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Pandemic Vaccine Prep

The case for a government-led response

Equities
Pharmaceuticals

- Developing a vaccine against a new virus that causes a pandemic is not just about discovering one and doing trials
- The availability of manufacturing capacity – and enough of it – is key; there are only five global vaccine manufacturers
- In our view, a co-ordinated government-funded increase in vaccine manufacturing capacity is needed

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Discover, develop, manufacture: It is not easy or straightforward to discover a new vaccine and develop it through clinical studies. Furthermore, being able to manufacture a vaccine – and at scale – is a complex process that can take years to put in place.

We believe a co-ordinated response for future pandemics is needed or history repeats itself: The majority of vaccine manufacturing capacity (and know-how) for global vaccine development and manufacturing resides in Europe. If a pandemic vaccine(s) were developed and manufactured in Europe, Europe would get the vaccine first ahead of the US, Asia and elsewhere. **Further, lack of preparation now for future pandemics could result in a repeat of the COVID-19 financial fall-out.**

Governments ideally would fund vaccine manufacturing capacity: Since the **financial incentives for the private sector to build that capacity are simply not there** (and private sector activities are not co-ordinated), in our view, it would be preferable for governments to co-ordinate and fund the cost of building and maintaining vaccine manufacturing capabilities over the long term. Such facilities should be able to produce sub-unit vaccines, antibodies, inactivated vaccines and attenuated live vaccines, we believe.

In an optimal structure, the vaccine companies, not governments or supra-national organisations, would be in charge, in our view: Vaccine manufacturing capabilities and know-how reside in a small number of companies that can manufacture a wide variety of vaccines at scale. We think it is those companies that are best placed to build and run new facilities for pandemic vaccines. These companies could utilise that manufacturing capacity for the production of other vaccines in between making pandemic vaccines to maintain the facility or facilities and optimise manufacturing processes.

What's in it for governments? 1. The ability to manufacture a new vaccine relatively quickly – and for it to be manufactured by vaccine experts – once the vaccine has been discovered and trialled; 2. **the avoidance of repeated significant financial and social consequences by being able to respond to a pandemic more quickly**; 3. the certainty that a vaccine can be manufactured when otherwise the financial incentives for the private sector are absent (due to high initial costs/ongoing capex with no certainty of generating an economic return).

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Insurance against future pandemics

- Globally there could be future pandemics due to different viruses with repeated financial fall-out
- But the financial incentives for the private sector to prepare for such uncertain events are simply not there
- In our view, vaccine manufacturing should be built now – ideally paid for by governments, run by vaccine companies – to prepare for future pandemics

Insurance against future pandemics and resulting financial fallout

The COVID-19 global pandemic is unprecedented in modern times, especially in its economic and social impact (see numerous notes from HSBC's Economics research team, including *Global Economics: Shockdown*, 2 April 2020). In our view, given the scale of the financial impact, governments need to consider preparing for future pandemics, however unlikely they may be to occur. **As such, we believe unprecedented action to enlist the help of vaccine companies and to pay for it – now – to build sufficient vaccine manufacturing capacity, is needed.**

Cost to prepare for multiple future pandemics	Cost of current pandemic
USD 20bn	USD multi-trn

Source: HSBC estimates

Although COVID-19 is the first major modern pandemic and it may too late for this outbreak to develop a vaccine that could be administered widely (the virus may have run its course by the time any vaccine candidate might be developed; alternatively, it could be seasonal or remain active permanently), **we believe it would be prudent to plan for further pandemics in the future caused by other viruses.** The private sector (pharma companies with vaccine divisions) has a role to play since it has the expertise and know-how to manufacture vaccines and manufacture them at scale. **However, for preparations for future virus-driven pandemics (NB plural)** – which may or may not happen and may or may not require a vaccine, which

means the economics for pharma companies do not work – **a government-led proposition would be the best option, in our view.**

The incentives for governments to act, given the economic damage occurring in real-time and on a global basis, are significant. Although we estimate the cost of building vaccine manufacturing capacity on a global scale could reach USD10-20bn (including maintenance costs over the long term), it pales into insignificance relative to the economic and social costs of not being prepared for further pandemics and especially if those costs were shared on a multi-national basis.

Why a private-sector solution cannot be relied upon

There could be repeated, multiple pandemics in the future that individually could reap significant economic harm, but as each pandemic could be relatively limited, the financial incentives for pharmaceutical companies to prepare for multiple pandemics are simply not there. Pharmaceutical companies need to invest for relatively certain financial returns, not for uncertain events that might mean they incur relatively certain losses or highly uncertain returns. **As such, although the private sector has the capabilities to deal with multiple pandemics, it does not necessarily have the financial incentives to do so.**

Further, although COVID-19 has now infected over 2m people globally and has a much greater mortality than seasonal influenza (currently c. 6.7% vs 0.1%; source Johns Hopkins University), it is not clear how many doses of vaccine would be needed in this or any future pandemic. Unlike seasonal influenza for which over 200m doses of vaccine are produced annually (which is cost-effective for several companies), a vaccine against COVID-19 or any subsequent pandemic virus may require a much lower level of dosing that would make it economically unviable for pharmaceutical companies to make build manufacturing capabilities for such scenarios.

Vaccine manufacturing is key and takes time

During this pandemic several companies have announced plans to develop a significant number of vaccines against COVID-19 (also potential therapeutics). **Aside from the challenges of developing a safe and effective vaccine (for example, there is still no vaccine against SARS or HIV after 20-30 years, respectively), these announcements ignore the fact that if a traditional vaccine that was safe and effective was developed, it could not be manufactured in the short term or on a large scale.**

Vaccine manufacturing is complex and can take over five years (usually more) to put in place. The upfront capex involved is significant, the ongoing capex is also notably higher than for traditional (small molecule) drug manufacturing and the payback period for companies developing and manufacturing vaccines is also prolonged relative to other drugs and can be economically unviable. The safety of vaccines, which is also governed by the manufacturing process, is key since vaccines are administered to otherwise healthy individuals, including to children and to those who are more vulnerable – people with pre-existing medical conditions (so the tolerance of side effects is low). Quality control plays a large part in ensuring vaccine safety, with over 100 quality or safety checks for every vaccine before it can be administered to a patient (Sanofi, for example, estimates that 70% of vaccine production time is dedicated to quality tests). **Even when manufacturing processes have been put in place and optimised, the manufacturing process for some vaccines can last 18-36 months.**

As an example, Pfizer notes that the manufacture of its Prevnar 13 vaccine (against pneumococcal bacteria) involves:

- 1,700 employees
- 678 quality tests
- 400 different raw materials
- 580 manufacturing steps
- 2.5 years to manufacture

Global vaccine manufacturing know-how is concentrated

Global vaccine manufacturing know-how and global manufacturing scale are concentrated in only five companies:

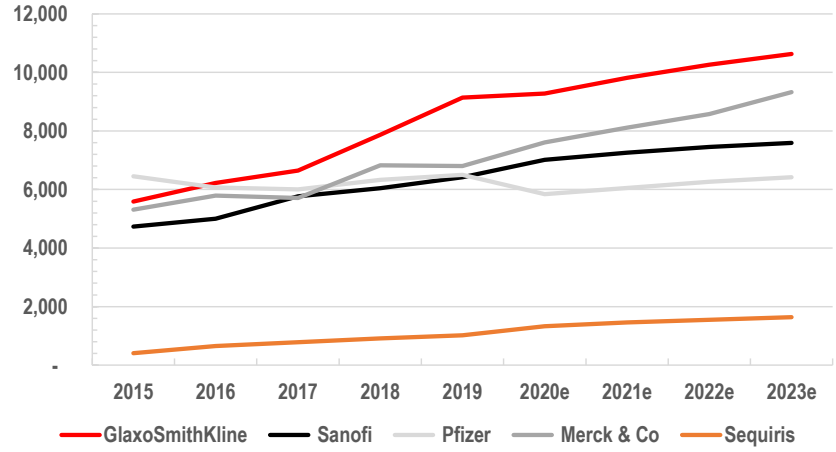
- GlaxoSmithKline (UK)
- Sanofi (France)
- Merck & Co (US)
- Pfizer (US, although mainly for one vaccine)
- Seqirus (UK, a subsidiary of CSL)

Further, vaccine manufacturing that generates the sales of the majority of vaccines globally has a high presence in Europe, with GSK's two main manufacturing facilities in Wavre and Rixensart in Belgium, Marburg in Germany and Siena in Italy, and Sanofi's at Val-de-Reuil, Marcy L'Etoile and Neuville-sur-Saone in France. Although both companies and other vaccine companies also have facilities elsewhere, there is a disproportionate concentration of vaccine manufacturing capabilities in Europe versus the US and Asia, for example.

In Asia, there are multiple local vaccine manufacturers in India, China and elsewhere. Aside from a limited number of companies in these territories, eg Serum Institute of India, Bharat Biotech, most manufacturers produce a limited number of vaccines in relatively small volumes overall. **In contrast, GlaxoSmithKline and Sanofi alone produce over 40 different types of vaccine and in 2019 produced over 1.7bn doses of vaccines.**

Existing manufacturing facilities are generally utilised for the manufacture of vaccines that are needed and therefore cannot be re-purposed for the manufacture of a pandemic vaccine. There is little spare capacity in the industry and there are examples of the need for extra manufacturing capacity, as shown by GSK's need for further Shingrix capacity and the inability of bodies such as the Developing Countries Vaccine Manufacturers Network (DCVMN) being unable to keep up with demand for current vaccines. **Hence, we think pandemic vaccine manufacturing capabilities – especially at scale – would need to be built.**

Global vaccine sales by the top 5 manufacturers (USDm)



Source: Company data, HSBC estimates, Bloomberg

So there is a need to prepare…and the need for government funding, in our view

Given the challenges outlined above, in our view governments would need to enlist vaccine companies to prepare for future virus pandemics. We estimate that building pandemic vaccine manufacturing capabilities would require at least two sites and cost up to c. USD20bn over say a 20-year period (including initial capex and maintenance capex costs). **Given the un-coordinated private sector response to COVID-19, we suggest it would be better for multiple governments to consider funding the building of that capacity, as part of a co-ordinated effort to mitigate the repeated medical, social and financial consequences of future pandemics (and potentially COVID-19 as well).**

Manufacturing mechanism

We think such manufacturing facilities ideally would be built and run by nominated vaccine companies since they have the expertise and know-how. Such facilities could be leased to the nominated vaccine companies on a perpetual lease for zero rent. Although the construction and running costs might be paid for by multiple governments, the nominated companies – as part payment for their expertise and know-how – could utilise the manufacturing capacity to manufacture other vaccines (which would also maintain the facilities and allow optimisation of processes), but might be required to switch manufacturing to the pandemic vaccine or alternatively, they might be required to keep a proportion of the manufacturing capacity idling for pandemic vaccine preparation. In our view, the facilities would have to be capable of manufacturing sub-unit vaccines, antibodies, inactivated vaccines and live attenuated vaccines and have all the necessary downstream processing as well as fill-and-finish capabilities, ie the whole range of potential vaccine therapeutics that might be developed in due course.

What governments would gain	What vaccine companies would gain
Certainty that a vaccine could be manufactured	Additional manufacturing capacity for no extra cost that could likely be utilised between pandemics for prolonged periods of time
Avoidance of repeated economic and social damage	

Pandemic vaccine manufacturing Q&A

Likely questions on our proposal and our answers:

1. Q. Who would fund the vaccine manufacturing capacity?
   A. Multiple governments.
2. Q. Who would own the manufacturing facility/facilities?
   A. There would be shared ownership commensurate to each country's contribution to construction and maintenance costs and with a perpetual lease granted to the nominated Vaccine company/companies.
3. Q. What if one of the contributing countries stopped paying their share of the ongoing costs?
   A. There would have to be a penalty clause that would restrict access to manufactured vaccines if any country defaulted on their share of the ongoing costs.
4. Q. Which countries would get the pandemic vaccines first?
   A. Distribution of manufactured vaccines would ideally be on a geographic and medical basis, with the most vulnerable individuals and countries prioritised. For example, at an outbreak of a pandemic in one country, it could be prioritised with vulnerable individuals in other countries also being vaccinated initially and with broader distribution to other countries and the wider population later as stocks become available. However, recognising that this might be a politically sensitive issue, distribution could be on the basis of percentage of the vaccine stock at a time to each country proportionate to their population.

The JNJ/BARDA plan – a US-centric solution?

Johnson & Johnson – a small player in the vaccines area – announced a collaboration with the US BARDA (Biological Advanced Research and Development Authority) to jointly commit USD1bn to research and develop a new vaccine against COVID-19 and to build manufacturing capacity for the vaccine. First, there is no guarantee that the first vaccine candidate will be effective or safe. Secondly, even if approved under emergency authorisation by 2021, we think it is unlikely that there would be sufficient manufacturing capacity available to produce the vaccine en masse. Thirdly, by building US manufacturing capacity in collaboration with a US government agency, it would probably ensure that the US population would preferentially gain access to any vaccine that was developed. That is not an unusual situation (cf smallpox vaccine manufacturing post-9/11), but it does add a US-centricity on any developed vaccine for a global problem. **As we noted earlier, in the absence of a co-ordinated response, vaccine development for COVID-19 and for future pandemics could easily become "everyone for themselves".**

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