

## Review of CGM products – frequently asked questions for suppliers

#### What is the main purpose of the review?

The main purpose of the Review is to make recommendations on the cost-effectiveness of CGM products.

For more details, refer to the Terms of Reference (ToR) of the review.

#### What is the timeline for the review?

Anticipated key dates for the Review include:

- 12 February Submissions received from suppliers and key stakeholder organisations.
- March to April Development of CGM Review Report (the Report) by an independent external evaluator
- May Comments sought from suppliers on the Report.
- June Evaluation Sub-Committee (ESC) meeting.
- July Suppliers receive ESC Advice for noting and pre-MSAC comment
- July MSAC meeting.
- August to September Outcomes of MSAC meeting shared with suppliers.

#### What products will be included in the CGM Review?

The Review will include currently subsidised <u>CGM products</u>, and new potential products that suppliers wish to have considered for inclusion in the CGM Initiative in the near future.

Note that consideration of new products in the Review does not equate to an application for subsidisation through the CGM Initiative.

# What information would the Department or MSAC like suppliers to provide? What form or format should suppliers complete for making submissions?

Submissions should address the ToR and all statements should be supported by relevant evidence.

Supplier submissions will be provided to the external evaluator for consideration in the

There is no need to make a separate submission for each product.

It is open to suppliers to address the ToR in as much detail as they consider is necessary.

For reference, examples of submissions made by sponsors against ToR for other reviews can be found via the following links:

- <u>Public Consultation on the Post-market review of the use of biologics in the treatment</u> of severe chronic plaque psoriasis
- Public Consultation on the Post-market Review of PAH medicines
- Public Consultation on the Post-market Review of COPD medicines

#### Are supplier submissions expected to be full cost-effectiveness submissions?

No. The independent external evaluator will undertake any required cost effectiveness analysis.

Any information that may inform or support assessment of cost effectiveness is welcome.

### How, and against what criteria, will these submissions be considered/evaluated?

Supplier submissions against the ToR are not assessed. They will be provided to the external evaluator for consideration in the Review.

MSAC will consider the Review and feedback provided on the Review by suppliers as well as supplier's pre-ESC and pre-MSAC comments.

Will the established MSAC evaluation procedures be followed? Yes.

Will the name of the external evaluator be made public?

### Will the assessment report receive third party critique/peer review?

No. The assessment report by the independent external evaluator will be shared with suppliers for comment and will be considered by ESC and MSAC.

Will suppliers have the opportunity to comment upon the assessment report before it is submitted to ESC and MSAC?

### Will there be broader public consultation on the assessment report?

Yes.

The Report will only be shared with suppliers for comment. Key stakeholder organisations and other interested parties have already been invited to make submission against the ToR.

### When do you intend to publish the final version of the assessment report?

It is not anticipated that the Report itself will be published. It is intended that when the Review is completed, a Public Summary Document summarising the Report's key findings and MSAC's advice will be shared with suppliers for comment before it is published on the MSAC website.

Will supplier submissions be exclusively used for clinical and economic evaluations or be used to supplement the Department's commissioned external evaluation irrespective of supplier submission?

Supplier submissions will be provided to the external evaluator for consideration in the Review.

Will the external evaluation utilise diabetes-appropriate modelling to consider the cost-effectiveness of products that evaluates short- and long-term sequelae and complications? What model will be used?

The external evaluator will choose the appropriate modelling.

Suppliers are welcome to recommend a specific approach or methodology in their submission.

How will the external evaluation account for CGM Products with various sensor durations, system componentry, calibration requirements or switching costs?

The external evaluator will determine this as part of the Review.

Suppliers are welcome to recommend a specific approach or methodology in their submission.

#### Will the Department use a price/user/year or price/user/day for each CGM Product?

The external evaluator will determine this as part of the Review process.

Suppliers are welcome to recommend a specific approach or methodology in their submissions.

#### Will supplier submissions be considered confidential in full?

Suppliers need to refer to the confidentiality arrangements discussed in the Supplier Submission Form.

As mentioned above, all supplier submissions will be provided to the external evaluator for consideration in the Review.

Suppliers need to clearly mark any commercial in confidence parts in their submissions.

Supplier submissions will not be published on the MSAC website or the Department of Health website.

Will currently-agreed confidential supplier information remain confidential throughout and after the CGM Review?

Yes.