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L'accès aux médicaments

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Should we question our current model for encouraging innovation in the pharmaceutical sector?

I will start with why we should question our current innovation model for medicines. I will first talk about a recent publication in the journal Nature¹. In this paper we argue that the current R&D system is not meeting the global public interest and we try to put forward the key reasons why it is not doing so and how it could be reoriented. I will not go through this in detail but will outline the key arguments. I wanted to start by saying that we have 4 different types of failures to meet the public interest.

First, a lack of new medicines, of course: a very market-based system does not provide the right incentives for all the kinds of innovation that we need; for example, we do not have the medicines we need for multiple areas, including neglected diseases, antibiotics, and emerging infectious diseases of pandemic potential. We have a second area of failure, which is the slow pace of progress, for example in Alzheimer's disease. A third area of concern is when we have significant risk of harm, such as those arising from adverse drug reactions. And last but not least, of course, a system that by design, restricts access to the technologies that result, through high prices, or ability to restrict production or supply. Covid has certainly been a reminder of all of these problems, but it has also opened up interesting opportunities to explore alternative ways of organizing research and development.

And this is the second main theme that I would like to cover in my opening remarks today. When we think about the current R&D model, there are 3 questions we can ask of it: does it generate inventions? Are those inventions globally available? Are they globally affordable?

Largely this is a market-driven system, a large-scale system. And increasingly, what used to be a vertically integrated system is now a relay-race with many players passing the baton from one actor to the next through the R&D process. This shift away has quite important implications.

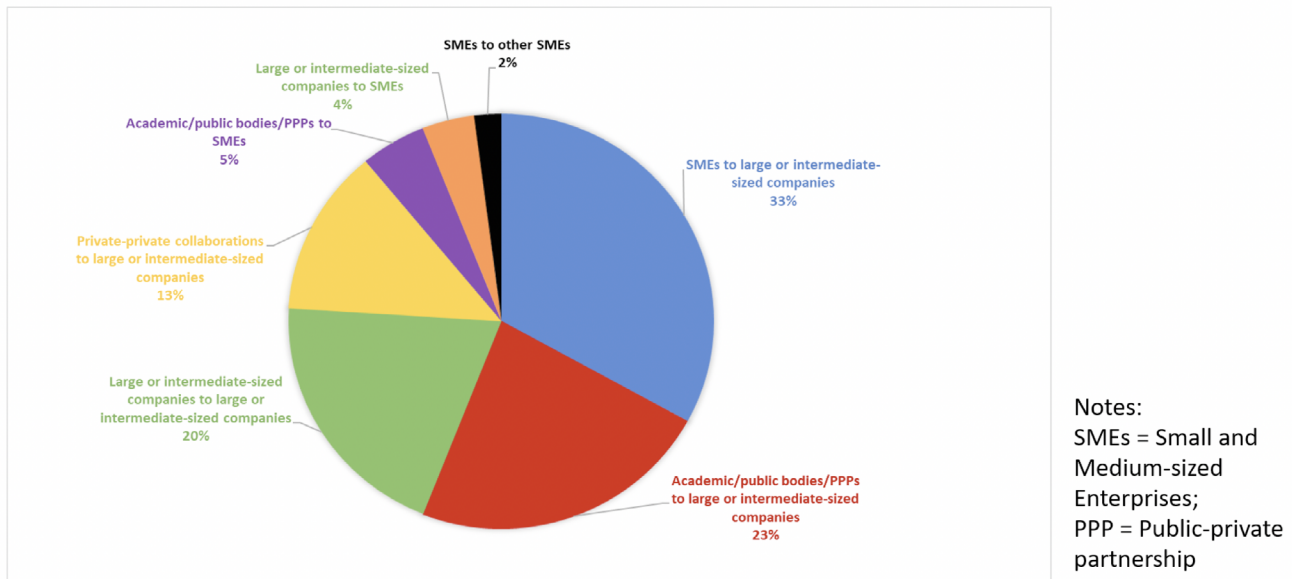
This system does generate inventions. However, there are several important gaps where the market does not deliver. And, by design, these are not globally available nor globally affordable medicines.

One of the most important shifts in the mainstream model is the rising importance of small and medium enterprises (SME), as well as academic institutions in generating innovation.

When we think about where does innovation originate, if you only read the mainstream media, you may believe it all originates from large pharmaceutical companies. And of course, large pharmaceutical companies play an important role, particularly in the last stages of development. But what you can see in this table below is that SME who later transfer the technology to larger firms, academic and public institutions, public-private partnerships do the same, etc.

1 - <https://www.nature.com/articles/d41586-022-00324-y>

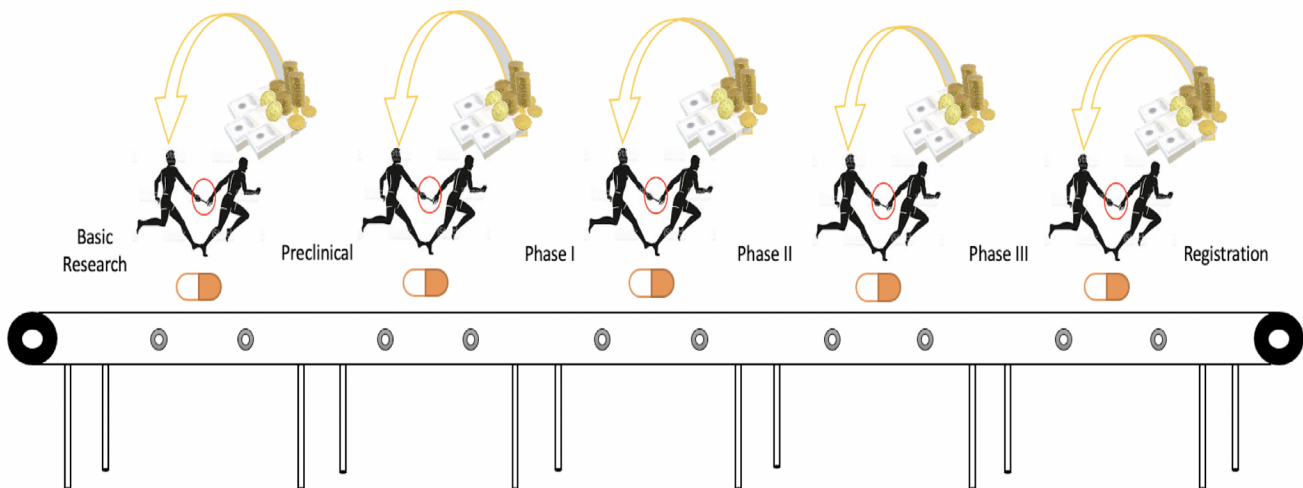
The current model: origins of innovation



Source: Fig. 3. Origins and transfers of new medicines, by type of developer
Moon et. al., forthcoming, based on data from Lincker et al. (2014).

There are also an increasing number of other kinds of collaboration (SME to SME, academics to SME, etc.). I flag this because I think the current innovation system is not as simple or as monolithic as we may assume that it is. Understanding that in fact the current system is changing is important when we try to figure out how do we improve the way the entire system functions for the global public interest.

With all these new actors (SMEs, academics, public-private partnerships, etc.), we have an ongoing relay-race. Each point where you see this baton being handed off from one runner to the next, you have an opportunity to intervene and to improve what are the final outcomes at the end of the R&D process.



Source de l'image : <https://apps.who.int/iris/handle/10665/361752>

We also have the opportunity, unfortunately, for knowledge to be privatized, for control of knowledge and control of the final outcomes of R&D to be in fact enclosed and limited further. And what happens at each of these key moments when the baton is passed is, in fact, highly consequential for who gets access to which products at the end of the day.

A big challenge, however, is that the passing of that baton is shrouded in secrecy. There is very little transparency. There is very little understanding and there is very little public information available on what are the terms and conditions for

a company picking up or passing on the baton. So, I am happy to see that in this seminar we will be looking closer at the issue of transparency in one of the next sessions. This is one of the big challenges in reforming the system. We have quite limited visibility on what is happening.

So, we have seen some of the problems with the current model, and some of the critiques of the current model. Are there some alternative innovation models that have already been developed? Alternatives have been implemented over the last 20 and in some cases 30 or 40 years. In our research, we refer to these as "niches" in the global pharmaceutical ecosystem, where alternative models have emerged. One of the first niches that we can speak about is an alternative niche in the broader system that is intended to develop products for neglected diseases. And what we see here is that financing is different: primarily, this is public money that goes into pushing R&D forward.

We have had important successes with product development partnerships (PDPs) for neglected diseases, and one of the other speakers will speak about this for DNDI in particular. Important successes generating inventions, but certainly many gaps, still. We have, by design, products that are intended to be globally available and affordable. For those that are developed by PDPs, this is the mission. But there are other incentives for neglected diseases, such as priority-review vouchers (PRVs), for which we do not necessarily have globally available or affordable products, even if we get those new products generated. So, it is not a perfect niche but it does show that there are alternative models possible.

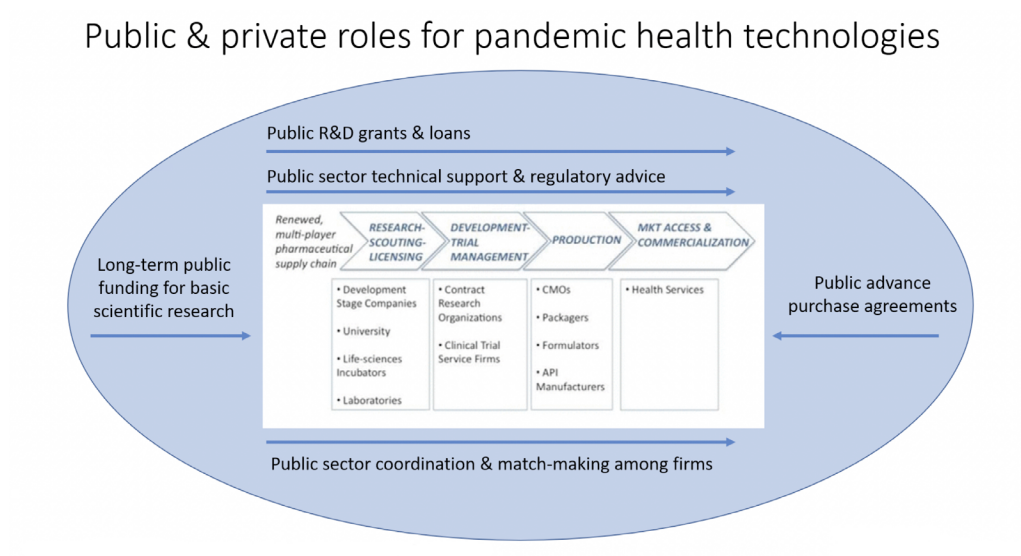
The second niche where you see an alternative model is for rare diseases, often called orphan diseases. For rare diseases we have had a mix of market incentives and policy incentives, including what we refer to as orphan drug legislation over the last 30 or 40 years. And this has been successful in generating new medicines for a number of rare diseases; but for the majority of rare diseases, actually we still do not have adequate medicines.

Of course, the big problem in this area is that the prices for orphan drugs is often absolutely astronomical. So, the incentive system has not been adequate to make these products available nor affordable.

Moving to the next niche, we see another sort of sub-system for biosecurity or diseases of pandemic potential. Here, even prior to Covid-19, we had a large publicly financed system, very much driven by governments, very much policy-driven. Indeed, again, significant successes in generating inventions. But the purpose of these biosecurity R&D models is not to make those products available or affordable globally, but rather, usually, to make them available at national level. So, for example, in the US there is a number of special agencies intended to generate new drugs and vaccines for pathogens of pandemic potential for the US, not necessarily for the world. We have seen, of course, in Covid-19, the terrible consequences of a system that does not develop technologies for global access.

I would like to talk about Covid because it remains top-of-mind for many of us. I would like to highlight that what we see in Covid is not, in fact, a rapid extension of the biosecurity model. There is something quite different from the mainstream R&D model. In this graph below we can see how the classic depiction of R&D happens: different stages, different actors who are involved.

Public & private roles for pandemic health technologies

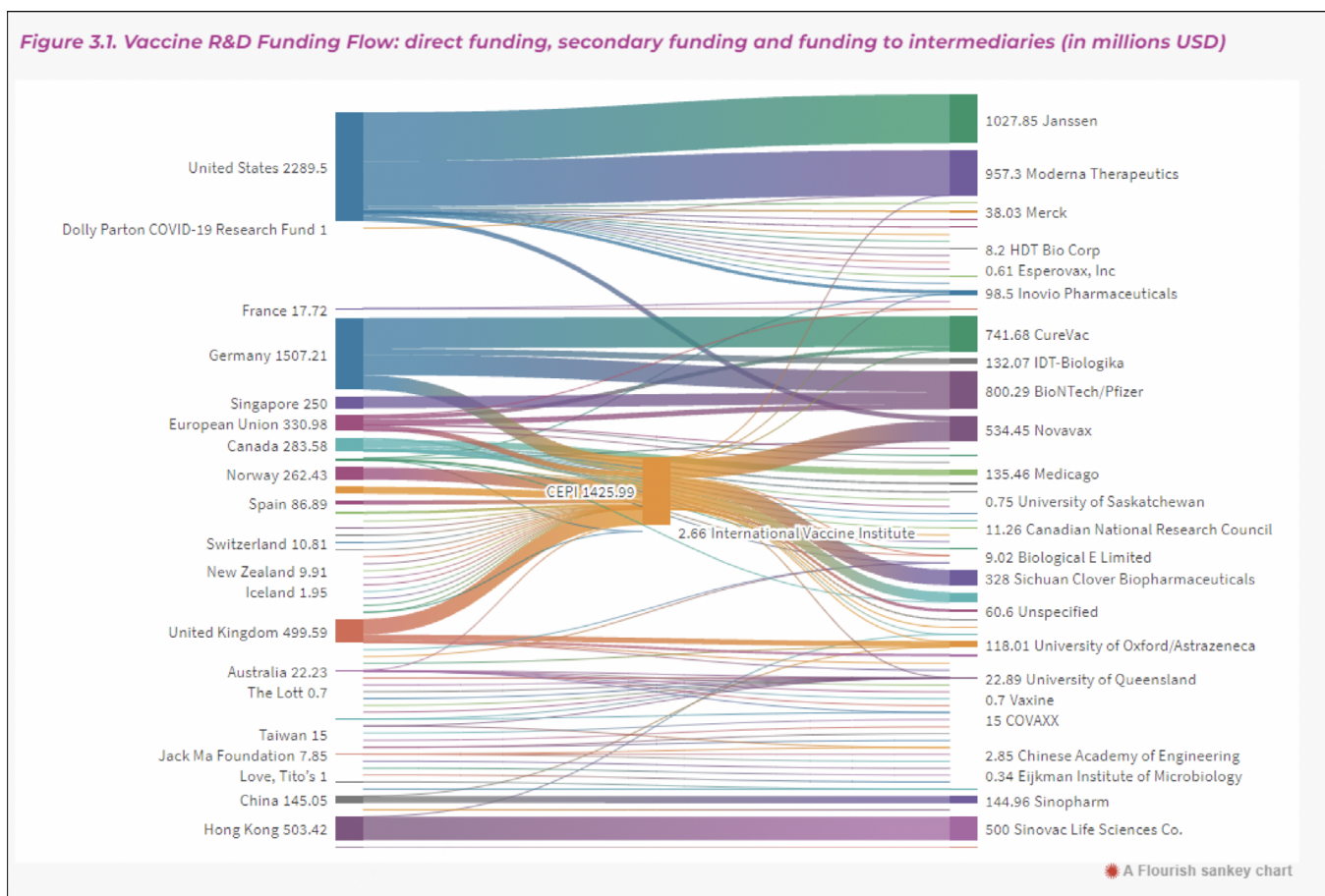


Sources : Capo, Brunetta & Boccardelli (2014) and Moon et al. (<https://www.who.int/europe/publications/i/item/9789289058124>).

When we think about what happened with Covid-19 vaccines in particular, you have the engagement of a public sector in multiple stages, and in fact, surrounding the entire R&D system, pushing it, pulling it, facilitating it, to a degree that is not widely recognized, at least not recognized enough. How did those vaccines develop in such short time? There has been some fantastic research. It is estimated that around six billion dollars of public funding enabled this in 2020, via public R&D grants that pushed R&D through the process. You had also public sector technical support, regulatory advice, support from regulatory authorities, in order to help to design clinical trials for example.

You also had public sector coordination, for example match-making among firms between different innovators, between producers who had capacity to actually rapidly scale-up manufacturing. Last but not least, at least 45 billion dollars of advance purchase agreements before any of those vaccines had had regulatory approval; and of course, many more billions spent after regulatory approval began to be granted in late 2020. What you can see when you look at this picture overall is indeed an R&D system that is completely embedded in and enabled by public sector money and intervention.

Here you can see the various flows of research from different countries: many more countries than we may necessarily think of as involved in R&D (see graph below).



Source : <https://www.knowledgeportalia.org/covid19-r-d-funding>

Today, we have over 30 covid-19 vaccines that have been developed, and one of the key shifts in this pandemic that we have seen is not widely appreciated: many of those vaccines were not developed in the global North. We had vaccines developed in China, in India, in Cuba, in Russia. Some vaccines are in the pipeline in middle-income countries. This is an important shift that may enable, in the future, further development of alternative models.

Let me now turn to the last niche. In the area of antibiotics, there is an effort to create new incentives, new rules, new financing; it is a mix of market and public-policy driven incentives, with the recognition that the current system is failing for antibiotics. It is too early to draw any conclusion on what the outcomes will be.

One of the take-aways here is that indeed, alternative models are possible, they have been built and they have delivered new medicines and new inventions, even if they may not always be as globally available and globally affordable as we would like.

I think we need to learn from these existing experiences.

To conclude, I would say that we need to question the model, because the current model is not fully meeting societal needs. The current model is changing and is increasingly complex. This offers new challenges but also new opportunities for intervention in the system.

With new countries, such as middle-income countries, beginning to conduct much more R&D, we have new opportunities to do R&D differently. These alternative R&D models have proven that they can work, even if they remain relatively small-scale and limited.

What we can conclude, based on the study of those existing alternative niches, is that they do not just emerge by accident, they have to be intentionally constructed: you need financing, they have to be organized differently and incentivized differently from the mainstream model, to work. And it is not enough just to have money or organizations, you also need laws and policies. We must change the rules of the game, the underlying structure of the system, if we want to realize some of the benefits that alternative R&D models can deliver.

Suerie Moon