



**Australian Government**

**Department of Health**

# **Supplier Submission Form**

## **for**

# **the Review of Continuous Glucose Monitoring (CGM) Products**

Please email your submission to: [cgm@health.gov.au](mailto:cgm@health.gov.au), and cc: [hta@health.gov.au](mailto:hta@health.gov.au).

**All submissions must be received by 12 pm (AEDT) on 12 February 2021.**

## 1. Introduction

The Review of Continuous Glucose Monitoring (CGM) Products is consistent with the periodic reviews of publicly funded pharmaceuticals and medical technologies undertaken by the Department. It is intended to ensure government-funding of CGM products, under the CGM Initiative, is based on strong evidence of clinical and cost effectiveness.

The Review will be considered by the Medical Services Advisory Committee (MSAC), an independent non-statutory committee established in 1998, comprising of individuals with expertise in clinical medicine, health economics and consumer matters.

The Review will include currently subsidised CGM products, and additional CGM products for which subsidisation under the initiative is being sought.

The outcomes of the Review will inform a consistent and transparent framework for considering the inclusion of new and emerging CGM products in the CGM Initiative.

Information provided by suppliers will be used to inform and provide input against the Terms of Reference (ToR) for the Review of CGM Products as discussed below.

Submissions made by suppliers are subject to an assessment and commentary by an external evaluation group. External evaluation reports will be provided to suppliers as appropriate and suppliers will have an opportunity to make comments on these reports prior to the Evaluation Sub-Committee (ESC) and MSAC considerations.

It is anticipated that the CGM Review will be considered by the ESC in June 2021, and then by MSAC in July 2021 as detailed on the [MSAC website](#).

## 2. Terms of Reference

The Terms of Reference for the Review are:

1. Review relevant clinical guidelines on management of type 1 diabetes mellitus (T1DM), specifically regarding advice around the frequency and type of monitoring that should be undertaken for each eligible population under the CGM Initiative, taking into account the differing clinical characteristics of patients within each population (e.g. age, glycaemic control, insulin pump users, non-insulin pump users).
2. Review the utilisation of CGM products currently subsidised or new products to be considered for subsidy under the CGM Initiative, including any information on the average number of products used per patient per year and product switching.
3. Review the clinically relevant outcomes and clinician and patient preferences related to the monitoring of blood glucose levels in patients with T1DM subsidised under the CGM Initiative, taking into account the differing clinical characteristics of patients within each population (e.g. age, glycaemic control, insulin pump users, non-insulin pump users).
4. Synthesise and evaluate evidence on the comparative safety and clinical effectiveness of CGM products currently subsidised through the CGM Initiative and other CGM products (noting additional products may be added as part of the submission and consultation activities), compared to self-monitoring of blood glucose levels. Compare the features of each CGM device/device category and how these address the clinical needs of each patient population and sub-population identified in ToR 3.
5. Review the cost-effectiveness of CGM products currently subsidised under the CGM initiative, and other CGM products, including any additional products identified through the consultation process, to determine a cost-effective price for individual devices, or by device category, for each patient population and sub-population identified in ToR3, noting that there are patients who require use of specific devices due to the nature of their disease which may preclude a generalisable recommendation on the

preferential use of those CGM products which are deemed the most cost-effective (e.g. the need to link to an insulin pump).

### 3. Supplier materials and documents

#### **Commercial-in-Confidence material**

Documents in the possession of the Department of Health are subject to the requirements of the *Freedom of Information Act 1982* which means that the Department may be required to grant access to documents in its possession.

Even if a document is considered commercial-in-confidence, this does not mean that access under this Act can be denied. The Department is required to consult with the author of the document when that document appears to have commercial-in-confidence material, and take the author's views into account when deciding to grant / not grant access to documents.

#### **Confidential material**

It is accepted that documents submitted throughout the MSAC process may contain information the supplier believes is confidential.

However, these claims will be agreed to by the Department on a case-by-case basis, in line with current Government policies (these include, but are not limited to, statistical data and positions of trust classifications).

In any claim for confidentiality, the supplier will be asked to state the basis on which the claim for confidentiality is being made. Further information on the relevant Government policies is available at Australian Governments Solicitors - Legal Briefing - number 64 - "Identifying and Protecting Confidential Information" webpage, located at <http://www.ags.gov.au/publications/legal-briefing/br64.htm>.

#### **Dissemination of the Submission Form and Evidence**

Submissions made by suppliers will be disseminated to MSAC committee and sub-committees, professional bodies / organisations and other individuals and organisations that the Department has deemed should be consulted with.

### 4. Making submissions for the CGM Review

Complete the following form for any products you wish to have considered by the Review.

- In case of currently listed/subsidised CGM products, each supplier may make one submission.
- For additional products that are not currently subsidised by the Commonwealth, a submission made by the supplier does not automatically guarantee subsidisation by the Commonwealth.

Please email your full submission in PDF and MS Word format to: [cgm@health.gov.au](mailto:cgm@health.gov.au), and cc: [hta@health.gov.au](mailto:hta@health.gov.au).

When you email your submission and attachments, depending on the file size of your documents, you may need to split the files into parts. If this is the case, please include a list of all parts and documents in each part, so that we can compile your submission in accordance with your list.

**All submissions must be received by 12 pm (AEDT) on 12 February 2021.**

# Supplier Submission Form for Review of CGM Products

## PART 1 – PERSONAL AND ORGANISATIONAL DETAILS

### 1. Supplier details

Entity name (business, corporation or organisation name):

Trading name:

ABN:

Primary contact (for the purpose of this review):

Telephone:

Mobile:

Email:

Alternative contact (if primary contact is not available):

Telephone:

Mobile:

Email:

### 2. (a) Are you a lobbyist acting on behalf of a supplier?

☐ Yes

☐ No

### (b) If yes, are you listed on the Register of Lobbyists?

☐ Yes

☐ No

## PART 2 – SUBMISSION AGAINST TERMS OF REFERENCE

Provide a detailed submission against the Terms of Reference (discussed above) in this section.

Your submission should be supported by relevant evidence. Please include a reference list of any key journal articles, research projects, or yet to be published research that you consider most relevant to informing the CGM Review.

Please provide full text articles of all the referenced and relevant materials as an attachment to your submission.

As part of your submission, please also include the following information in relation to your CGM product(s):

- Name and succinct description of your CGM product(s);
- Comparable products available;
- Detail eligible population, including age;
- Indicate if the product is in the Australian market and the associated wholesale price/s;
  - If the product is not available in the Australian market, please advise the registration status of the product with the Therapeutic Goods Administration, and indicate your plan for bringing the product to Australia;
- Indicate if the product is currently listed on the CGM Initiative; and
- Provide names and costs of any consumables related to the use of your product.

Any confidential materials need to be clearly marked.