

ADDENDUM #1

SOLICITATION NUMBER: SN21002

SCIENTIFIC LITERATURE SEARCH SERVICES

Addendum #1 is issued to answer questions submitted by Proponents.

Questions and Answers:

Question 1:

This enquiry pertains to Section R1. Bidder's Sample Reports, part b:

“A sample report prepared using PMPRB format, as shown in Annex A1: Report Template. This sample report is for a pre-selected drug and indication as detailed below:

- i. For Imfinzi for treatment of locally advanced or metastatic urothelial cancer (information up to 2018) that has progressed on platinum-based therapy.”

- A. Why the date of 2018 was chosen?
- B. Can you please clarify whether "information up to 2018" refers to information up to and including 2018 or up until 2018 (i.e., the end of 2017)?
- C. Certain challenges exist in preparing a report that includes information up until a certain date in the past:
 - (1) previous versions of product monographs are not widely available,
 - (2) the WHO ATC DDD 2018 index is no longer accessible,
 - (3) previous versions of guidelines that are published only on-line may not be available, and
 - (4) databases such as UpToDate only provide current information.

Answer 1:

- A. The date of 2018 was chosen as the cut-off because PMPRB has the materials on file to aid in the assessment of proposals.
- B. "Information up to 2018" is intended as meaning up to and including December 31, 2017.
- C. The concerns expressed are noted and the intent is not to make the process a burden for the Proponents. However, PMPRB is asked to review medications historically from time to time so this scenario is not outside the scope of the work that may be required. In addition, we are aware of the challenges and will take these in to consideration when evaluating the sample as part of the bid. No changes will be made to this requirement.

Question 2:

Regarding the report that needs to be prepared by the bidder:

In french it reads: "pour Imfinzi pour le traitement du cancer urothélial localement avancé ou métastatique (**informations jusqu'en 2018**) qui a évolué sous traitement à base de platine" I've put in bold what we're not sure about. Even in English, it says "up to 2018".

We need a clarification:

Does that mean that we have to search as if we were in year 2018 (and therefore search in the literature from before 2018 and up to 2018)?

OR

Does that mean that CEPMB already has updated information up to 2018 (and therefore we have to search in the literature from 2018 to now for that indication)?

Answer 2:

Please see Answer 1b above. The searcher would approach the report as if in year 2018 and therefore search in the literature from before 2018.

All terms and conditions of the RFP remain unchanged.