GLOBAL ACCESS TO HEPATITIS DRUGS AND DIAGNOSTICS
CONSULTATION WITH PHARMACEUTICAL AND DIAGNOSTICS COMPANIES
16 June 2014, Geneva, Switzerland
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### ACRONYMS AND ABBREVIATIONS

<table>
<thead>
<tr>
<th>Acronym</th>
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<tr>
<td>ANRS</td>
<td>Agence Nationale de Recherche sur le SIDA et les Hépatites Virales</td>
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<td>Global Fund</td>
<td>Global Fund to Fight AIDS, Tuberculosis and Malaria</td>
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<tr>
<td>LIC</td>
<td>low-income countries</td>
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<tr>
<td>LMIC</td>
<td>low- and middle-income countries</td>
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<td>MIC</td>
<td>middle-income countries</td>
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<td>MSF</td>
<td>Médecins Sans Frontières</td>
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<td>PCR</td>
<td>polymerase chain reaction</td>
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BACKGROUND

The World Health Organization’s (WHO) Global Hepatitis Programme organized a one-day meeting with pharmaceutical and diagnostics companies that produce or have a significant development pipeline of drugs for hepatitis treatment, or laboratory tests for the diagnosis and monitoring of hepatitis. This meeting was organized as a part of the Programme’s outreach to stakeholders who are active in the area of hepatitis.

The consultation was held on 16 June 2014 in Geneva, Switzerland, and gathered 45 participants from the innovator and generic drug industry, producers of diagnostic tests, professionals from partner organizations, representatives from missions to the United Nations based in Geneva and nongovernmental organizations.

The objectives of the meeting were as follows:

- to present the policy environment in which WHO’s Global Hepatitis Programme is developing;
- to present the WHO 2014 recommendations on the screening, care and treatment of hepatitis C, recent technical developments, and inform participants of anticipated future developments;
- to present options for WHO’s engagement as part of a global strategy to tackle viral hepatitis, including which outputs it will and may produce in the near future;
- to present and discuss options and assumptions on which to base a feasible approach to secure sustainable universal access to the diagnosis, treatment and prevention of viral hepatitis.

This report summarizes the main points discussed after the presentations at the meeting. The report and presentations are available at: http://www.who.int/hiv/topics/hepatitis/en/

OPENING SESSION

Dr Hiroki Nakatani (Assistant Director-General, HIV/AIDS, Tuberculosis, Malaria and Neglected Tropical Diseases, WHO) and Cornelis De Joncheere (Director, Department of Essential Medicines and Health Products, WHO) gave the opening address. They highlighted the increased commitment of WHO to the hepatitis agenda, and reflected on recent institutional changes in the Organization, with the Global Hepatitis Programme joining the Department of HIV/AIDS. This will enable WHO to play a stronger role in hepatitis. They also elaborated on the role of different departments and offices that support the fight against hepatitis.
This session began with a presentation by Gottfried Hirnschall (Director, Department of HIV/AIDS, WHO). It provided the context for the Global Hepatitis Programme. The recent 2014 World Health Assembly resolution WHA67.6 mandates that WHO provide technical support to Member States to develop national hepatitis strategies, improve surveillance, and work with key stakeholders to facilitate equitable access to quality treatment.¹ It urges countries to develop activities for viral hepatitis control along four axes (partnership development and resource mobilization; data, policy and action; prevention of virus transmission; and screening and treatment). It also highlights the fact that the global response to the burden of viral hepatitis is lacking in a number of areas, due to lack of awareness of the magnitude of the problem, good data, funding, and access to prevention and treatment. Dr Hirnschall also gave examples of lessons that could be learned from the global scale up of HIV treatment. These include the strong voice of the community, global movement with multistakeholder engagement, strong government commitment, strategies to promote affordable and equitable access to treatment with simplified guidance, using a public health approach, and achieving major drug price reduction.

DISCUSSION

WHO budget
A representative from Médecins Sans Frontières (MSF) asked whether WHO’s budget for viral hepatitis has now increased. The response was that it had, but not enough.

A representative from Merck and Co. asked what percentage of the hepatitis budget is covered by WHO, and which Member States contribute to it. Dr Hirnschall (WHO) responded that for hepatitis, WHO’s budget is made up of extrabudgetary contributions. WHO has a budget gap for the 2014–2015 budget in many areas and will need to fill these gaps. While most of the work on hepatitis is unfunded currently, WHO hopes to obtain funding from Member States and organizations championing the cause of hepatitis.

World Health Assembly resolution on hepatitis
A representative from Roche inquired whether countries will act on hepatitis, following World Health Assembly resolution WHA67.6. WHO responded that Member States are committed to addressing hepatitis more comprehensively by endorsing resolution WHA 67.6 on hepatitis, which engages countries to take action. However, budgetary and capacity limitations will need to be overcome for this to happen.

Support by the donor community

A question was asked about why funders do not come to the table sooner to provide funding for procuring new hepatitis medications. WHO responded that it would be easier for donors and Member States to engage in improving access to treatment if the cost of medicines became affordable. At present, none of the global health donors, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), include hepatitis in their funding activities.

SESSION 2. EXPANDING ACCESS TO DIAGNOSIS AND TREATMENT OF VIRAL HEPATITIS

This session included two presentations: one on the burden of disease of hepatitis, and the new and future WHO hepatitis guidelines; and one on the WHO prequalification programme for medicines.

1) BURDEN OF HEPATITIS AND WHO HEPATITIS GUIDELINES

Stefan Wiktor (Team Lead, Global Hepatitis Programme, WHO) gave a presentation outlining the prevalence estimates of chronic hepatitis C from the Global Burden of Disease Study 2010.² About 90% of the estimated 184 million people with hepatitis C virus (HCV) infection live in low- and middle-income countries (LMIC). Countries with the largest number of persons with HCV infection are China, India, Egypt, Indonesia and Pakistan, followed by Russia, the USA, Democratic Republic of the Congo, Nigeria and Japan. The presentation also highlighted the need for more data in low-income countries (LIC) and health system requirements for scaling up HCV treatment (diagnosis, assessment of level of fibrosis, quality and affordable medicines, trained healthcare workers). Finally, a summary of the HCV treatment guidelines was presented.

The HCV guidelines and forthcoming HBV guidelines answer the following questions:

- Who should be tested and with which assays?
- How can we slow progression of the disease and protect those infected and others?
- What medicines to use and whom to treat?
- How to monitor?

As the field of treatment of hepatitis is changing rapidly, key hepatitis guidelines will be revised and will be combined in a set of consolidated guidelines in 2015.

2) **WHO PREQUALIFICATION PROGRAMME FOR MEDICINES AND HEPATITIS**

Wondiyfraw Worku (Assessor, Essential Medicines and Health Products Department, WHO) spoke on prequalification requirements and anti-hepatitis C medicines. The presentation sought to inform participants about the prequalification programme for medicines, vaccines and diagnostics. Funded by UNITAID and the Gates Foundation, prequalification is limited to priority medicines, as published in invitations for Expressions of Interest. Current therapeutic areas include HIV/AIDS, malaria, tuberculosis, reproductive health, influenza, acute diarrhoea in children and neglected tropical diseases. The two main routes to prequalification are the full dossier route and the stringent regulatory authority route. Currently, no HCV drugs are invited for prequalification, but this will change in the near future as a follow up to the release of the new WHO HCV treatment guidelines in April 2014.³

**DISCUSSION**

**WHO guidelines**

A representative from Daktari Diagnostics inquired whether there were guidelines on genotype diagnostics. WHO responded that the current treatments are genotype specific; thus, it is important that genotyping be done. Detailed recommendations on the use of genotyping will be included in the forthcoming guidelines on the diagnosis of hepatitis. However, it is hoped that the introduction of direct-acting antiviral agents with pan-genotypic efficacy will in the future obviate the need for genotyping.

**Support by donor communities**

A representative from MSF asked whether any donors have been identified for funding in the area of HCV, in order to expand prequalification. WHO responded that UNITAID has given the programme some funding to begin work but there is no long-term donor.

**WHO budget**

A representative from Roche asked whether it would help the prequalification programme if the pharmaceutical industry had to pay fees. WHO replied that the prequalification programme had not charged any fees for more than 10 years but now there was a need to begin charging fees in order to bridge gaps between projects. The programme began charging fees on an experimental basis in September 2013. A fee is charged when the dossier is accepted for assessment. First-time applications are not charged and the fees gradually increase with repeat applications. For subsequent products, fees are charged according to a fee structure (maximum $8000 per application). The system favours new products. However, as the fees do not cover the cost of the prequalification programme, the programme still needs additional funding.

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SESSION 3. HOW BIG IS THE POTENTIAL MARKET FOR HCV TREATMENTS?

In this session, there were two presentations: global forecasts for hepatitis C medicines, and the role of UNITAID in hepatitis.

1) GLOBAL FORECASTS FOR HEPATITIS C MEDICINES

Jean Paul Moatti (Université d’Aix-Marseille, Agence Nationale de Recherche sur le SIDA et les Hépatites Virales [ANRS], France) presented forecasts of the demand for hepatitis C medicines in LMIC for 2014–2023. The model showed that markets in LIC would remain relatively small in size unless current prices are dramatically reduced and demand boosted by subsidy/third party coverage. In lower-middle-income countries and upper-middle-income countries, the markets would largely increase as tiered pricing strategies are implemented. Current WHO guidelines recommend the prioritization of treatment for persons with advanced fibrosis (stages F3 and F4). However, with improved access to safer and more convenient drug regimens, this recommendation could one day be changed to include all stages of fibrosis (F0 to F4). Thus, increasing treatment eligibility from advanced stages of fibrosis (F3 and F4) to include the early stages (F0 to F4) would greatly increase demand. A more rapid fall in the global price of HCV medicines (through the introduction of generics) would greatly increase their uptake and have a significant impact on the epidemic. A number of practical limitations of the model were acknowledged. These included the absence of both reinfection and coinfection, the use of constant incidence rates as well as the categorization of infected individuals based on their stage of fibrosis (F0 to F4).

DISCUSSION

Data estimation

A representative from Institut Pasteur, France asked how the size of the F3 and F4 populations is estimated, as this is difficult to assess, and observed that treatment will probably expand to beyond the F3 and F4 stages. ANRS responded that the size of the F3 and F4 populations is extrapolated from published data, and emphasized the need for more reliable data to reduce the uncertainties in the present model.

Barriers to demand

Participants asked what barriers, other than price, exist to creating a sufficient demand for medicines. ANRS responded that other barriers, such as the likelihood that a patient will be diagnosed and that treatment will be offered, were taken into account in the model and could be modified by changing the relevant assumptions. It would be useful if more data on the uptake of the new treatments were generated.
Country situation
A representative from the Indonesian Mission stated that the magnitude of HCV is huge (28 million people are infected in Indonesia). Universal health coverage was launched in Indonesia in January this year. There is a strong push from many stakeholders to put new essential medicines onto the list of medicines that will be covered under the universal health coverage scheme. Lower prices for medications are a must and this can only be achieved through partnership with WHO and the private sector. ANRS responded that these comments confirm that the real issue is whether HCV treatment can be included in universal health coverage. Donors can play a role but it is important for national governments to take the lead.

Middle-income countries
A representative from MSF asked whether another assumption could be looked at for middle-income countries (MIC), as little is known about this group of countries. In order to give the model a stronger footing in reality, a benchmark case is needed. At present, there is no real-life experience with the roll-out of HCV treatment in low- and middle-income settings. Therefore, the assumptions were similar between models. Different variations between models can be added after creation of a benchmark case. ANRS replied that the current model included a benchmark case based on the present situation in the developing world, which was then modified to study different scenarios. Sensitivity analyses were carried out to check the robustness of the results.

2) UNITAID AND HEPATITIS C
Philippe Duneton (Deputy Executive Director, UNITAID) spoke about the role of UNITAID in hepatitis C. The presentation highlighted the “push and pull” theory, and the need to address barriers to access and patents on medications. Currently, HCV is not on the list of interventions by major donors. Donor governments are pressured by national budgetary restrictions. Thus, there is a need for generating evidence and clear plans to make progress in mobilizing the international community. LIC could be financially supported while MIC would be able to contribute 50% of the cost of treatment. HCV differs from HIV and these differences should be addressed when developing a model for HCV. There is also a need to focus on HCV in the context of coinfection with HIV.

DISCUSSION

Treatment for HBV monoinfection
A representative from Gilead stated that there are large inequalities in treatment in Africa and LIC with regard to HBV monoinfection. UNITAID stated that the price for an HBV drug is twice that of a drug to treat HIV. A representative from MSF stressed the importance of the HBV birth dose vaccine.

Access to diagnostics and treatment in LIC
It was mentioned that the Global Fund could leverage work done in HIV to address coinfection but currently it does not fund HCV activities, with the exception of one or two country grants. If innovative solutions are created for MIC, then the Global Fund can be approached to provide help to LIC where HCV is not as prevalent.
SESSION 4. MANAGING INTELLECTUAL PROPERTY

INNOVATION, ACCESS AND INTELLECTUAL PROPERTY RIGHTS

Peter Beyer (Senior Advisor, Public Health, Innovation and Intellectual Property, WHO) spoke about access to the new hepatitis treatments and intellectual property. He presented the role of intellectual property in innovation and the impact of the patent situation on treatment cost, highlighting the example of sofosbuvir. He drew parallels to the situation with respect to HIV treatment, where many antiretroviral drugs are still under patent, and described the different measures and actions that have contributed to increasing access to these antiretroviral drugs. He pointed out the different measures taken by WHO, including expanding the Global Price Reporting Mechanism\(^4\) to include hepatitis C treatments, as well as the work undertaken on patent landscapes. He described the approach taken by WHO with respect to requests for assistance received from various WHO Member States, including Egypt. Based on resolution WHA67.6, the Secretariat provides advice to Member States on how to access new treatments at affordable prices, taking into account all possible options, including local production if there are no patents and, if patents are granted, price negotiations, voluntary license agreements and the possible use of flexibilities in the World Trade Organization (WTO)’s Trade-Related Aspects of Intellectual Property Rights (TRIPS). In this context, there is no one-size-fits-all solution. WHO tries to help the respective ministries of health to identify the best possible solution for their country.


SESSION 5. ACCESS TO DIAGNOSTIC AND MONITORING TESTS

In this session, two presentations covered the WHO prequalification programme for diagnostics, and perspectives on the future use of diagnostics for hepatitis.

1) ACCESS TO QUALITY-ASSURED DIAGNOSTICS THROUGH WHO PREQUALIFICATION AND PROCUREMENT MECHANISMS

Robyn Meurant (Technical Officer, WHO Prequalification of In Vitro Diagnostics Assessment Group, Essential Medicines and Health Products Department, WHO) gave a presentation on access to quality-assured diagnostics through WHO prequalification and procurement mechanisms. The programme focuses on priority diseases due to limited funding.
The process of prequalification is as follows:

- Manufacturer applies any time.
- WHO examines the prioritization criteria and, if accepted, ask for a dossier.
- If the dossier is deemed incomplete after a screening process, prequalification does not proceed, and the manufacturer is advised.
- If the dossier is complete, WHO proceeds to review the dossier, undertakes laboratory evaluation to verify performance claims and conducts an inspection of the site of manufacture to assess the effectiveness of the manufacturer’s quality management system.
- The role of WHO is broader than that of a regulator responsible for the product in a specific jurisdiction, as WHO assesses safety and performance for all jurisdictions, especially resource-poor settings.

DISCUSSION

Priority areas
WHO was asked what its priority areas are in diagnostics for hepatitis C. WHO responded that it looks at antibody tests and viral load. There are not many applications for prequalification, so there are opportunities for companies to apply. WHO can meet with companies individually to discuss applications. UNITAID added that it funds the diagnostics prequalification programme and supports WHO to be proactive regarding new technology. UNITAID projections will give an indication of what is needed for diagnostics to be procured by WHO.

2) PERSPECTIVES ON REQUIREMENTS FOR LABORATORY TESTS FOR HCV THERAPY

Isabelle Andrieux-Meyer (MSF) gave a presentation on the necessity for reliable laboratory tests for HCV screening. WHO needs to work on the prequalification of devices used for screening. Currently, only 11% of at-risk populations in LIC have access to screening. The prices and reliability of tests are fundamental issues. There is a need for affordable polymerase chain reaction (PCR) and confirmatory tests that are quick to perform and apply to all genotypes. Scaling up testing and reducing the price of tests needs to be considered. In addition, there is currently reluctance in mobilizing funding mechanisms for the treatment of hepatitis, unless patients are coinfected with HIV. Awareness of HBV also needs to increase.

DISCUSSION

New diagnostic tools
A representative from Daktari Diagnostics stated that in the next few years, there will be products that can assess genotype and viral load in one test procedure for HCV but for HBV it will take longer.
According to him, some mistakes made in the scale up of HIV testing should be avoided in the scale up of treatment for hepatitis:

- Quality assurance was neglected (this needs addressing with HCV).
- Molecular testing for HIV viral load needed scaling up, but this did not happen in LIC at all, and only to a limited extent in MIC.
- Insufficient funding was earmarked for diagnostics in HIV: there was a $20 per year budget for laboratory testing in most settings. With HCV, we need to be well aware of the cost of diagnostics and discuss it further.

**Price of HCV screening**

A representative from MSF stated that in Ukraine, a full package of HCV screening, diagnostic confirmation, genotyping, liver function assessment and treatment monitoring costs $200, which is the best price today. This is still very expensive. A representative of ANRS stated that for a full analysis to be conducted of screening and treatment costs, a form of standardization of the different diagnostic pathways and their costing is needed. A representative from MSF stated that from the clinical point of view, simplicity is desirable. WHO stated that with the advent of treatment that is effective across genotypes, the diagnostic pathways might be simplified in the future, which would make them less expensive.

**Drug resistance**

A participant asked whether assessing drug resistance would be part of the assessment of response to treatment. MSF responded that there is an assumption that patients will be treatment naive in most instances, so resistance will not be an issue. Resistance is more of an issue with HBV, due to increased exposure to antivirals in resource-poor settings. A representative from Gilead reiterated that HBV has more issues around resistance and that the resistance profile for new drugs for HCV is robust.

**CLOSING REMARKS**

Stefan Wiktor (Team Lead, Global Hepatitis Programme, WHO) thanked everyone for their participation, and for committing to keep open lines of communication with technical partners and companies developing and producing medicines and diagnostics for hepatitis.
# ANNEX 1: AGENDA

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<tr>
<th>Time</th>
<th>Session</th>
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<tr>
<td>9:00</td>
<td>Registration</td>
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<td>All participants</td>
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<tr>
<td>9:45</td>
<td><strong>Opening</strong></td>
<td>Hiroki Nakatani, Assistant Director-General, HTM Kees De Joncheere, Director, EMP Department</td>
<td>All participants</td>
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<tr>
<td></td>
<td>Welcome</td>
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<td></td>
<td>Introductions</td>
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<tr>
<td>10:15</td>
<td>Enhanced engagement for global hepatitis prevention and treatment Q &amp; A</td>
<td>Gottfried Hirnschall, Director, HIV Department</td>
<td>All participants</td>
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<td><strong>Expanding access to diagnosis and treatment of viral hepatitis</strong></td>
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<td>10:45</td>
<td>WHO hepatitis treatment guidelines Q &amp; A</td>
<td>Stefan Wiktor, Team Lead, Global Hepatitis Programme</td>
<td>All participants</td>
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<tr>
<td>11:15</td>
<td>Coffee break</td>
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<td>11:30</td>
<td>Prequalification requirements and anti-hepatitis C medicines Q &amp; A</td>
<td>Wondiyfraw Worku WHO Essential Medicines and Health Products Department</td>
<td>All participants</td>
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<td><strong>How big is the potential market for HCV treatments?</strong></td>
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<td>12:00</td>
<td>Global forecasts for hepatitis C medicines</td>
<td>Jean Paul Moatti Agence Nationale de Recherche sur le SIDA et les Hépatites virales</td>
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<td>13:00</td>
<td>Lunch</td>
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<td>14:00</td>
<td>UNITAID and hepatitis C</td>
<td>Philippe Duneton, Acting Executive Secretary, UNITAID</td>
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<td>14:30</td>
<td><strong>Managing intellectual property</strong></td>
<td>Peter Beyer Public Health, Innovation and Intellectual Property Unit, WHO/EMP</td>
<td>All participants</td>
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<td>Innovation, access and intellectual property rights Q &amp; A</td>
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<td>15:00</td>
<td><strong>Access to diagnostic and monitoring tests</strong></td>
<td>Robyn Meurant WHO Essential Medicines and Health Products Department</td>
<td>All participants</td>
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<td></td>
<td>Access to quality-assured diagnostics through WHO prequalification and procurement mechanisms Q &amp; A</td>
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<td>15:30</td>
<td>Coffee break</td>
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<tr>
<td>16:00</td>
<td>Perspectives on requirements for laboratory tests for HCV therapy Q &amp; A</td>
<td>Isabelle Andrieux-Meyer Médecins Sans Frontières</td>
<td>All participants</td>
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<tr>
<td>16:30</td>
<td>Closing</td>
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</table>
ANNEX 2: LIST OF PARTICIPANTS

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