; and

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c) to contribute to the improvement of the health of the people in Singapore and Australia through, among other things, cooperation in the provision of timely and affordable access to medicines and health technologies, having regard to the prevailing laws, policies, procedures and regulations in the respective countries.

PARAGRAPH 2 PURPOSES

- 1. The purposes of this MOU are:
 - a) to facilitate the exchange of information and rationalisation of the Participants' workloads relating to the conduct of health technology assessment for medicines, medical devices and any other health technologies;
 - b) to promote effective communication and exchange of knowledge and expertise between the Participants in the areas of health technology assessment, pricing negotiations (subject to confidentiality obligations to third parties) and relevant strategies (including risk share arrangements) and other collaborative activities involving medicines, medical devices and any other health technologies;
 - c) to strengthen communication between the Participants;
 - to enhance the Participants' abilities to protect and promote the health and safety of the people in their respective countries and achieve optimal patient outcomes; and

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- to enhance the Participants' health technology assessment outcomes e) through the sharing of regulatory expertise and relevant experience.
- Unless both Participants jointly decide otherwise, each Participant will bear its 2. own costs and expenses associated with its participation in this MOU (including in the Activities (as defined in Paragraph 3(1) below)).
- Any Participant may limit the scope of the information shared under this MOU 3. where dissemination or exchange of certain information is prohibited or restricted under laws, policies or procedures applying to that Participant, or could undermine any government policy or specific interests including, among other things:
 - commercial, industrial or professional secret a)
 - protection of the individual and privacy
 confidentiality; and
 the public interest

 PARAGRAPH 3 b)
 - c)
 - d)

SCOPE

- The Participants may engage in activities under this MOU, including the 1. exchange of advice, information and expertise ("Activities"), in the following fields of cooperation ("Fields of Cooperation"):
 - genomics and precision medicine; a)
 - gene therapies; b)

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- c) cancer treatments;
- d) joint health technology assessment activities;
- e) drug utilisation review;
- f) medicine shortages;
- g) capability building on health technology assessment and related skills
 (e.g. negotiating risk share arrangements, etc);
- h) educating stakeholders and public about health technology assessment;
- i) consumer engagement and education as part of health technology assessment process;
- j) diagnostics;
- k) any other emerging health technologies as determined by the Participants:
- I) anti-microbial resistance; and
- m) national medicines policy (e.g. quality use of medicines).
- The Participants may also determine to cooperate in any other field of healthcare as mutually determined by the Participants having regard to the interests and resources of both Participants. Such other mutually determined activities will form part of the Activities under this MOU.

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 The Participants may mutually decide upon the forms of engagement to carry out the Activities.

PARAGRAPH 4 SPECIFIC ARRANGEMENTS, PROGRAMMES AND PROJECTS

The Participants may implement the Activities through specific and separate arrangements, programmes or projects entered into between the appropriate agencies and offices of the Participants. Such arrangements, programmes or projects may specify, among other things, the objectives to be pursued, activities to be undertaken and how they are to be organised, the financial arrangements and other necessary matters which may be set out in separate documentation.

PARAGRAPH

CONFIDENTIALITY AND TREATMENT OF SHARED INFORMATION

- 1. The Participants understand and acknowledge that:
 - a) information exchanged between them may include information that possesses a quality of confidence, is communicated in confidence, and is not publicly available in the country of the Participant providing the information ("Confidential Information");
 - b) it is important to the sustainability of this MOU and future cooperation that Confidential Information shared between them and their respective agencies or branches be protected according to their respective national laws concerning unauthorised use and disclosure;

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- the sharing of Confidential Information will take place in accordance with the laws, policies and procedures applying to each Participant; and
- d) Confidential Information will not be used or disclosed by a Participant for any purpose other than the purposes specified at Paragraph 2(1) or as required by any laws applying to a Participant.
- Each Participant will maintain the confidentiality of any Confidential Information communicated to it under this MOU, except as required by any laws applying to the Participant.
- 3. If a Participant is contemplating:
 - a) the public disclosure of Confidential Information
 - b) the disclosure of Confidential Litter parties; or
 - c) any other disclosure of confidential information to third parties not otherwise mentioned in this MOU.

it will consult with the other Participant prior to disclosure, and that other Participant may give its written consent to disclosure of the information in accordance with laws policies and procedures applying to that other Participant.

- In relation to Confidential Information, each Participant will make reasonable efforts to:
 - a) promptly inform the other of any attempts made pursuant to a judicial,
 legislative or other authority to obtain such information; and

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- b) if disclosure is required, consult with the other Participant prior to the disclosure, and will make reasonable efforts to ensure that the information will be disclosed in a manner that protects the information from any subsequent disclosure that is not authorised by the judicial, legislative or other authority. The Participants will enter into separate confidentiality arrangements or agreements as mutually determined by the Participants.
- 5. Each Participant will make reasonable efforts to notify the other Participant if the information being communicated by it is Confidential Information or not. For avoidance of doubt, the lack of such notification by a Participant does not mean that the information being communicated by it is not Confidential Information.
- 6. Each Participant will make reasonable efforts to inform the other Participant of any changes to laws, policies or procedures applying to the Participant that may affect the treatment of Confidential Information received or expected to be received under the terms of this MOU.

PARAGRAPH 6

- The Participants may amend or revise any part of this MOU by mutual written consent. Any such revision or amendment will be an integral part of this MOU and take effect on such date as may be decided by the Participants in writing.
- Any revision or amendment will not prejudice any specific agreement between the Participants arising from, or based on, this MOU (including, but not limited to, any specific arrangements, programmes, or projects mutually determined under Paragraph 4 of this MOU) before, or up to, the date of such revision or amendment.

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PARAGRAPH 7 SETTLEMENT OF DISPUTES OR DIFFERENCES

- Any disputes or differences between the Participants arising out of this MOU
 will be resolved amicably and in good faith through consultations between the
 Participants and will not be referred to any national or international court or
 tribunal or third party for settlement.
- This MOU (including any amendments made pursuant to Paragraph 6) does not, and is not intended to, constitute or create any legally binding rights or obligations for either at international law or under the Participants' respective domestic law.

PARAGRAPHA

COMMENCEMENT, DURATION AND DISCONTINUATION

- 1. This MOU will commence on the date it is signed on behalf of the last of the Participants to sign and will remain in effect for a period of 5 (five) years unless discontinued earlier in accordance with sub-paragraph 3.
- 2. The term of this MOU may be extended for such period or periods as the Participants may mutually decide upon in writing.
- 3. Either Participant may discontinue this MOU by giving 3 (three) months' written notice to the other Participant. The Participants will consult each other to determine how any outstanding matters should be dealt with, including the validity and duration of any ongoing agreement between the Participants arising from, or based on, this MOU (including, but not limited to, any specific arrangements, programmes, or projects mutually determined under paragraph 4 of this MOU) before, or up to, the date of such discontinuation.

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PARAGRAPH 9 ETHICAL CONDUCT AND FRAUD

In respect of this MOU, the Participants will be committed to a zero-tolerance approach to corruption, fraud and fraudulent behaviour and will fully co-operate with each other in respect of any investigations into such events arising out of Activities undertaken under this MOU where possible. Each Participant will comply with all laws, rules and regulations applying to the Participant.

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Australia Singapore

The foregoing represents the understanding reached between the Participants.

Signed as a non-legally binding memorandum of understanding in the English Language.

For the Ministry of Health of the Government of Singapore:

Name:

Chan Yeng Kit

Date:

9th June 2021

Title: Permanent Secretary (Health)

For the Government of Australia as represented by the Department of

Health:

Name:

Date:

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Attachment B

Memorandum of Understanding between Australia and Singapore in the Field of Health Cooperation

Talking points

What is the purpose of the MoU?

The Memorandum of Understanding between Australia and Singapore in the Field of Health Cooperation (the MoU) has been entered into by the Parties to facilitate the exchange of information, knowledge and expertise between the Singapore Ministry of Health (MOH) and the Commonwealth of Australia Department of Health (Health), particularly in the areas of Health Technology Assessment and relevant strategies in managing the high costs of patented medicines and devices and achieve patient access to timely and affordable treatment.

What activities will be conducted by MOH and Health under the MoU?

Details of specific projects for collaboration are still being determined, and will need to be agreed by the Parties.

What kind of activities are contemplated by the MoU?

The MoU facilitates the exchange of advice, information and expertise, subject to obligations of confidence, in a wide range of shared priority areas, including health technology assessment, medicine shortages, genomics and precision medicine, gene therapies, and anti-microbial resistance, among others.

The Participants may also determine to cooperate in any other field of healthcare as mutually agreed by the Participants.

Will the Participants share confidential information, including confidential pricing information?

<u>No</u>. The MoU expressly states that the Participants may not share or exchange information, the dissemination or disclosure of which is prohibited or restricted under laws, policies or procedures applying to that Participant.

Specifically, the MoU does not support any action that could undermine any government policy that among other things covers:

- a) commercial, industrial or professional secrecy;
- b) protection of the individual and privacy interests;
- c) confidentiality; and
- d) the public interest.

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Does the MoU permit joint evaluations of medicine submissions for the purposes of reimbursement or health technology assessment?

The MoU contemplates that the Participants may exchange advice, information and experience in the field of joint health technology assessment.

However, the MoU expressly states that the Participants may not share or exchange information, the dissemination or disclosure of which is prohibited or restricted under law. The Participants will therefore not exchange confidential information without the permission of the party to whom the information relates.

Details of specific projects for collaboration are still being worked out.

Does the MoU permit joint procurement?

Joint procurement is not currently contemplated by the terms as set out in the MoU.

However, the MoU provides that the Participants may determine to cooperate in any other field of healthcare that is not currently covered by the MoU as mutually agreed.

Details of specific projects for collaboration are still being worked out.