

TERMS OF REFERENCE

Consultancy services to provide an overview of medicines, including pipeline products, for treatment of hepatitis B and/or hepatitis D

PURPOSE OF THESE TERMS OF REFERENCE

These Terms of Reference (TOR) serve as an overall framework for the services to be provided under this project.

DESIRED TIMEFRAME

Requested start date: 15 Oct 2024
Duration of contract period: 4 months

Completion date: 15 Feb 2025

TERMS OF REFERENCE

1. BACKGROUND

Unitaid has been at the forefront of supporting the elimination of hepatitis C in low- and middle-income countries. Unitaid is currently preparing to support efforts to reduce the vertical transmission of hepatitis B virus (HBV), in the context of supporting the triple elimination of vertical transmission HIV, syphilis and hepatitis B. While this work will focus on integration and increasing the uptake of products that are already on the market, Unitaid would like to have a better understanding of the pipeline of new HBV treatments and their potential role in the treatment and elimination of hepatitis B, including in resource limited settings.

Currently available treatments for hepatitis B require long-term, and often life-long, treatment. Multiple new treatment options for hepatitis B are on the horizon – including, potentially, options (medicines or combinations thereof) for a functional cure of hepatitis B. Unitaid would like to better understand the (potential) value of such new and pipeline products and combinations thereof, relative to each other and relative to existing treatment options.

Moreover, WHO estimates that, globally, about 5% of the 254 million people with hepatitis B infection are co-infected with the hepatitis D virus¹ (HDV), and notes that the combination of HBV and HDV infection is the most severe form of chronic hepatitis, with more rapid progression to liver disease. Addressing HDV infection will therefore probably

¹ Hepatitis D Key facts. WHO, July 2023. Available [here](#).

play a key role in reducing deaths due to viral hepatitis. A new treatment of HDV has recently been approved in several high-income countries – with other products in the pipeline. It is therefore pertinent to expand the analysis to include new and pipeline treatments for HDV.

2. OBJECTIVE OF THE ACTIVITY

Unitaid is seeking services of external qualified contractor(s) to collect, analyze and compile information on medicines for hepatitis B and D that have recently been launched and that are currently in development. In particular, contractors should provide an up-to-date overview of these products and assess their actual or potential place in treatment, based on available information in published literature, information shared at conferences as well as expert opinion. The information should be compiled and summarized in an accessible, written report (or two separate reports, for hepatitis B and D respectively).

Scope of work

The contractor(s) will develop technology landscape documents on medicines for hepatitis B and/or hepatitis D with a focus on products that have recently been launched and that are in development. This will include:

1. Brief, high-level background section: Provide a short overview of the disease burden, global landscape, and commodity access issues, focusing on recent developments/trends, and gaps/barriers to access treatment to hepatitis B and/or D in low- and middle-income countries.
2. Technology landscape: Provide a brief overview of current treatment for hepatitis B and D, as well as a thorough landscape of new product that have recently been approved or that are in the R&D pipeline. The descriptions should include developer/manufacturer/supplier, class of medicine/mechanism of action, stage of development and a summary of clinical trial data. It should assess the (potential) value of such new and pipeline products, relative to each other and relative to existing treatment options, and to the extent possible indicate the expected date of regulatory approval and market entry.
3. Market section: Provide a brief overview of the current market of existing and recently launched treatments for hepatitis B and D. Market characteristics such as total market value and volume, share of high-income countries vs. low- and middle-income countries, regulatory approvals and launch prices of new products should be described based on the best available data.

3. WORK TO BE PERFORMED

Bidders can submit bid/proposal corresponding to one of the below disease areas (HBV or HDV); or for both areas of HBV and HDV. Unitaid may award the contract to a single

Contractor for both HBV and HDV; or award separate contracts to two (2) Contractors for HBV and HDV respectively (based on the relative strength of the proposal for each disease area).

Re: new and pipeline products for the treatment of hepatitis B

1. Perform desk review of existing published and unpublished recent scientific and medical literature, clinical trial reports and other relevant reports (e.g. presentations at relevant medical/scientific conferences) on products that have recently been approved, are under review or are in development for treatment of hepatitis B. Summarize existing data.
2. Assess the strengths and weaknesses of such products, including combinations that are being studied (if any), and the possible or likely combinations that may emerge. For pipeline products, indicate, if possible, when the product may be launched.
3. Assess the (potential) value of such new and pipeline products, individually or in combination, relative to each other and relative to existing treatment options (notably tenofovir disoproxil fumarate (TDF) and entecavir).
4. Validate findings with key stakeholders and experts.
5. Synthesize the information in a draft report, in line with Unitaid standards for structure, language and approach. The report may use graphics to synthesize information.
6. Incorporate input from Unitaid Secretariat and reviewers into a revised version of the report.
7. Prepare slides summarizing key issues and findings on new and pipeline medicines for hepatitis B.

Re: new and pipeline products for the treatment of hepatitis D

1. Perform desk review of existing published and unpublished recent scientific and medical literature, clinical trial reports and other relevant reports (e.g. presentations at relevant medical/scientific conferences) on products that have recently been approved, are under review or are in development for treatment of hepatitis D. Summarize existing data.
2. Assess the strengths and weaknesses of such products, including combinations that are being studied (if any), and the possible or likely combinations that may emerge. For pipeline products, indicate, if possible, when the product may be launched.
3. Assess the (potential) value of such new and pipeline products, individually or in combination, relative to each other and relative to current treatment options.
4. Validate findings with key stakeholders and experts.

5. Synthesize the information in a draft report², in line with Unitaid standards for structure, language and approach. The report may use graphics to synthesize information.
6. Incorporate input from Unitaid Secretariat and reviewers into a revised version of the report.
7. Prepare slides summarizing key issues and findings on new and pipeline medicines for hepatitis D.

4. TIMELINES

It is expected this assignment will run over 4 months, with deliverables to be submitted on the following indicative dates (actual dates will be confirmed during the inception meeting):

Phase	Steps/Deliverables	Target dates
Inception	Kick-off meeting with the Secretariat	15 Oct 2024
Execution	<u>Deliverable #1</u> : Short inception report, summarizing the approach/methodology, proposed report* outline, timeline, and proposed key stakeholders for validation of findings (point 4 in section 3 above).	30 Oct 2024
	<u>Deliverable #2</u> : Early draft report* for comments by Secretariat	15 Nov 2024
	<u>Deliverable #3</u> : Draft report* for review by Secretariat and potentially selected external reviewers.	20 Jan 2025
Closing	<u>Deliverable #4</u> : Final report*, incorporating input and addressing comments from Secretariat and reviewers <u>Deliverable #5</u> : Powerpoint slides summarizing key issues and findings on new and pipeline medicines for hepatitis B as well as hepatitis D	10 Feb 2024

* It can be either a combined report on new and pipeline treatments for hepatitis B and D, or separate reports (one on hepatitis B and one on hepatitis D).

5. QUALIFICATION AND SKILLS

The firm and the proposed team member(s) shall demonstrate adequate qualifications as below:

² This can either be a separate report, or can be combined with the report about new and pipeline treatments for hepatitis B (if bidders have the expertise and opt to bid for both HBV and HDV scopes).

Essential experience and educational requirements:

- At least 10 years' work experience in global public health.
- Experience in horizon scanning for new technologies in global health.
- Experience working on viral hepatitis, preferably experience related to enhancing access to treatments for viral hepatitis for low- and middle-income countries.
- Excellent written communication skills in English, with experience in developing technical reports and the ability to distil complex subjects in clear and accessible messages for a range of audiences (please include samples or links to the similar reports produced)

Desirable experience:

- Experience working on hepatitis B and/or hepatitis D.
- Experience with compiling, assessing and comparing clinical trial data.
- Experience in horizon scanning for new technologies in viral hepatitis.
- Having a well-established network of relevant contacts in industry, academia, international agencies, etc.
- Working knowledge of Unitaid and/or the World Health Organization.
- Product development and commercialization in global health, and particularly related to hepatitis B and/or hepatitis D treatments.

6. PLACE OF WORK AND MANAGEMENT

Place of Performance

The Contractor will work remotely and in close communication with Unitaid and is expected to be available for meetings during normal business hours in the Geneva time zone. Travel is not seen as a necessity for the purpose of this project. The Contractor is also expected to operate in a manner that minimises their carbon footprint during this exercise.

Management, communication and reporting requirements

The Contractor will work closely with Unitaid's Strategy team during the project. In addition to adequate frequency of video calls and phone calls, the Contractor and its proposed team members are expected to participate in a virtual kick-off and inception meeting and to deliver a virtual presentation of the results during an exit meeting.

Confidentiality

The supplier shall treat all data and information to which it may gain access for or in the course of the services as confidential and proprietary to Unitaid.

7. BUDGET

Unitaid is an Organization that is dependent on the budgetary and extra-budgetary contributions it receives for the implementation of its activities. Bidders are, therefore, requested to propose the best and most cost-effective solution to meet Unitaid requirements, while ensuring a high level of service. All bidders are expected to submit their proposed budget, broken down across Hepatitis B and D. Bidders are also requested to provide an indication of the level of effort related to products for hepatitis B and hepatitis D respectively.

8. PAYMENT TERMS AND SCHEDULE

For *professional fees*, payments will be made following satisfactory completion of the ToR deliverables and submission of corresponding invoices detailing the actual level of effort incurred.

For *travel costs (if requested by Unitaid)*, payment will be made in accordance with WHO policies and rates and upon submission of invoices indicating actual travel costs with proof of payment. The Contractor is responsible for organising all travel logistics, including hotel booking and local transportation, in the most economical manner.

Basis for Payment	Payment Percentage
1. Upon satisfactory completion of Deliverable #1 and #2 and acceptance by Unitaid	20% of Professional Fee
2. Upon satisfactory completion of Deliverable #3 and acceptance by Unitaid	40% of Professional Fee
3. Upon satisfactory completion of Deliverables #4 and #5 and acceptance by Unitaid	40% of Professional Fee