2nd Global Health Forum of the Boao Forum for Asia, Qingdao, China

HCV Gaps Overview, R&D and Access: Meeting the innovation needs of neglected populations through a public health oriented, alternative research and development model.

Dear Dr Chen Zhongdan, Chair for this Hepatitis C forum; fellow panelists Tan Sri Dr Noor Hisham, Dr SunJing, Dr Jinzi, Mrs ZhenYan & Mickael Le Paih; Organisers, dear collegues, ladies, and gentlemen,

Greetings from Geneva.

I am delighted to be with you today, albeit virtually, at the Boao for Asia 2nd Global Health Forum. I am grateful for the organisers for giving me the opportunity to speak about a disease which is of tremendous importance for DND*i*, and also represents a powerful symbol for me in the fight for access to treatment for all.

Ladies and gentlemen, Hepatitis C is a **silent killer,** but DNDi's vision is one of hope. Indeed, HCV is a disease with a cure, a disease which WHO and member countries have committed to eliminate by 2030. Today during the session: "Towards Elimination of Hepatitis C in Asia: Moving from Unaffordable Treatments to Accessible Solutions" we will hear examples of countries or initiatives that can make this commitment a reality.

I would like to call countries, especially China, to join the examples of Egypt, Malaysia or Cambodia in displaying leadership both at home and abroad to work towards the Hepatitis C elimination goal.

Elimination is possible but we need more leadership, and that leadership should come from you!

Dear colleagues, eliminating Hepatitis C Virus has been a long ongoing battle. Most of the population living with HCV do not realise they are carriers to the virus. This contributes to the consistent increase in the number of yearly deaths caused by HCV, reaching **300,000 yearly deaths in 2019 with 58 million people infected by HCV**. Despite its vicious spread worldwide, it remains a silent global epidemic that is aggressively affecting the most vulnerable and marginalized groups in the global south, with **4 persons out of 5** unaware of their HCV status and with **ONLY 10% of people** with HCV having access to treatment.

The good news is that now an **effective cure** for HCV.

Before the arrival of the Direct Acting Antivirals (the so-called DAAs) - the revolutionary safe and simple treatment for HCV - patients living with HCV have had to go through hell with extremely painful and long treatment processes with equally burdening side effects. Literature showed that often, the side effects of

treatment impaired the patient's quality of life, with only 50% chance of being cured. This led to patients under treatment asking the inevitable question of whether those slim chances were worth going through drastic treatment regimen or not.

Then came the DAAs, the first of revolutionary treatments that are safe, simple and without side effects. Moreover, they are highly effective, with **90-100% cure rate**. This meant that the global health scene can think about the possibility for elimination of the disease. For patients and doctors alike, this is a unique and fantastic opportunity that few other diseases can even envision.

For the first time in history, the disease can be cured... Hepatitis C remains a major global health concern, but the opportunity now exists to eliminate the disease.

- The Nobel Prize in Physiology or Medicine 2020 (Press release of the Nobel Assembly at Karolinska Institute (Harvey J. Alter, Michael Houghton and Charles M. Rice): https://www.nobelprize.org/uploads/2020/10/press-medicine2020.pdf)

On top of the commitment towards elimination, we have a global strategy with the WHO Global Health Sector Strategy on Viral Hepatitis 2016-2021.

With all these positive news, we might believe that everything is in place for a successful global campaign to eliminate Hepatitis C - but with less than 10 years to go for countries to meet the WHO Hepatitis C elimination target, there is still a huge lack of international leadership. The global health infrastructure is not yet organized, not as it is for other diseases such as HIV and Malaria.

We will hear from Dr Hisham, the Director General of the Ministry of Health of Malaysia, my dear friend, on how they have managed to implement free diagnostic testing and free treatment for **ALL** Malaysians. The example of Cambodia by Mickael of MSF on simplification and decentralization, and from other countries like Egypt, show that it is possible to implement national strategies of elimination.

There are still many gaps of course. **DAAs are still too expensive in many countries, like China, and there are barriers to access to affordable treatment** as Zhenyan will develop in her presentation. These barriers can be overcome with smart strategies that encourage market competition, but they require strong leadership at a national level as well as partnership and collaboration at the international level as access to drugs, or vaccines, remain a complex multidisciplinary issue. Many legal and administrative barriers continue to exist.

The **financing of these national hepatitis strategies remains a challenge too**. But again, I am optimistic on this issue. With an investment case model that integrates the total programmatic cost for HCV

elimination, we can close the gap and demonstrate the clinical and economic **benefits** of investing in HCV elimination. We can identify appropriate financing mechanisms which can help resource nationallevel gaps rather than solely relying for international donors to step in. For example, Dr Sunjing will give us a hindsight of how a country like China can include HCV treatment in its national health insurance system.

We must acknowledge that investments are also needed for diagnostics. Even if rapid tests are affordable today, confirmation tests remain expensive.

That brings me to my next point, if we want to confront the medical needs of today and tomorrow, **we need alternative models & south-south collaboration**. So, I would like to take the example of DND*i* and HCV to elaborate this point.

DND*i* is a non for profit, partnership model. We work with governments, NGOS, Universities, and the private sector to deliver affordable treatment for neglected patients.

In 2015, DND*i* decided to work on HCV as we realized that the cost of these amazing new treatments would remain too high, especially for middle income countries. A coalition of DND*i*, Thai & Malaysian MOH, MSF, industrial partners like Pharmaniaga & Pharco, and collaborators around the world developed a new DAA – ravidasvir, in combination with Sofosbuvir. Ravidasvir is also available through the Chinese company Ascletis and Dr Jinzi will tell us how local production can be at the center of the national response.

DND*i* conducted the STORM-C-1 open label trial to assess the efficacy, safety, tolerance, and pharmacokinetics of ravidasvir combined with sofosbuvir. Cure rates were very high even for the hardest-to-treat patients. Importantly, patients combining several risk factors were cured, and no unexpected safety signals were detected. The results indicate that the sofosbuvir/ravidasvir combination is comparable to the very best hepatitis C therapies available today, but it is priced affordably and provides an alternative option in countries excluded from pharmaceutical company access programs. With effective pan genetypic DAA, treatment and screening of HCV can be very simple and easily implemented at primary care level.

This story demonstrates that alternative model & collaboration can deliver affordable and effective treatment for the world.

To conclude, the elements of successful elimination strategies of Hepatitis C are in sight, but strong leadership is needed:

- To change old habits and decentralize and simplify treatment at primary health care level,
- To find and screen patients
- To bring the price of DAAs and diagnostics to an affordable level for national health financing mechanism
- To find new mechanisms for financing HCV elimination in low-income countries

South to South collaboration can deliver this paradigm change as it has been demonstrated in Malaysia and Egypt. As a non-for-profit collaborative organization we are keen to establish a coalition of likeminded organizations, industries and countries that together can work towards the elimination of HCV.

I believe that HCV is a real opportunity for China to take the lead, first by implementing a strong elimination strategy at home but also by taking the lead internationally, together with partners such as DND*i* to further develop the tools of access for low-income countries.

We look forward to continuing this collaboration.