ANALYSING THE PATENT SITUATION OF KEY PIPELINE PRODUCTS FOR TREATMENT OF HEPATITIS C

Request for Proposals (RFP)
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1. INTRODUCTION

1.1 Objective of the RFP

The purpose of this Request for Proposals (RFP) is to enter into a contractual agreement with a successful bidder to carry out the following work:

ANALYSING THE PATENT SITUATION OF KEY PIPELINE PRODUCTS FOR TREATMENT OF HEPATITIS C

WHO 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 WHO requirements, while ensuring a high level of service.

1.2 About WHO

The World Health Organization was established in 1948 as a specialized agency of the United Nations. The objective of WHO (www.who.int) is the attainment by all peoples of the highest possible level of health. Health, as defined in the WHO Constitution, is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. WHO's main function is to act as the directing and coordinating authority on international health work.
2. DESCRIPTION OF SUBJECT / PRESENT ACTIVITIES

2.1 Overview and objectives

The project will assess the patent status of the key pipeline products for Hepatitis C to allow an assessment regarding the possibilities of transfer of technology, expected generic versions originating from developing country manufacturers and allowing discussions with patent holders about ways to increase access to these products.

BACKGROUND

KEY FACTS

- Hepatitis C is a liver disease caused by the hepatitis C virus transmitted through contact with the blood of an infected person. Hepatitis C is found worldwide with some countries having chronic infection rates as high as 5% and above. It can lead to cirrhosis of the liver or liver cancer.

- Globally, about 150 million people are chronically infected with hepatitis C virus of which more than 350,000 people die every year from hepatitis C-related liver diseases.

- There is currently no vaccine for hepatitis C, but it can be treated using antiviral medicines such as pegylated interferon.¹

- There are a number of promising new treatments in Clinical Phase III that are expected to be much more efficacious than existing treatments. If these expectations become reality, making these treatments accessible to all people infected who need them will be a huge challenge.

- The question to what extent these products are patented and how these patents will be managed by the patent holders will be decisive for the question whether there will be only one provider for each product or whether generic alternatives will be available.

CURRENT TREATMENT

There are 6 different genotypes of the hepatitis C virus (genotypes 1-6). Currently, combination antiviral therapy with interferon and ribavirin is the mainstay of hepatitis C treatment. This treatment regime however has certain shortcomings. Not all virus genotypes respond equally well to interferon and interferon is not always well tolerated. This is one reason why people who take interferon do not always finish their treatment. Availability of interferon in many developing countries is also limited. This means that while hepatitis C is generally considered to be a curable disease, for many people this is not a reality.

TREATMENT PIPELINE

Scientific advances have led to the development of new antiviral drugs for hepatitis C that are currently in clinical phase II and III and, which are expected to be more effective and better tolerated than existing therapies, although only final evaluation of the safety, quality and efficacy profile will show to what extent the current pipeline products are superior than existing treatment.

If the expectations become reality, sustained efforts of the global public health community are needed to make the new treatment available globally to reach the patients in need. The

experience in scaling up access to antiretroviral treatment for HIV/AIDS has shown that one key aspect is the availability of affordable generics. In this respect, it is decisive to know to what extent and in which countries these products are protected by patents. The nature of the patents will allow an assessment of the strength of the patent and whether it is likely to be granted in various jurisdictions, particularly India. The patent landscape will also provide an overview about patent opposition procedures in various jurisdictions. Knowing the patent situation of a medicine across national jurisdictions is also a prerequisite for possible transfer of technology and the successful negotiation of voluntary license agreements with the patent holders that can be a means to allow for early availability of affordable generic versions.

<table>
<thead>
<tr>
<th>AGENT</th>
<th>SPONSOR</th>
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<tbody>
<tr>
<td>sofosbuvir (GS-7977)</td>
<td>Gilead Sciences</td>
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**Non-nucleoside polymerase inhibitors**

<table>
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<tr>
<th>AGENT</th>
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<tbody>
<tr>
<td>ABT-333</td>
<td>AbbVie</td>
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**NS5A inhibitors**

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<tr>
<td>ABT-267</td>
<td>AbbVie</td>
</tr>
<tr>
<td>daclatasvir (BMS-790052)</td>
<td>Bristol-Myers Squibb</td>
</tr>
<tr>
<td>ledipasvir (GS-5885)</td>
<td>Gilead Sciences</td>
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**Protease inhibitors**

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<th>SPONSOR</th>
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<tbody>
<tr>
<td>ABT-450/ritonavir (ritonavir-boosted)</td>
<td>AbbVie</td>
</tr>
<tr>
<td>simeprevir (TMC435)</td>
<td>Janssen</td>
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Not all products currently in Phase III trials have been included in this project. The selected products include those which are closest to market authorization with sofosbuvir and simeprevir submitted for approval to the US Federal Drug Authority (FDA). It is expected that future treatment regimes will include combination therapies of different medicines. The selected products are likely to be part of the first fixed-dose combinations (ABT-267/ABT-450/r and sofosbuvir/ledipasvir).

### 2.2 Activity coordination

The project will be supervised by the group on Public Health, Innovation, and Intellectual Property (PHI) which is situated within the WHO Department of Essential Medicines and Health Technologies (EMP) in collaboration with the WHO Transfer of Technology Initiative (TTi).
3. REQUIREMENTS

3.1 Work to be performed

WHO requires the successful bidder, the Contractor, to carry out the following tasks:

Task 1: Patent Search
A patent search for relevant granted patents and patent applications with respect to the products listed in Table 1. The search should focus on patents that could hinder the production of the listed products by another manufacturer.

Patents should be classified according to:

a) Primary patents that would constrain generic production

b) Secondary patents that could constrain generic production

Secondary patents should be indexed according to:

- Physical forms of the compound (salts, polymorphs etc.)
- Combinations with other drugs (with pegylated interferon, ribavirin or any of the products listed in Table 1)
- Galenic forms/formulations (e.g. tablet, oral dosage, soft capsule)
- Production processes
- Medical use claims for Hepatitis A, B, C or viral infection

Task 2: Family Member Search
Once the relevant patents identified the contractor is required to search for patent family members in the following jurisdictions:

Argentina
ARlPO (one reference country)
Brazil
Chile
China
EPO (one selected reference country)
Egypt
Ethiopia
Eurasian Patent Office
India
Indonesia
Israel
Jordan
Task 3: Patent Oppositions
The contractor is requested to provide information on patent oppositions with respect to the patents identified under Task 1 for as many of the countries listed under Task 2 as possible, but at least EPO.

Task 4: Final Report
The contractor should provide the patent data in an appropriate form (excel file with hyperlinks to the patent publications where possible) in two sets in form of a memory stick or CD ROM. The final report shall include a brief description of each of the patents considered relevant with an explanation why it is considered relevant.

3.2 Method of work
Bidders shall present a detailed description of the suggested method of work, including which databases s/he intends to use and how s/he intends to search for family members in the various jurisdictions.

3.3 Reporting requirements and timelines
The future contractor shall be in regularly contact with WHO. 14 days after the start of the contract the bidder shall validate the suggested search methodology with WHO.

The contractor shall submit the preliminary search report for all compounds, including the description of the relevant patents not later than 31 December 2013. The contractor shall review the search report based on feedback received.

The contractor shall submit the data on patent oppositions and family members not later than the 13 January 2014. The contractor shall review the search report based on feedback received.

The contractor shall review the search report based on feedback received and submit the final report not later than 31 January 2014.
3.4 Characteristics of the provider

3.4.1 Status
The provider shall be a for profit or not for profit institution operating in the field of intellectual property and health, with proven expertise in patent searches in the area of medical products.

3.4.2 Previous experience
- Previous work with WHO, other international organizations and/or major institutions in the field of health;
- Proven experience in patent searches.

3.4.3 Logistical capacity
The provider shall be able to guarantee the finalization of the project in the given timelines. The provider shall detail that s/he has enough resources available to meet deadlines.

3.4.4 Staffing
The provider shall detail the competencies of staff who will work on the project.
4. INSTRUCTIONS TO BIDDERS

Bidders should follow the instructions set forth below in the submission of their proposal to WHO.

4.1 Language of the Proposal and other Documents

The proposal prepared by the bidder, and all correspondence and documents relating to the proposal exchanged by the bidder and WHO shall be written in the English language.

4.2 Cost of Proposal

Bidders shall bear all costs associated with the preparation and submission of the proposal, including but not limited to the possible cost of discussing the proposal with WHO, making a presentation, negotiating a contract and any related travel. WHO will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the selection process.

4.3 Contents of the Proposal

Proposals must offer the total requirement. Proposals offering only part of the requirement may be rejected.

4.4 Joint Proposal

Two or more entities may form a consortium and submit a joint proposal offering to jointly undertake the work. Such a proposal must be submitted in the name of one member of the consortium - hereinafter the "lead organization". The lead organization will be responsible for undertaking all negotiations and discussions with, and be the main point of contact for, WHO. The lead organization and each member of the consortium will be jointly and severally responsible for the proper performance of the contract.

4.5 Communications during the RFP Period

A prospective bidder requiring any clarification on technical, contractual or commercial matters may notify WHO via email at the following address:

Email for submissions of all queries: phidepartment@who.int

The PHI Team at WHO will respond in writing (via email only) to any request for clarification of the RFP that it receives by the deadline indicated above. WHO's responses to all questions (including an explanation of the query but without identifying the source of enquiry) will be sent to all prospective bidders who have received the RFP.

There shall be no individual presentation by or meeting with bidders until after the closing date. From the date of issue of this RFP to the final selection, contact with WHO officials concerning the RFP process shall not be permitted, other than through the submission of queries and/or through a possible presentation or meeting called for by WHO, in accordance with the terms of this RFP.
4.6 Format of Proposals and closing date

The bidder shall submit a complete proposal, including a signed cover letter before the end of 28 October 2013 by email to

phidepartment@who.int

Proposals must be received at WHO at the above mentioned address no later than 17:00 hours, Geneva time.

WHO may, at its own discretion, extend this closing date for the submission of proposals by notifying all bidders thereof in writing. Any proposal received by WHO after the closing date for submission of proposals may be rejected.

4.7 Period of Validity of Proposals

The offer outlined in the proposal must be valid for a minimum period of 120 calendar days after the closing date. A proposal valid for a shorter period may be rejected by WHO. In exceptional circumstances, WHO may solicit the bidder’s consent to an extension of the period of validity. The request and the responses thereto shall be made in writing. Any bidder granting such an extension will not, however, be permitted to otherwise modify its proposal.

4.8 Receipt of Proposals from Non-invitees

WHO may, at its own discretion, if it considers this necessary and in the interest of the Organization, extend the RFP to bidders that were not included in the original invitation list.

4.9 Amendment of the RFP

WHO may, at any time before the closing date, for any reason, whether on its own initiative or in response to a clarification requested by a (prospective) bidder, modify the RFP by written amendment. Amendments could, inter alia, include modification of the project scope or requirements, the project timeline expectations and/or extension of the closing date for submission.

All prospective bidders that have received the RFP will be notified in writing of all amendments to the RFP and will, where applicable, be invited to amend their proposal accordingly.

4.10 Proposal Structure

The contents of the bidder’s proposal should be concisely presented and structured. Any information which the bidder considers confidential, if any, should be clearly marked confidential.

Bidders shall submit general information about the firm/organization submitting the proposal, including relevant experience, and expertise of staff involved and the financial situation.

Bidders shall submit a financial proposal specifying the budget corresponding to the five tasks specified further above in US$.
5. OPENING AND EVALUATION OF PROPOSALS

5.1 Clarification of Proposals

WHO may, at its discretion, ask any bidder for clarification of any part of its proposal. The request for clarification and the response shall be in writing. No change in price or substance of the proposal shall be sought, offered or permitted during this exchange.

5.2 Preliminary Examination of Proposals

WHO will examine the proposals to determine whether they are complete, whether any computational errors have been made, whether the documents have been properly signed, and whether the proposals are generally in order.

Please note that WHO is not bound to select any bidder and may reject all proposals. Furthermore, since a contract would be awarded in respect of the proposal which is considered most responsive to the needs of the project concerned, due consideration being given to WHO's general principles, including economy and efficiency, WHO does not bind itself in any way to select the bidder offering the lowest price.

5.3 Evaluation of Proposals

A two-stage procedure will be utilized in evaluating the proposals, with technical evaluation of the proposal being completed prior to any focus on or comparison of price.

The technical and financial evaluations of proposals will be accomplished by a Selection Panel. The Selection Panel will evaluate all proposals which have passed the Preliminary Examination of Proposals.

5.4.1 Technical Evaluation

The technical evaluation of the proposals will include:

- the extent to which WHO's requirements and expectations have been satisfactorily addressed;
- the quality of the overall proposal;
- the appropriateness of the proposed approach;
- the quality of the technical solution proposed;
- the management strategy/plan detailed in the document;
- the experience of the firm in carrying out related projects;
- the qualifications and competence of the personnel proposed for the assignment;
- the proposed timeframe for the project;

5.4.2 Financial Evaluation

During the Financial Evaluation, the price proposal of all bidders who have passed the Technical Evaluation will be compared.
6. AWARD OF CONTRACT

6.1 Award Criteria, Award of Contract

WHO reserves the right to

a) Award the contract to a bidder of its choice, even if its bid is not the lowest;
b) Award separate contracts for parts of the work, components or items, to one or more bidders of its choice, even if their bids are not the lowest;
c) Accept or reject any proposal, and to annul the solicitation process and reject all proposals at any time prior to award of contract, without thereby incurring any liability to the affected bidder or bidders and without any obligation to inform the affected bidder or bidders of the grounds for WHO’s action;
d) Award the contract on the basis of the Organization’s particular objectives to a bidder whose proposal is considered to be the most responsive to the needs of the Organization and the activity concerned;
e) Not award any contract at all.

WHO has the right to eliminate bids for technical or other reasons throughout the evaluation/selection process. WHO shall not in any way be obligated to reveal, or discuss with any bidder, how a proposal was assessed, or to provide any other information relative to the evaluation/selection process or to state the reasons for elimination to any bidder.

NOTE: WHO is acting in good faith by issuing this RFP. However, this document does not obligate WHO to contract for the performance of any work, nor for the supply of any products or services.

6.2 WHO’s Right to modify Scope or Requirements during the Evaluation/Selection Process

At any time during the evaluation/selection process, WHO reserves the right to modify the scope of the work, services and/or goods called for under this RFP. WHO shall notify the change to only those bidders who have not been officially eliminated due to technical reasons at that point in time.

6.3 WHO’s Right to Extend/Revise Scope or Requirements at Time of Award

WHO reserves the right at the time of award of contract to extend, reduce or otherwise revise the scope of the work, services and/or goods called for under this RFP without any change in the base price or other terms and conditions offered by the selected bidder.

6.4 WHO’s Right to enter into Negotiations

WHO also reserves the right to enter into negotiations with one or more bidders of its choice, including but not limited to negotiation of the terms of the proposal(s), the price quoted in such
proposal(s) and/or the deletion of certain parts of the work, components or items called for under this RFP.

### 6.5 Signing of the Contract

Within 30 days of receipt of the contract, the successful bidder shall sign and date the contract and return it to WHO according to the instructions provided at that time. If the bidder does not accept the contract terms without changes, then WHO has the right not to proceed with the selected bidder and instead contract with another bidder of its choice.
7. GENERAL AND CONTRACTUAL CONDITIONS

The contract between WHO and the selected bidder ("the Contract") will, unless otherwise explicitly agreed in writing, include the provisions as set forth in this section, and will otherwise inter alia address the following issues:

- responsibilities of the selected bidder(s) ("the Contractor(s)") and WHO;
- clear deliverables, timelines and acceptance procedures;
- payment terms tied to the satisfactory performance and completion of the work;
- notices.

The prices payable by WHO for the work to be performed under the Contract shall be fixed for the duration of the Contract and shall be in a UN convertible currency (preferably US Dollars), based on the UN exchange rate of the date of invoice. The total amount payable by WHO under the Contract may be either a lump sum or a maximum amount. If the option for payment of a lump sum applies, that lump sum is payable in the manner provided, subject to satisfactory performance of the work. If the option for payment of a maximum amount applies:
- the Contract shall include a detailed budget;
- the Contractor shall be held to submit a financial statement together with each invoice;
- any advance payments by WHO shall be used by the Contractor exclusively for the work in accordance with the budget and any unspent balance shall be refunded to WHO;
- payment by WHO shall be subject to satisfactory performance and the acceptance of the Contractor's financial statements; and
- all financial reports shall be subject to audit by or on behalf of WHO, including examination of supporting documentation and relevant accounting entries in the Contractor's books. In order to facilitate financial reporting and audit, the Contractor shall keep systematic and accurate accounts and records in respect of the work.

Unless otherwise specified in the Contract, WHO shall have no obligation to purchase any minimum quantities of goods or services from the Contractor, and WHO shall have no limitation on its right to obtain goods or services of the same kind, quality and quantity as described in the Contract, from any other sources at any time.

7.1 Conditions of Contract

Any and all of the Contractor's (general and/or special) conditions of contract are hereby explicitly excluded from the Contract, i.e., regardless of whether such conditions are included in the Contractor's offer, or printed or referred to on the Contractor's letterhead, invoices and/or other material, documentation or communications.

7.2 Responsibility

The Contractor will be responsible to ensure that the work performed under the Contract meets the agreed specifications and is completed within the time prescribed. The Contractor shall facilitate the operational audit related to the execution of the work and the compliance with the obligations set forth in the Contract, by persons so designated by WHO. In this regard, the Contractor shall make all relevant operational information, without restriction, available to persons so designated by WHO and provide satisfactory explanations to all queries arising in connection therewith.
7.3 **Source of Instructions**

The Contractor shall neither seek nor accept instructions from any authority external to WHO in connection with the performance of the work under the Contract. The Contractor shall refrain from any action which may adversely affect WHO and shall fulfil its commitments with the fullest regard to the interests of WHO.

7.4 **Warranties**

The Contractor warrants and represents to WHO as follows:

1) The deliverables shall meet the specifications called for in the Contract and shall be fully adequate to meet their intended purpose. The Contractor furthermore warrants that the deliverables shall be error-free. The Contractor shall correct any errors in the deliverables, free of charge, within fifteen days after their notification to the Contractor, during a period of at least one year after completion of the work. It is agreed, however, that errors and other defects which have been caused by modifications to the deliverables made by WHO without agreement of the Contractor are not covered by this paragraph.

2) The deliverables shall, to the extent they are not original, only be derived from, or incorporate, material over which the Contractor has the full legal right and authority to use it for the proper implementation of the Contract. The Contractor shall obtain all the necessary licenses for all non-original material incorporated in the deliverables (including, but not limited to, licenses for WHO to use any underlying software, application, and operating deliverables included in the deliverables or on which it is based so as to permit WHO to fully exercise its rights in the deliverables without any obligation on WHO's part to make any additional payments whatsoever to any party.

3) The deliverables shall not violate any copyright, patent right, or other proprietary right of any third party and shall be delivered to WHO free and clear of any and all liens, claims, charges, security interests and any other encumbrances of any nature whatsoever.

4) The Contractor, its employees and any other persons and entities used by the Contractor shall not violate any intellectual property rights, confidentiality, right of privacy or other right of any person or entity whomsoever.

5) Except as otherwise explicitly provided in the Contract, the Contractor shall at all times provide all the necessary on-site and off-site resources to meet its obligations hereunder. The Contractor shall only use highly qualified staff, acceptable to WHO, to perform its obligations hereunder.

6) The Contractor shall take full and sole responsibility for the payment of all wages, benefits and monies due to all persons and entities used by it in connection with the implementation and execution of the Contract, including, but not limited to, the Contractor’s employees, permitted subcontractors and suppliers.

Contractor furthermore warrants and represent that the information provided by it to WHO in response to the RFP and during the bid evaluation process is accurate and complete. Contractor understands that in the event Contractor has failed to disclose any relevant information which may have impacted WHO's decision to award the Contract to Contractor, or has provided false information, WHO will be entitled to rescind the contract with immediate effect, in addition to any other remedies which WHO may have by contract or by law.
7.5 **Legal Status**

The Contractor shall be considered as having the legal status of an independent contractor vis-à-vis WHO, and nothing contained in or relating to the Contract shall be construed as establishing or creating an employer/employee relationship between WHO, on the one hand, and the Contractor or any person used by the Contractor in the performance of the work, on the other hand.

Thus the Contractor shall be solely responsible for the manner in which the work is carried out. WHO shall not be responsible for any loss, accident, damage or injury suffered by the Contractor or persons or entities claiming under the Contractor, arising during or as a result of the implementation or execution of the Contract, including travel, whether sustained on WHO premises or not.

The Contractor shall obtain adequate insurance to cover such loss, accident, injury and damage, before commencing work on the Contract. The Contractor shall be solely responsible in this regard and shall handle any claims for such loss, accident, damage or injury.

7.6 **Relation Between the Parties**

Nothing in the Contract shall be deemed to constitute a partnership between the Parties or to constitute either Party as the agent of the other.

7.7 **No Waiver**

The waiver by either Party of any provision or breach of the Contract shall not prevent subsequent enforcement of such provision or excuse further breaches.

7.8 **Liability**

The Contractor hereby indemnifies and holds WHO harmless from and against the full amount of any and all claims and liabilities, including legal fees and costs, which are or may be made, filed or assessed against WHO at any time and based on, or arising out of, breach by the Contractor of any of its representations or warranties under the Contract, regardless of whether such representations and warranties are explicitly incorporated here in or are referred to in any attached Appendices.

7.9 **Assignment**

The Contractor shall not assign, transfer, pledge or make any other disposition of the Contract or any part thereof, or any of the Contractor’s rights, claims or obligations under the Contract except with the prior written consent of WHO.

7.10 **Officials not to Benefit**

The Contractor warrants that no official of WHO has received or will be offered by the Contractor any direct or indirect benefit arising from the Contract or the award thereof. The Contractor agrees that breach of this provision is a breach of an essential term of the Contract.
7.11 **Indemnification**

The Contractor shall indemnify and hold WHO harmless, from and against the full amount of any and all claims and liabilities, including legal fees and costs, which are or may be made, filed or assessed against WHO at any time and based on, or arising out of, the acts or omissions of the Contractor, or the Contractor's employees, officers, agents, partners or sub-contractors, in the performance of the Contract. This provision shall extend, *inter alia*, to claims and liabilities in the nature of workmen's compensation, product liability and liability arising out of the use of patented inventions or devices, copyrighted material or other intellectual property by the Contractor, its employees, officers, agents, servants, partners or sub-contractors.

7.12 **Contractor's Responsibility for Employees**

The Contractor shall be responsible for the professional and technical competence of its employees and will select, for work under the Contract, reliable individuals who will perform effectively in the implementation of the Contract, respect the local laws and customs, and conform to a high standard of moral and ethical conduct.

7.13 **Subcontracting**

Any intention to subcontract aspects of the Contract must be specified in detail in the proposal submitted. Information concerning the subcontractor, including the qualifications of the staff proposed for use must be covered with same degree of thoroughness as for the prime contractor. No subcontracting will be permitted under the Contract unless it is proposed in the initial submission or formally agreed to by WHO at a later time. In any event, the total responsibility for the Contract remains with the Contractor.

The Contractor shall be responsible for ensuring that any and all subcontracts shall be fully consistent with the Contract, and shall not in any way prejudice the implementation of any of its provisions.

7.14 **Place of Performance**

The place of performance of the work under the Contract shall depend on the place of residence of the contractor.

7.15 **Language**

All communications relating to the Contract and/or the performance of the work thereunder shall be in English.

7.16 **Confidentiality**

1) Except as explicitly provided in the Contract, the Contractor shall keep confidential all information which comes to its knowledge during, or as a result of, the implementation and execution of the Contract. Accordingly, the Contractor shall not use or disclose such information for any purpose other than the performance of its obligations under the Contract. The Contractor shall ensure that each of its employees and/or other persons and entities having access to such information shall be made aware of, and be bound by, the obligations of the Contractor under this paragraph. However, there shall be no obligation of confidentiality or restriction on use, where: (i) the information is publicly
1) All rights pertaining to any and all deliverables under the Contract and the original work product leading thereto, as well as the rights in any non-original material incorporated therein as referred to in section 7.4.2 above, shall be exclusively vested in WHO.

2) WHO reserves the right to revise the work, to use the work in a different way from that originally envisaged or to not use the work at all.

3) At WHO's request, the Contractor shall take all necessary steps, execute all necessary documents and generally assist WHO in securing such rights in compliance with the requirements of applicable law.

7.18 Termination and Cancellation

WHO shall have the right to cancel the Contract (in addition to other rights, such as the right to claim damages):

1) In the event the Contractor fails to begin work on the date agreed, or to implement the work in accordance with the terms of the Contract; or

2) In the event the progress of work is such that it becomes obvious that the obligations undertaken by the Contractor and, in particular, the time for fulfilment of such obligations, will not be respected.

In addition, WHO shall be entitled to terminate the Contract (or part thereof), in writing:

1. At will with the provision of thirty (30) days prior notice in writing; and

2. With immediate effect (in addition to other rights, such as the right to claim damages), if, other than as provided above, the Contractor is:
   a. In breach of any of its material obligations under the Contract and fails to correct such breach within a period of thirty (30) days after having received a written notification to that effect from WHO; or
   b. Adjudicated bankrupt or formally seeks relief of its financial obligations.
7.19 **Force Majeure**

No party to the Contract shall be responsible for a delay caused by *force majeure*, that is, a delay caused by reasons outside such party's reasonable control it being agreed, however, that WHO shall be entitled to terminate the Contract (or any part of the Contract) forthwith if the implementation of the work is delayed or prevented by any such reason for an aggregate of thirty (30) days. Such termination shall be subject to payment of an equitable part of the Contract sum and/or other reasonable charges. In the event of such termination, the Contractor shall, in accordance with the ownership rights referred to in section 7.17 *Title rights*, deliver to WHO all work products and other materials so far produced.

In the event of and as soon as possible after the occurrence of any cause constituting *force majeure*, the Contractor shall give notice and full particulars in writing to WHO, of such occurrence or change if the Contractor is thereby rendered unable, wholly or in part, to perform its obligations and meet its responsibilities under the Contract. The Contractor shall also notify WHO of any other changes in conditions or the occurrence of any event which interferes or threatens to interfere with its performance of the Contract. The notice shall include steps proposed by the Contractor to be taken including any reasonable alternative means for performance that is not prevented by *force majeure*. On receipt of the notice required under this section, WHO shall take such action as it, in its sole discretion, considers to be appropriate or necessary in the circumstances, including the granting to the Contractor of a reasonable extension of time in which to perform its obligations under the Contract.

7.20 **Surviving Provisions**

Those rights and obligations of the Parties as set forth in sections 7 and 8 that are intended by their nature to survive the expiration or earlier termination of the Contract shall survive indefinitely. This includes, but is expressly not limited to, any provisions relating to WHO's right to financial and operational audit, conditions of contract, warranties, legal status and relationship between the parties, breach, liability, indemnification, subcontracting, confidentiality, title rights, use of the WHO name and emblem, successors and assignees, insurance and liabilities to third parties, settlement of disputes, observance of laws, privileges and immunities, no terrorism or corruption, foreign nationals and compliance with WHO policies.

7.21 **Use of WHO name and emblem**

Without WHO's prior written approval, the Contractor shall not, in any statement of an advertising or promotional nature, refer to the Contract or its relationship with WHO. In no case shall the Contractor use the name or emblem of the World Health Organization, or any abbreviation thereof, in relation to its business or otherwise.

7.22 **Successors and Assignees**

The Contract shall be binding upon the successors and assignees of the Contractor and the Contract shall be deemed to include the Contractor’s successors and assignees, provided, however, that nothing in the Contract shall permit any assignment without the prior written approval of WHO.
7.23 Payment

Payment will be made against presentation of an invoice in a UN convertible currency (preferably US Dollars) in accordance with the payment schedule contained in the Contract, subject to satisfactory performance of the work. The price shall reflect any tax exemption to which WHO may be entitled by reason of the immunity it enjoys. WHO is, as a general rule, exempt from all direct taxes, custom duties and the like, and the Contractor will consult with WHO so as to avoid the imposition of such charges with respect to this contract and the goods supplied and/or services rendered hereunder. As regards excise duties and other taxes imposed on the sale of goods or services (e.g. VAT), the Contractor agrees to verify in consultation with WHO whether in the country where the VAT would be payable, WHO is exempt from such VAT at the source, or entitled to claim reimbursement thereof. If WHO is exempt from VAT, this shall be indicated on the invoice, whereas if WHO can claim reimbursement thereof, the Contractor agrees to list such charges on its invoices as a separate item and, to the extent required, cooperate with WHO to enable reimbursement thereof.

7.24 Title to Equipment

Title to any equipment and supplies that may be furnished by WHO shall remain with WHO and any such equipment shall be returned to WHO at the conclusion of the Contract or when no longer needed by the Contractor. Such equipment, when returned to WHO, shall be in the same condition as when delivered to the Contractor, subject to normal wear and tear. The Contractor shall be liable to compensate WHO for equipment determined to be damaged or degraded beyond normal wear and tear.

7.25 Insurance and Liabilities to Third Parties

The Contractor shall provide and thereafter maintain:

(i) insurance against all risks in respect of its property and any equipment used for the execution of the Contract;

(ii) all appropriate workmen's compensation insurance, or its equivalent, with respect to its employees to cover claims for personal injury or death in connection with the Contract; and

(iii) liability insurance in an adequate amount to cover third party claims for death or bodily injury, or loss of or damage to property, arising from or in connection with the performance of the work under the Contract or the operation of any vehicles, boats, airplanes or other equipment owned or leased by the Contractor or its agents, servants, employees, partners or sub-contractors performing work in connection with the Contract.

Except for the workmen's compensation insurance, the insurance policies under this section shall:

a) Name WHO as additional insured;

b) Include a waiver of subrogation to the insurance carrier of the Contractor's rights against WHO;

c) Provide that WHO shall receive written notice from the Contractor's insurance carrier not less than thirty (30) days prior to any cancellation or material change of coverage.

The Contractor shall, upon request, provide WHO with satisfactory evidence of the insurance required under this section.
7.26 Settlement of Disputes

Any dispute relating to the interpretation or application of the Contract shall, unless amicably resolved, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or, in the absence of agreement, with the rules of arbitration of the International Chamber of Commerce. The parties shall accept the arbitral award as final.

7.27 Observance of Laws

The Contractor shall comply with all laws, ordinances, rules, and regulations bearing upon the performance of its obligations under the terms of the Contract.

7.28 Authority to Modify

No modification or change of the Contract, no waiver of any of its provisions or any additional contractual relationship of any kind shall be valid and enforceable unless signed by a duly authorized representative of both parties.

7.29 Privileges and Immunities

Nothing in or relating to the Contract shall:
- be deemed a waiver of any of the privileges and immunities of WHO in conformity with the Convention on the Privileges and Immunities of the Specialized Agencies approved by the General Assembly of the United Nations on November 21, 1947 or otherwise under any national or international law, convention or agreement; and/or
- be construed as submitting WHO to any national court jurisdiction.

7.30 No Terrorism or Corruption

The Contractor warrants that:

(i) it is not and will not be involved in, or associated with, any person or entity involved in terrorism, that it will not make any payment to any such person or entity and that it will not enter into any employment or subcontracting relationship with any such person or entity; and

(ii) it shall not engage in any illegal, corrupt, fraudulent, collusive or coercive practices in connection with execution of the Contract.

The Contractor agrees that breach of this provision is a breach of an essential term of the Contract.

Any payments used by the Contractor for the promotion of any terrorist activity or any illegal, corrupt, fraudulent, collusive or coercive practice shall be repaid to WHO without delay.
8. PERSONNEL

8.1 Approval of Contractor Personnel

WHO reserves the right to approve any employee, subcontractor or agent furnished by the Contractor and Contractor's consortium partners for the performance of the work under the Contract (hereinafter jointly referred to as "Contractor Personnel"). All Contractor Personnel must have appropriate qualifications, skills, and levels of experience and otherwise be adequately trained to perform the work. WHO reserves the right to undertake an interview process as part of the approval of Contractor Personnel.

The Contractor acknowledges that the qualifications, skills and experience of the Contractor Personnel proposed to be assigned to the project are material elements in WHO's engaging the Contractor for the project. Therefore, in order to ensure timely and cohesive completion of the project, both parties intend that Personnel initially assigned to the project continue through to project completion. Once an individual has been approved and assigned to the project, such individual will not, in principle, thereafter be taken off the project by the Contractor, or reassigned by the Contractor to other duties. Circumstances may arise, however, which necessitate that Personnel be substituted in the course of the work, e.g. in the event of promotions, termination of employment, sickness, vacation or other similar circumstances, at which time a replacement with comparable qualifications, skills and experience may be assigned to the project, subject to approval of WHO.

WHO may refuse access to or require replacement of any Contractor Personnel if such individual renders, in the sole judgment of WHO, inadequate or unacceptable performance, or if for any other reason WHO finds that such individual does not meet his/her security or responsibility requirements. The Contractor shall replace such an individual within fifteen (15) business days of receipt of written notice from WHO. The replacement will have the required qualifications, skills and experience and will be billed at a rate that is equal to or less than the rate of the individual being replaced.

8.2 Project Managers

Each party shall appoint a qualified project manager ("Project Manager") who shall serve as such party's primary liaison throughout the course of the project. The Project Manager shall be authorized by the respective party to answer all questions posed by the other party and convey all decisions made by such party during the course of the project and the other party shall be entitled to rely on such information as conveyed by the Project Manager.

The Project Managers shall meet on a monthly basis in order to review the status of the project and provide WHO with reports. Such reports shall include detailed time distribution information in the form requested by WHO and shall cover problems, meetings, progress and status against the implementation timetable.
8.3 Foreign Nationals

The Contractor shall verify that all Contractor Personnel is legally entitled to work in the country or countries where the work is to be carried out. WHO reserves the right to request the Contractor to provide WHO with adequate documentary evidence attesting this for each Contractor Personnel.

Each party hereby represents that it does not discriminate against individuals on the basis of race, gender, creed, national origin, citizenship.

8.4 Compliance with WHO’s Policies

The Contractor shall at all times comply with and ensure that the Contractor and each of its partners, subcontractors and their employees and agents comply with any applicable laws and regulations and with all WHO policies and reasonable written directions and procedures relating to: (i) occupational health and safety, (ii) security and administrative requirements, including, but not limited to computer network security procedures, (iii) sexual harassment, (iv) privacy, (v) general business conduct and disclosure, (vi) conflicts of interest and (vii) business working hours and official holidays.

In the event that the Contractor becomes aware of any violation or potential violation by the Contractor, its partners, subcontractors or any of their employees or agents, of any laws, regulations, WHO policies or other reasonable written directions and procedures, the Contractor shall immediately notify WHO of such violation or potential violation. WHO, in its sole discretion, shall determine the course of action to remedy such violation or prevent such potential violation, in addition to any other remedy available to WHO under the Contract or otherwise.

8.5 Ethical Behaviour

WHO, the Contractor and each of the Contractor’s partners, subcontractors and their employees and agents shall adhere to the highest ethical standards in the performance of the Contract. In this regard, the Contractor shall also ensure that neither Contractor nor its partners, subcontractors, agents or employees will engage in activities involving child labour, trafficking in arms, promotion of tobacco or other unhealthy behaviour, or sexual exploitation.

8.6 Engagement of Third Parties and use of In-house Resources

The Contractor acknowledges that WHO may elect to engage third parties to participate in or oversee certain aspects of the project and that WHO may elect to use its in-house resources for the performance of certain aspects of the project. The Contractor shall at all times cooperate with and ensure that the Contractor and each of its partners, subcontractors and their employees and agents cooperate, in good faith, with such third parties and with any WHO in-house resources.