# SCHEDULE 2 ITEM 16 COSTING INFORMATION

https://github.com/ZKis-ZK

Detailed Tables prepared that include far more than requested in pp34-46 of Schedule 2 are from published repositories above.

Folder names are the dates they were uploaded. Folders also include the peer reviewed articles that data supported and supplementary material for the more recent set.

Note the substantial differences between June and December last year. Expect bigger changes in the next few years.

Especially raw materials and consumables affected by inelastic supply chains now and possible reduction in demand by two orders of magnitude when taRNA technology replaces current.

Trans amplifying RNA corresponds to the 5th column on p2 of Supplementary Materials for December 2020. Dosage of 0.1 is two orders of magnitude less than 100 for Moderna.

As shown in the papers, costs of raw materials and consumables completely dominate when operating at economic scale with currently available platforms.

## /1_2020-12-22/

https://github.com/ZKis-ZK/LNP-formulated-RNA-vaccine-drug-substance-production-cost-modelling

## /2_2020-06-01/

https://github.com/ZKis-ZK/RNA-vaccine-drug-substance-production-techno-economic-modelling

## /3_Economics/

1. BioNTech provides Update on Vaccine Production Status at Marburg Manufacturing Site.pdf

The current economic scale for an mRNA manufacturing facility is about 20 million doses per week (in batches of 8 million per 2 to 3 days). This is >1000 million doses per year, an order of magnitude larger than mentioned by Approach to Market prepared with assistance of offshore management consultants and secret expert panel. That facility has 400 staff of which half are on 24/7 shifts.

BioNTech has the know how to operate at this scale. Moderna uses about 3 times as much raw materials per dose, which is the main cost. Moderna has not yet achieved the same scale, has not been able to deliver reliably and costs more. Moderna may be able to catch up, but any agreement with CSL and the Australian government would be unlikely to help it do so.

2. Fosun_BioNTech_Term_Sheet_202105097255.pdf
   https://www.fosunpharma.com/uploads/202105097255.pdf

In March 2020 BioNTech allied with Fosun for mRNA covid vaccines in China the day before it allied with Pfizer for the rest of the world excluding China.

A year later they reached a comprador Joint Venture agreement to build a 1 billion dose manufacturing facility in China. The JV is to be chaired by BioNTech with BioNTech Vice Presidents controlling Finance and Compliance. In exchange for know how and key personnel BioNTech gets a 50% share. Fosun provides the rest.

This means BioNTech is now able to do a technology transfer for what was previously only tacit knowledge of how to rapidly go through multiple stages until able to operate at that scale.

“You can have it quick, cheap and high quality - pick any two”

3. Product-Eligibility_COVAX-Facility_Dec2020_0.pdf

The high quality requirements for vaccines are determined both in Australia and on the world market by Stringent Regulatory Authorities (SRAs) such as Australia’s TGA.

The only trade off remaining is between quick and cheap.

Economic analysis of the costs of delay, even without considering the cost in lives and misery, determines that the focus must be on speed of delivery.

Delivery is much faster from facilities designed at economic scale. A facility able to manufacture at 20 million doses per week can deliver more than eight times faster than one only able to manufacture 100 million per year. Cost per dose is also much lower.

Any decisions ignoring these simple facts would necessarily attract the attention of the Auditor General as well as Parliamentary inquiries

Proposals for a “population scale” facility that would merely provide two doses per Australian over 9 months would be intentionally planning for future pandemics to result in remaining the same situation we are in today (Friday 2021-07-16) with the two largest cities locked down at a purely economic cost of billions per week, at less than 6 months after vaccine rollout commenced. That is not what the government intends to take to the next election.

Global plans are for vaccines in the next pandemic to start being manufactured within 100 days (14-15 weeks). It would be ridiculous to not finish until after another 9 months (39 weeks).

For a dose interval of 4 weeks the surge production campaign should only take at most 4 weeks to produce 80 million doses.

4. www.globaltimes.cn_China_testing_2021-06-06.pdf Guangzhou speeds up world's largest citywide nucleic acid testing as COVID-19 cases rise By Lu Yameng Published: Jun 06, 2021

https://www.globaltimes.cn/page/202106/1225531.shtml

China collected about 16 million covid test samples in about 12 days in one city from 2021-05-25 to Saturday 2021-06-04. That is about 1.3 million per day using 5,600 staff. Say 238 per staff per day.

Vaccination, including registration, takes less time than sample collection. The 200 dose pouch prefilled syringes proposed here can be used to vaccinate much faster than that, with less staff and less skills required than for collection.

It simply makes no economic sense to prolong a lockdown costing billions by keeping smaller stockpiles of raw materials, less manufacturing capacity and less deployable surge staff reserves than are needed to keep up with the rate at which vaccines can be delivered.

Even the most fanatical determination not to let a single dose reach countries where the hospital system is collapsing until after Australia is fully vaccinated at the "head of the queue" could not explain a proposal to actively focus on costs instead of delivery speed and thus raise the costs per dose by reducing the total capacity to deliver at all below the current economic scale.

5. w28492.pdf http://www.nber.org/papers/w28492

PREPARING FOR A PANDEMIC: ACCELERATING VACCINE AVAILABILITY Working Paper 28492 NATIONAL BUREAU OF ECONOMIC RESEARCH

ABSTRACT Vaccinating the world's population quickly in a pandemic has enormous health and economic benefits. We analyze the problem faced by governments in determining the scale and structure of procurement for vaccines. We analyze alternative approaches to procurement. We find that if thegoal is to accelerate the vaccine delivery timetable, buyers should directly fund manufacturing capacity and shoulder most of the risk of failure, while maintaining some direct incentives for speed. We analyzed the optimal portfolio of vaccine investments for countries with different characteristics as well as the implications for international cooperation. Our analysis, considered in light of the experience of 2020, suggests lessons for future pandemics.

6. moderna-large-scale-production-sars-cov-2-vaccine.pdf

Heavily redacted procurement contract between US Operation Warp Speed and Moderna. 2020-08-09. Documents US Trump administration's "America First" policy to procure vaccine manufacture capacity of only 500 million doses over 20 months for a two dose regime with a population over 300 million (p19 of 53). This

“America First” and “vaccine nationalist” policy contributed to over 600,000 US deaths and a global excess mortality of 3 million in 2020 (expected to be much higher this year).

Any Minister proposing actual contracts based on a similar “Australia First” policy to Cabinet can expect to eventually be prosecuted for misconduct in public office, along with the staff who advised it and any offshore consultants or members of secret panels of experts that can be found within the jurisdiction. It seems implausible that a former Attorney General would knowingly commit that crime or that any DISER officer would fail to draw the Minister’s attention to the matter and to use whistleblower protection legislation if that was insufficient.

7. 2021-icc-summary-for-policymakers.pdf

8. covid_vaccine_sko_nber.pdf

The Economic Case for Global Vaccinations: An Epidemiological Model with International Production Networks January, 2021 Abstract COVID-19 pandemic had a devastating effect on both lives and livelihoods in 2020. The arrival of effective vaccines can be a major game changer. However, vaccines are in short supply as of early 2021 and most of them are reserved for the advanced economies. We show that the global GDP loss of not inoculating all the countries, relative to a counterfactual of global vaccinations, is higher than the cost of manufacturing and distributing vaccines globally. We use an economic-epidemiological model of international production and trade networks and calibrate the model to 65 countries. Our estimates suggest that up to 49 percent of the global economic costs of the pandemic in 2021 are borne by the advanced economies even if they achieve universal vaccination in their own countries.

## /4_How/

1. IntelligenSuiteJanuary2013.ppt

132pp explanation of freely available software used in ZKis-ZK repo Costing Tables here. Any competent process engineer could generate both desired tables and far more relevant schedules for speed of construction AFTER specification of a process and expected costs of raw materials and consumables as well as equipment, site, staff etc.

2. Establishing-Manufacturing-Capabilities-for-Human-Vaccines-ebook.pdf

WHITE PAPER Establishing Manufacturing Capabilities for Human Vaccines Key cost drivers and factors to consider when planning the establishment of a vaccine production facility Global UNIDO Project: Strengthening the local production of essential medicines in developing countries through advisory and capacity building support

Includes explanation of why one should start with the Fill and Finish plant.

## /5_Not_for_the_Faint_of_Heart/

CSL is a major use of egg products to make flu vaccines. It successfully persuaded the Australian government to commit $1 billion to upgrading its 1940s technology to 1980s cell based technology in November 2020 when it had already become clear that mRNA vaccines would become dominant for covid-19 and for many other diseases including flu.

1. www.pm.gov.au_1_billion_dollar_to_CSL

$1 billion manufacturing agreement secures Australia's national health security MEDIA RELEASE 16 Nov 2020 Prime Minister, Minister for Health, Minister for Industry, Science and Technology https://www.pm.gov.au/media/1-billion-manufacturing-agreement-secures-australias-national-health-security

That move successfully delayed mRNA flu vaccines as well as covid vaccines that would have left both CSL's egg product business and its $800 million investment in 1980s cell based technology as stranded assets.

According to CSL's Managing Director, Paul Perreault:

"This (mRNA vaccines for covid-19) is not for the faint of heart. These are difficult biologics, and I think it's a great opportunity for the future and we'll continue to look at what role we'll be able to play there. But it's not going to happen overnight."

https://www.smh.com.au/business/companies/not-for-the-faint-of-heart-csl-interested-in-mrna-development-20210221-p574e2.html

See also:

https://www.smh.com.au/politics/federal/locally-produced-mrna-vaccine-won-t-be-available-until-at-least-2023-20210714-p589rh.html

https://www.afr.com/companies/healthcare-and-fitness/csl-chief-s-personal-mission-to-get-australia-vaccinated-20210625-p584d1

https://www.news.com.au/finance/work/leaders/wages-of-australias-top-bosses-revealed/news-story/37836781c82797aadc6c132003d457ff

"Realised pay – cash salary plus the value of equity that vested during the year – soared past $40m for the first time, with Paul Perreault, who leads biotech giant CSL, enjoying an eye-watering improvement from $30.53m for the previous 12 months."

2. 20180816_BioNTech-Signs-Collaboration-Agreement-with-Pfizer.pdf

The present alliance between BioNTech and Pfizer to manufacture and market mRNA vaccines for covid-19 throughout the world except for China arose directly from their prior similar agreement in August 2018, before covid, to:

"...jointly conduct research and development activities to help advance mRNA based flu vaccines. Pfizer will assume sole responsibility for further clinical development and commercialization of mRNA-based flu vaccines, following

BioNTech's  completion of a first in human clinical study."

The Australian government might have looked to a horse breeder to help General Motors establish an industry producing "horseless carriages" in Australia. Instead it chose a carriage builder (Holden) whose interests were not diametrically opposed to the elimination of horses from transport.

Even if the Australian government now looks to an egg product producer of flu vaccines to help wipe out its very lucrative business, it is highly unlikely that Pfizer/BioNTech would agree to risk the obvious conflict of interest with CSL.

Both BioNTech and Moderna have extensive mRNA products pipelines.

3. BioNTech Announces First Quarter 2021 Financial Results and Corporate Update.pdf

Moderna's would also include flu vaccines. Perhaps they are more naive?

The lack of interest in discussions with Australia from the Pfizer/BioNTech alliance is not because they do not need or want to scale out yet. There is simply no CDMO to talk to in Australia that actually understands what is involved and has the capacity and desire to do it.

Changing that situation requires first finding a way to recruit the necessary key personnel and workforce to establish a new Contract Development Manufacturing Organization (CDMO).

CSL has many of the highly skilled staff experienced in technology transfers that would be needed.

Extracting those staff from CSL's owners and managers would require serious effort. Such efforts could include establishment of a "Pharmaceutical Reserve" that engineers and others with the necessary skills could join on a part-time basis until mobilized during a health emergency (such as the one that now exists). Staff joining and training with the Reserve would need legal protection from discrimination by their employers as with Defence force reserves. They are likely to need to train harder and be deployed for longer than other reserves that can be mobilzed to defend against attacks.

To enable that, it is necessary to first recruit some key engineering and other technical staff as onshore consultants. Technical staff can largely work from home via internet. Part time employees with homes in places like Marburg and Kalamazoo could be particularly useful. They are onshore if they are part of an Australian team that pays their salaries rather than part of an offshore consultancy firm. Some can move to Australia and join with local staff when needed.

## /6_Then_WHO/

The capital markets are flooded with funds wanting to invest in mRNA.

Asking local manufacturers what to do won't help. Nor will offering them money to find out.

The government support needed is very simple.

Recruit engineers immediately.

Get advice on how to recruit them from the authors of the published costing tables here eg Zoltán Kis.

They work with:

Imperial College Future Vaccine Manufacturing Research Hub

1. shattock_talk1_hub.pdf
   http://www.dcvmn.net/IMG/pdf/shattock_talk1_hub.pdf

2. Imperial-College-London-FVMR-Hub-Annual-Report-2019.pdf
   https://www.imperial.ac.uk/future-vaccine-hub

https://gtr.ukri.org/projects?ref=EP%2FR013764%2F1

Director Robin Shattock is also participant in research project recently funded by "mRNA Victoria":

https://research.monash.edu/en/projects/a-safe-effective-and-rapidly-tuneable-sars-cov-2-vaccine

An "Institute for mRNA manufacturing capability" could be useful. Recruit engineers to initially staff that. Then you won't need to rely on offshore consultants to understand costing information for a project to bring a capability onshore.

Institute Motto: "No we don't know how manufacture mRNA at scale. But we are willing to learn".

4. www.who.int_mRNA_vaccine_technology_transfer_hub.pdf

Should work with W.H.O.:

Establishment of a COVID-19 mRNA vaccine technology transfer hub to scale up global manufacturing 16 April 2021 Expression of interest

https://www.who.int/news-room/articles-detail/establishment-of-a-covid-19-mrna-vaccine-technology-transfer-hub-to-scale-up-global-manufacturing

Helping to accelerate the end of the current global pandemic will reduce the numbers of Australians killed by the more highly virulent variants that are already starting to emerge from the deadly combination of leaky vaccines and delayed deployment.

See:

5. journal.pone.0250780.pdf Van Egeren D et al. (2021) Risk of rapid evolutionary escape from biomedical interventions targeting SARS-CoV-2 spike protein. PLoS ONE 16(4): e0250780. https://doi.org/10.1371/journal.pone.0250780 Published: April 28, 2021

6. pbio.1002198.pdf Read AF et al. (2015) Imperfect Vaccination Can Enhance the Transmission of Highly Virulent Pathogens. PLoS Biol 13(7): e1002198.https://doi.org/10.1371/journal.pbio.1002198