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## Séminaire n°2: "Should we question our current model for encouraging innovation in the pharmaceutical sector?" du 16 mars 2022

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## L'accès aux médicaments

### Cycle de conférences sur l'accès aux médicaments, Séminaire n° 2 : « Should we question our current model for encouraging innovation in the pharmaceutical sector? » du 16 mars 2022

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#### Marie-Paule Kieny

Director of Research at Inserm, Chair of the Board of Drugs for Neglected Diseases Initiative (DNDi), Chair of the Governance Board of Medicines Patent Pool Foundation (MPPF)

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My aim today is to present two remarkable initiatives that have shown that it is possible to change the dominant R&D paradigm; to innovate differently; to ensure access to innovative medicines for resource-limited countries; and all this in order to reduce inequity in access to healthcare worldwide. These are not generic solutions, but rather examples of progress that can be made and of elements that can be considered when we want to build a more comprehensive system that would cater more effectively to the needs of many.

Let me first talk about DNDI. DNDI is the “Drug for Neglected Diseases initiative”. DNDI was created in response to a frustration of physicians who didn't have effective drugs to cater for diseases of the poorest of the world, as well as in response to the desperation of patients faced with medicines that were ineffective, unsafe, unavailable, unaffordable or all of that. This was especially the case for what was called drugs for neglected tropical diseases and that we now call drugs which are needed for neglected populations. Only 1.1 % of the new drugs developed between 1975 and 2000 were for neglected diseases, while those diseases represent 12 % of the global disease burden. More than 1 in 5 people worldwide are affected by diseases you may never have heard of. So, this desperation, and the funding by MSF, who has received - by that time - a Nobel Prize, allow the set-up of DNDI as a foundation under Swiss law located in Geneva.

There are three pillars to our mission. First, it is to innovate, to save lives, to discover and develop urgently needed treatment for neglected patients. The second is to foster inclusive and sustainable solutions. Finally, it is to advocate for change. We want not only to provide an example of what can be done, we want more changes to take place in a more systemic way in order to change the paradigm and to have the right drugs developed for people who need them.

We create value for partnerships, working with and through academic and public health research institutes, identifying the needs, setting priorities, and supporting execution of discovery science.

In parallel, we work with partners who focus on diagnosis – such as FIND, another Geneva based product development partnership – because we increasingly understand the need to go for “test and treat” strategies. We also partner for access because once a drug is developed, we need partners who are able to deliver this drug, and partners who are able to pay for it. Moreover, we partner with local scientists through disease-specific networks in low and middle-income countries. Last but not least, we also partner with major pharmaceutical companies in high-income countries and more recently in middle-income countries, because DNDI, as a virtual organization, needs to partner with industry to actually produce these drugs.

So far, we have developed 9 new treatments in order to save millions of lives of patients affected with deadly diseases.

## 9 NEW TREATMENTS DEVELOPED FOR 6 DEADLY DISEASES, SAVING MILLIONS OF LIVES

EASY-TO-USE ▶ AFFORDABLE ▶ FIELD-ADAPTED ▶ NON-PATENTED



The two first were for malaria: ASAQ and ASMQ. In 2009 we developed a treatment for sleeping sickness, but this was quite an intensive treatment, which led us more recently to develop a very innovative drug called Fexinidazole, which is a complete change of paradigm for the treatment of sleeping sickness.. We also developed a treatment for visceral leishmaniasis and one for Chagas disease, as well as a superbooster therapy for HIV in children; especially for children who also suffer from tuberculosis. Our latest drug is Ravidasvir, which is part of a novel easy-to-use treatment for Hepatitis C.

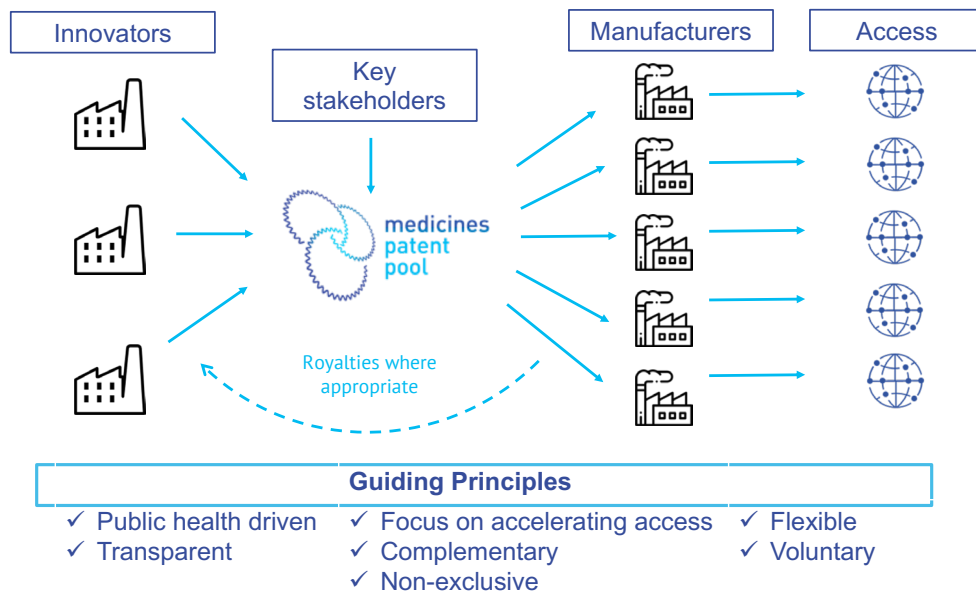
We advocate for change and we want to promote public responsibility and advocate for a change in public policies. Indeed, we believe that the public sector should take the lead of a partnership with the private sector to ensure that the right drugs are developed and made available to those who need them at an affordable price. We want to enable a global biomedical R&D system, which is needs-driven, open and transparent. We want the system to be inclusive, equitable, sustainable, and to be both collaborative and coordinated. And only with this can we ensure that innovation is reaching those who need it and that access is equitable for all.

I also wanted to introduce you to Medicines Patent Pool (MPP). Like DNDi, MPP is a Foundation under Swiss law, located in Geneva. Its aim is to increase access to health technologies (developed by large pharmaceutical firms) in low and middle-income countries. MPP is a public health organization which was established in 2010 by UNITAID in order to accelerate access to new HIV medicines in low and middle-income countries, and to facilitate the development of new formulations needed in these countries. It operates through voluntary licenses to facilitate early entry of generic manufacturers in low and middle-income countries. The affordability of these medicines is ensured by the fact that there is competition between generic manufacturers. We have extended the work of MPP from HIV to also include hepatitis C, tuberculosis, essential drugs for non-transmissible diseases and covid-19.

How does it work? Innovators, mainly from the big pharma, take advantage of innovation or discovery coming from academics or small biotechs in order to bring these medicines to the market.



## Public Health Licensing via MPP



MPP negotiates a license to the needed intellectual property acquired by innovators and sub-licenses these licenses to generic manufacturers in low and middle-income countries mainly. These can then produce these new drugs and introduce them on the markets corresponding to the original license. At there will be competition between the generic manufacturers, affordable prices will facilitate access in these countries. We do, indeed, have a possibility to offer royalties to innovators, when appropriate, but it has never been the case for HIV for example.

Our guiding principles are as follows.:

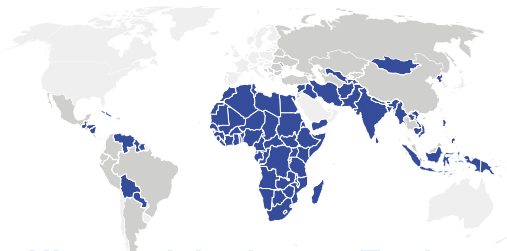
- We are public health driven, all our licenses are transparent, they are available to review on the MPP website.
- We focus on accelerating access. Our action is complementary to other access programs.
- Our license is always non-exclusive, and we work in a flexible manner, through a voluntary licensing process.

I will now give you some examples of what we have recently done on COVID-19. We have licensed two main active antivirals: Molnupiravir from Merck, and Nirmatrelvir from Pfizer.

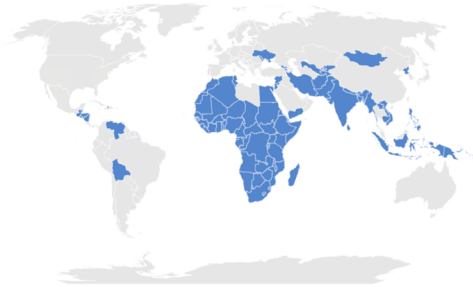


## Molnupiravir Licence Territory

- Licences allow MPP to grant sub-licences
- Include confidential know-how
- Royalty-free during the WHO PHEIC
- Licensees can supply 105 or 95 countries respectively (approx. 4.1 billion people covered)
- Supply possible outside the territory if no patent infringement, including when a country issues a compulsory licence
- Require approval by WHO PQ or emergency use authorization
- Licences are fully transparent, available on MPP website



## Nirmatrelvir Licence Territory



Both licenses do not cover the whole world, but these were the only territories that we could license so far. Importantly, there is a possibility to supply outside the territory if there is no patent infringement, and we will seek to extend these territories in the future.

Our COVID-19-related include confidential know-how, and are royalty-free as long as COVID-19 is a WHO Public health emergency of international concern (PHEIC). We request the generic manufacturer to go for WHO prequalification or emergency use authorization. These licenses can supply 105 or 95 countries respectively, which covers slightly above 4 billion people so, we can argue that this is certainly worthwhile.

As regards diagnosis, we have also negotiated a license on an invention that was made by CSIC, a public organization in Spain. We obtained this license through the WHO C-TAP. This license allows us to grant sub-licenses to manufacturers anywhere in the world. The license is royalty-free for low and middle-income countries and entails only 15 % royalties for high-income countries. We have not found generic manufacturers interested in this license, but we will certainly look out if anybody is willing to take this on.

Finally, for COVID-19 we have been working on vaccines, which we had never done before. Together with WHO we have helped set up a hub for technology transfer for mRNA COVID-19 vaccine in South Africa. On this project, we work with global partners and WHO: WHO has the scientific and technical coordination, and the overall leadership on the project. We provide assistance on IP, on drafting agreements, on monitoring and implementation of a project. The hub has three main elements:

1) The hub itself is a biotech company called Afrigen, located in Cape Town, South Africa. They will receive technology from various academics in order to make mRNA vaccines for COVID-19. We mainly intend to replicate the Moderna vaccine, based on publicly available information.

2) The first "spoke" is Biovac, the national South-African vaccine manufacturer. It will receive tech transfer from Afrigen, after the technology has been validated. We hope that this will start taking place in the second half of 2022.

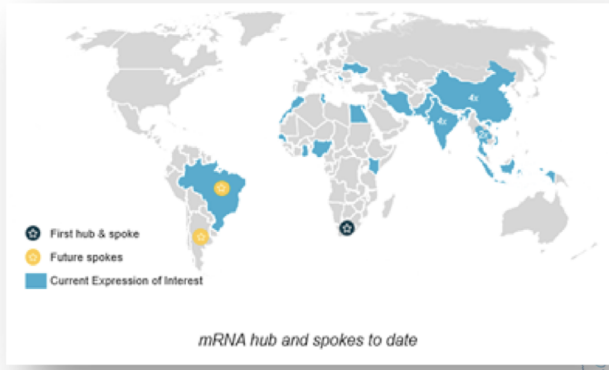
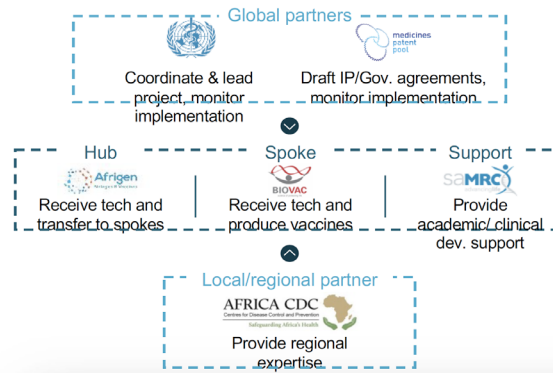
3) The third partner in the hub is the South African MRC, which provides academic and clinical development support and will be building a pipeline of mRNA vaccine for South Africa and the rest of the world.

We are working on this project with Africa CDC and with the ministry of Science & Innovation in South Africa. WHO has recently announced who will be the additional spokes beyond South Africa: these future spokes are located in countries on the African continent and beyond.

Classified as Internal

**South African consortium set up to build tech transfer hub & spokes network with local/regional partners**

### The mRNA Technology Transfer Hub



We hope that we will be able to bring to the market a new technology, free of rights for most countries in the world.

While I am not pretending that DNDi and MPP, the two examples I gave you will resolve all the systemic problems, at least they are moving the needle, which is something very positive, and will increase equity for the most vulnerable people in the world.

**Marie-Paule Kieny**