**Executive Board, 138th Session, 2016**
**Agenda Item 9. 2**
**Draft Global Health sector strategy - Viral Hepatitis**

## Background

Médecins Sans Frontières (MSF) is witnessing first-hand the lack of access to reliable diagnostics and affordable medicines for people living with viral hepatitis, especially hepatitis B and C, in several low and middle income developing countries. In particular, MSF is currently implementing viral hepatitis C treatment programs for people co-infected with HIV in India, Myanmar, Iran, Uganda, Kenya and Mozambique, and treating people mono-infected with the hepatitis C virus (HCV) in Pakistan.

There is a striking absence of reliable epidemiological data, an absence or very recent initiation of national programs, lack of trained national staff and insufficient civil society mobilization. Above all else, people are unaware of their virological status and only diagnosed at very advanced stage of liver disease. Furthermore, in countries which are neither a commercial priority for the multinational pharmaceutical industry, or have not been selected by companies as a 'priority access country', it is currently impossible to procure Hepatitis C direct–acting-anti-virals (DAAs) such as sofosbuvir and daclatasvir, in particular because these medicines are not registered in the countries or because Drug Regulatory Authorities are not prioritising new DAAs and adopting accelerated approval processes. For chronic hepatitis B infection– entecavir and tenofovir (TDF) are in generic production but have multiple patents covering them in many jurisdictions. TDF access for HIV treatment is not replicated for HBV patients in public health systems of developing countries.

MSF observes emerging needs of HCV/HBV diagnosis and treatments among vulnerable populations, like prisoners in Ukraine, Syrian refugees who inject drugs in Lebanon, people co-infected with multidrug resistant tuberculosis in Eastern Europe, or even epidemics among the population based on injecting drug abuse or iatrogenic infections in Cambodia or Myanmar.

Pregnant women living with chronic HBV infection, who are at high risk of transmitting infection to their child at birth, as well as all children, adolescents, or health care workers, who have not been properly vaccinated against hepatitis B, are left behind. We also observe very low coverage of HBV birth dose immunization in African settings, and the lack of appropriate management for people living with HBV chronic infection, especially children and adolescents and young adults.

Hepatitis A and E infections remain concerns in the vast majority of places where people live in precarious conditions, especially persons displaced or living in refugee camps, if water and sanitation conditions are insufficient.

## Feedback on WHO draft Global Health sector strategies-Viral Hepatitis.

MSF welcomes the WHO Global Health sector strategy on viral hepatitis, 2016-2021. The feedback on the Viral Hepatitis strategy is arranged according to the five core components, around which MSF would like to offer its feedback.

**Strategic component 1: Towards eliminating viral hepatitis**:

MSF supports this ambitious goal of viral hepatitis elimination within the next 15 years. While there are medical tools and public health evidence to achieve this goal, MSF remains concerned about the political will, lack of funding and the level of prioritization dedicated to viral hepatitis in several low and middle income developing countries which face competing health priorities. In addition, opportunities to address viral hepatitis with the experience and infrastructure of national HIV programmes are being ignored.

MSF notes that there are unprecedented opportunities to act: there is a vaccine for hepatitis A, B, and E; a HBV birth dose immunization to prevent mother to child transmission, interventions to provide safe injections, blood transfusions and surgical procedures, control of hepatitis B virus replication, and a cure for hepatitis C.

But the elimination of viral hepatitis as a major public health threat by 2030 will only happen if fundamental political decisions are taken and implemented: pro-active actions against prohibitive prices for life-saving new drugs, promotion of generic competition through the use of all TRIPS flexibilities, ensuring rigorous examination of all patent applications to ensure no secondary patent claims on derivatives or fixed dose combinations are granted, the establishment of compassionate use programs for early access, reducing the time lag for the registration of new drugs in developing countries, the rejection of unethical anti-diversion policies, universal access to low cost quality generics, and a price structure for a viral hepatitis package of care and treatment at national level adapted to what people can afford to pay.

**Strategic component 2: Framing the strategy:**

MSF supports the design of this strategy to contribute to the attainment of the 2030 Agenda for Sustainable Development, and specifically to the health-related goal 3, target 3.3.

**Strategic component 3: Global vision, goal, and targets**:

MSF supports the vision of a world where viral hepatitis transmission is halted and everyone living with hepatitis has access to safe, affordable and effective care and treatment. MSF supports the goal of viral hepatitis elimination as a public health threat by 2030, and the set of targets for 2020-2030. The targets are ambitious but correspond to needs.

**Strategic component 4: strategic directions and priority actions:**

Good data is crucial to understand viral hepatitis epidemics at the national level and to design and monitor proper interventions, including cost-effectiveness.

MSF supports the five core viral hepatitis interventions proposed to maximise impact: vaccination, particularly for hepatitis B virus; injection, blood and surgical safety and universal precautions; prevention of mother to child transmission of hepatitis B virus; harm reduction services for people who inject drugs; treatment of chronic hepatitis B virus and hepatitis C infection, and access to high levels of sanitation, safe food and water.

We encourage countries to improve and promote access to all hepatitis vaccines. It is particularly important to improve the actual 38% coverage of HBV birth dose immunization. Vaccines must be quality-assured, fit to resource constrained areas, including by improving their labelling for extended thermostability and use in the controlled temperature chain and through their packaging in as small a volume as possible.

Access to care and harm reduction services for the most vulnerable groups, including people using drugs, men who have sex with men or commercial sex workers, who are often marginalised, discriminated and excluded from the health systems, is essential.

Less than 5% of persons living with chronic viral hepatitis know their status. Development and rapid access to affordable, WHO-quality assured, reliable, rapid diagnostic tests for viral hepatitis B and C is crucial for a massive and decentralised scaling-up of voluntary viral hepatitis testing programmes.

The integration of simple viral hepatitis packages of services at all possible levels of the health care system will facilitate implementation; in particular of chronic care and treatment services, antenatal and perinatal care structures, in HIV and tuberculosis consultations, and even primary health care services.

Less than 1% of people with chronic viral hepatitis are receiving treatment. To accelerate access to treatment for all, policy makers must prioritize the development and early access to quality generic medicines. In HCV, access to quality-assured generic oral HCV direct-acting agents for simple, highly effective, affordable pan-genotypic treatment regimens is essential. Two molecules already represent great hope for resource-limited settings: sofosbuvir and daclatasvir, which can be used with ribavirin if needed. For chronic hepatitis B infection, access to quality assured affordable sources of generic tenofovir, as well as entecavir, will be urgently needed. We need a cure for HBV chronic infection.

We encourage countries to plan and implement a national hepatitis medicine and commodities access strategy to reduce prices of hepatitis-related tools and treatment, in particular, where needed, through promotion of competition and the application of TRIPS flexibilities in overcoming intellectual property barriers to such access. We also advocate for improved terms and conditions of voluntary licenses negotiated by the Medicines Patent Pool with pharmaceutical companies to ensure the maximum inclusion of all hepatitis patients in need in developing countries. Furthermore, efforts to improve access to quality-assured generics can be accelerated via the WHO prequalification program, and technical support for accelerated registration process of generics at the national level.

The time lag for manufacturers to submit drug dossiers for registration in ‘non-priority countries’ remains a significant concern. Denial of requests for compassionate use (name patient access) from treatment providers and patients with advanced liver disease by originator companies is a matter of real concern in countries where antivirals are yet to be registered. If an originator pharmaceutical company does not want to submit for registration, then access is denied unless the Drug Regulatory Authority and Ministry of Health encourage generic companies to apply for registration and create an accelerated and time efficient regulatory pathway for manufacturers. In several low and middle income countries, there has been no filing for registration for sofosbuvir and daclatasvir, and in many countries, tenofovir and/or entecavir are not registered for its hepatitis B indication. Barriers to effective treatment can be expected for people living in these countries. To avoid even longer delays, countries should implement a fast-track and also collaborative registration process, approving more WHO or stringent regulatory approved products.

**Strategic component 5: Implementation**

The Global Fund, GAVI, PEPFAR and other major donors or development agencies should contribute towards the implementation of the Global Health Sector Strategy on Viral Hepatitis.

**MSF recommendations:**

- MSF supports the draft Global Health Sector Strategy on Viral Hepatitis. The Executive Board should make a recommendation for its endorsement by the Sixty-ninth World Health Assembly.

- We urge WHO and Member States to commit and provide resources to implement the global health sector strategy on viral hepatitis.

- The Global Fund, GAVI, PEPFAR, and other major donors or development agencies should contribute towards the implementation of the Global Health Sector Strategy on Viral Hepatitis, following the adoption of the 2030 Agenda for Sustainable Development, and this aspirational target 3.3: "By 2030, end of the epidemics of AIDS, tuberculosis, malaria and neglected tropical disease and combat hepatitis, water-borne diseases and other communicable diseases".

- The elimination of viral hepatitis as a major public health threat by 2030 will only happen if fundamental political decisions are taken and implemented: pro-active action against prohibitive prices for life-saving new drugs, promotion of the generic competition through the use of TRIPS flexibilities to ensure that patent monopolies do not restrict treatment to only those who can afford to pay, reduction of the regulatory time lag for the registration of new drugs in low and middle income countries, the refusal of any unethical anti-diversion policies, universal access to low cost quality generics, and a public health programme for a viral hepatitis package of care and treatment at national level adapted to resource poor settings.