KPMG

Market study - Project Bio

September 2021

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Private and confidential

Ministerie van Economische Zaken en Klimaat
Directoraat Generaal Bedrijfsleven en Innovatie
Bezuidenhoutseweg 73
2594 AC Den Haag

Amstelveen, September 2021

Dear 5.1.2e

Project Bio

In accordance with our framework agreement dated 30 November 2020 ('our Framework Agreement') and our proposal including detailed scope dated 15 July 2021, we enclose our report on Project Bio.

This final written report supersedes all previous oral, draft or interim advice, reports and presentations, and no reliance can be placed by you on any such oral, draft or interim advice, reports or presentations other than at your own risk.

You should note that our findings do not constitute recommendations to you as to whether or not you should proceed with the plan to potentially provide support to Applikon. The 'Important notice' on page 3 should be read in conjunction with this letter.

Our report is for the benefit and information of the addressees only and should not be copied, referred to or disclosed, in whole or in part, without our prior written consent, save as permitted in our Framework Agreement.

Yours faithfully

KPMG Advisory NV

5.1.2e

Important notice

Our report is for the benefit and information of the addressees of our Framework Agreement ('the addressees') only and should not be copied, referred to or disclosed, in whole or in part, without our prior written consent, except as specifically permitted in our Framework Agreement. To the fullest extent permitted by law, we will not accept responsibility or liability to any other party (including the addressees' legal and other professional advisors) in respect of our work or the report.

Our work commenced on 19 July 2021. This report has been based on field work until 10 August 2021. We have not undertaken to update our report for events or circumstances arising after that date. This final Report takes precedence over any draft of the Report provided to you and no reliance will be placed by you on any draft Report other than at your own risk.

In preparing our report, our primary source has been interviews with market experts in the EU, external desk research and several discussions with KPMG experts. Details of our principal information sources are set out in the basis of preparation and we have satisfied ourselves, so far as possible, that the information presented in our report is consistent with other information which was made available to us in the course of our work. We have not, however, sought to establish the reliability of the sources by reference to other evidence.

Demand scenarios have been developed by KPMG and approved by VWS. In relation to forward looking information, we must emphasize that the realization of the forecasts/projections is dependent on the continuing validity of the assumptions on which they are based. We accept no responsibility for the realization of the projections. Since the forecasts/projections relate to the future, actual results are likely to be different from the projected results because events and circumstances frequently do not occur as expected, and the differences may be material.

This engagement is not an assurance engagement conducted in accordance with any generally accepted assurance standards and consequently no assurance opinion is expressed.

We would like to emphasize that we do not express an opinion or any form of assurance on the information presented in this report (including Appendices). Furthermore, we do not make any representations regarding the sufficiency of the procedures we performed for your informational needs.

Our report makes reference to 'KPMG analysis'; this indicates only that we have (where specified) undertaken certain analytical activities on the underlying data to arrive at the information presented; we do not accept responsibility for the underlying data.

We do not accept or assume responsibility to anyone other than to addressees, for our work, for the report or for any judgements, findings, conclusions, recommendations or opinions that we have formed or made. To the fullest extent permitted by law, we do not accept or assume responsibility to any other party as a result of provision of the report to such a party.

This Report nor its content may not be disclosed or used for any other purpose without prior written consent of KPMG.

KPMG was not and will not be involved in any decision making by EZK and/or VWS.

The work was undertaken and the report was issued, on agreed terms of engagement, in order that we might state to the addressees those matters on which we agreed to report and for no other purpose. The report was not created for, and should not be treated as suitable for, any other purpose.

Contents

Glossary

Bn	Billion
CAGR	Compound annual growth rate
CMO	Contract manufacturing organisation
COVID-19 (COVID)	Coronavirus disease of 2019
CRO	Contract research organisation
EU	European Union (incl. UK)
EUR	Euro
FC	Forecast
L	Litres
M	Million
SUB	Singe Use Bioreactor
#	Number of ..

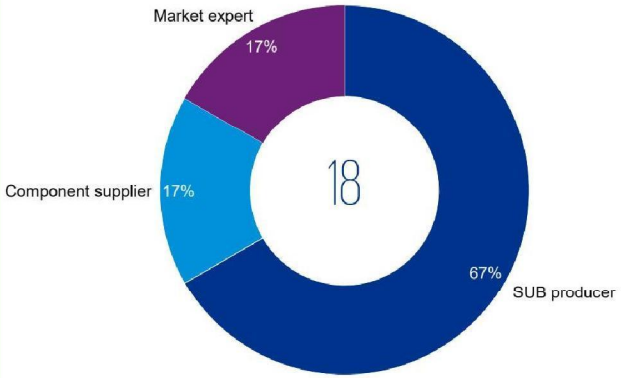
Basis of preparation

Primary research – Interviews

External interviews (Σ: 18)

— Small to largest SUB producers
— Academic researchers
— End-users
— Component suppliers of SUB producers

Breakdown of types of interviews



Secondary research

Main secondary sources

— Documentation provided by VWS
— 'Towards Vaccinating the World,' IFPMA
— Leading single use Bioreactors by Magna
— Global Innovative Market Forecast 2021 for Single Use Bioreactors
— Report on European Bioreactor market by The Insight Partners
— Report on Imaging & Diagnostics by BNP Paribas
— Reports on Bioreactors by Barclays
— WHO report on Covid vaccine development
— Competitor analysis by Morgan Stanley
— Company information by respective company annual reports and websites
— New articles on Covid vaccines and demand of SUBs.
— BioPlan Associates annual surveys
— EvaluatePharma

Our methodology to identify potential SUB shortages is based on comparison of a bottom-up supply and a top-down demand estimate

KPMG approach to estimate demand and supply over time

	Supply	Other bottlenecks	Demand
	Capacity is estimated bottom-up on a variety of qualitative and quantitative estimations.		**Demand is estimated top-down based on COVID scenario's and non-COVID market data.**
2020	**Detailed breakdown of EU production plants with *estimated* capacity** • *Tier-1 players* • *Tier-2 players* • … *Capacity includes UK capacity* *See page 13*	**Other bottlenecks** to the supply chain have been analysed in the last section of this report	**Non-COVID base demand for SUBs is estimated on market reports (to estimate proportional base demand)** • Validated by interviews • Triangulated based on various sources *Demand includes UK demand*
Expected Δ	**Estimated capacity expansion as per interview feedback** • *Player-1* • *Player-2* • *Player-3* • …		**Estimation of COVID impact in EU is based on:** • Total EU vaccine demand • Translation to SUB demand *See pages 17-19* **+ Expected growth in non-COVID demand**
2021-2023	**Indicative capacity roll-out 2021-2023** • *Player-1* • *Player-2* • *Player-3* • …		**Estimated non-COVID demand for SUBs** **+ Estimated use of SUBs for EU COVID vaccine demand**
	For a breakdown and forecast refer to pages 13-15.		*See slide 16-20 for calculation steps and demand scenarios*

Top-down demand scenarios were developed by KPMG and validated by VWS

COVID demand scenarios	Description per scenario	Impact on EU single use bioreactor (SUB) demand: Vaccines, '21-'23, #bn
1 Finish the current vaccination campaign	In this scenario only the current vaccination program will be completed: all willing EU citizens (est. 70% of adult population) will receive both a first and second dose. Afterwards the COVID vaccine production will be stopped	~0.5
2 Additional single booster	All willing EU citizens (est. 70% of adult population) will, on top of the double vaccinations that are part of the current program, receive an additional single booster in 2022, after which no further COVID vaccines will be produced for EU	~0.8
3 Yearly booster	All willing EU citizens (est. 70% of adult population) will receive a yearly booster from 2022 onwards, after completion of the current vaccination program. Production in EU will continue in this scenario	~1.0
4 Contracted doses	In this scenario the number of estimated EU vaccine demand equals the volumes contracted for by the European Commission (i.e. Pfizer, Moderna, AstraZeneca, Johnson & Johnson, Sanofi and CureVac)	~4.3

Low

High

This scenario is used in our calculations as it implies the highest number of vaccines and therefore has the largest impact on SUB demand

Source: COVID EU Vaccination Tracker, European Commission: EU Vaccine Strategy for Authorized Vaccines, KPMG analysis.

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Executive summary

Executive summary

Analyses suggest that EU supply additions should become sufficient to meet EU SUB demand in 1-2 years

Headline		Supporting arguments	KPMG view
EU SUB supply is expected to become (more than) sufficient to meet EU demand end of year 2022		**In 2019-2021 the EU supply of SUBs was not sufficient to meet EU demand**, due to increased COVID demand worsened by the Defence Act and because the EU imported around 10%-20% of SUBs from the US. Planned supply additions of around +100% of current capacity in EU are expected as indicated by interviews with SUB producers. Additional **capacity is estimated to be sufficient to meet additional COVID demand** (including the backlog) in the EU as well as the strong underlying growth in demand for SUBs in coming years. Additionally, prior to COVID, the EU was a net importer, however the **new planned capacity** is likely to substitute part of the former US imports by regional production, **shifting the EU towards a net export position.**	
Supply	*Current production capacity of SUBs in the EU is estimated at 80,000-100,000 units and is expected to almost double before 2023*	— Local SUB production capacity in the EU **comprises over 15 facilities operated by ~10 players**. Top-4 players with EU-based production account for ~80% of SUB supply — The EU SUB production capacity is **forecast to almost double by 2023** primarily driven by the top producers. Further expansions are planned if demand growth continues in later years — The global SUB market is **dominated by four key players which jointly account for a ~90% market share**. The footprint of some of these global players in the EU is still fairly limited, however most of them are increasing their EU capacity by building new production facilities	
Demand	*The non-COVID segment comprises of ~95% of SUB demand and grows with ~20% p.a., with COVID causing a ~5% uptake in short-term demand*	— The **non-COVID segment comprises around 95% of total SUB demand** in 2021, where long-term growth of SUB demand of 20% p.a. is expected due to increasing adoption of single-use technology and the advancement of the biopharmaceutical market — **Although COVID accounts for a limited share of total demand (~5% or around 5k units in 2021), it has created additional SUB demand growth in the short term.** The Defence Act has worsened the impact of this demand effect in the EU by prioritizing US over EU demand, imposing export restrictions from US to EU	
Provided that other bottlenecks in the SUB supply chain are expected to be resolved as expected in the short-term		Current waiting times are expected to go down in the next six months when the (**upstream) capacities are fully scaled up** (i.e. 100+ components used in SUB production) and COVID backlogs are solved. **Lack of adequate personnel** and **compliance validation** are indicated to be the main challenges for capacity expansions for SUB and component production in which the (NL) government could potentially provide support.	

Key: No structural issues in the value chain expected in short-term Severe issues in the value chain expected in short-term.

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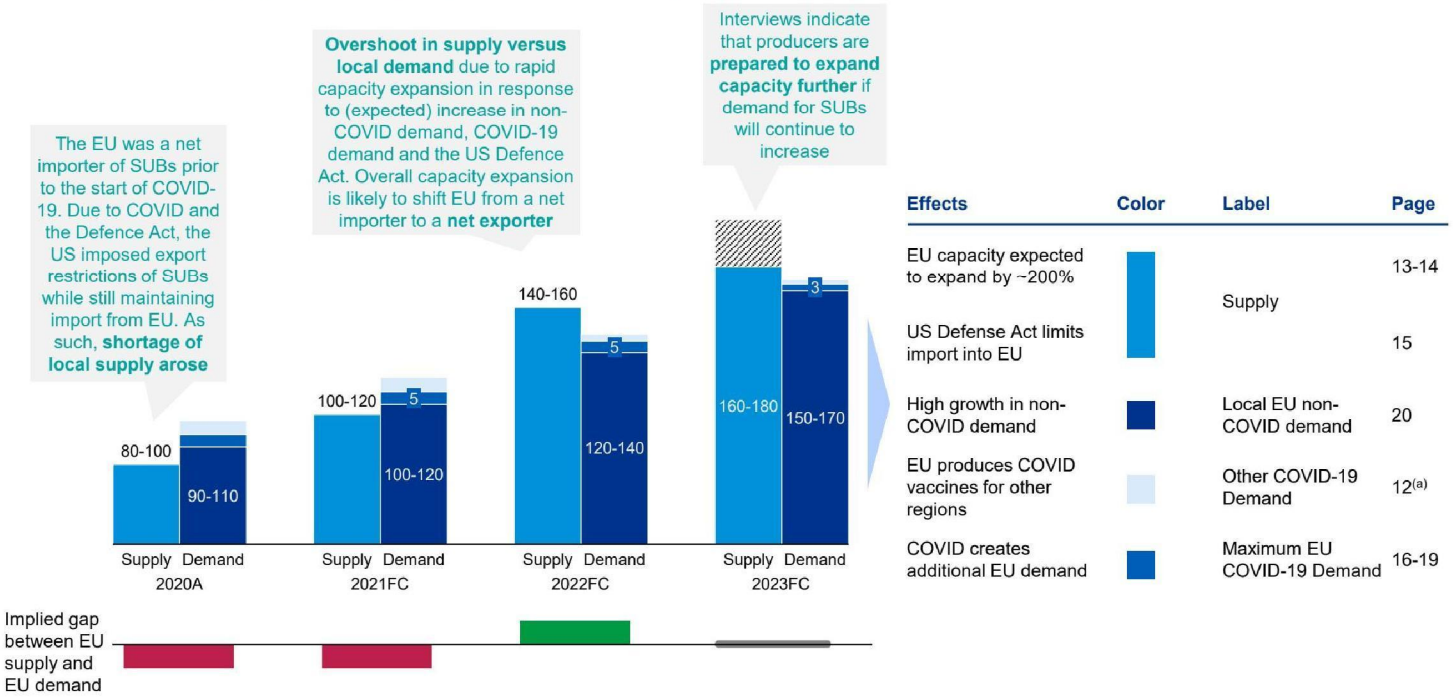
Supporting analyses

Supply versus demand

Uptick in demand due to COVID-19 and export limitations by US has resulted in a temporary disbalance, but additional capacity is expected to resolve this

EU demand and supply (production capacity estimates) of SUBs, 2020-2023FC, #000

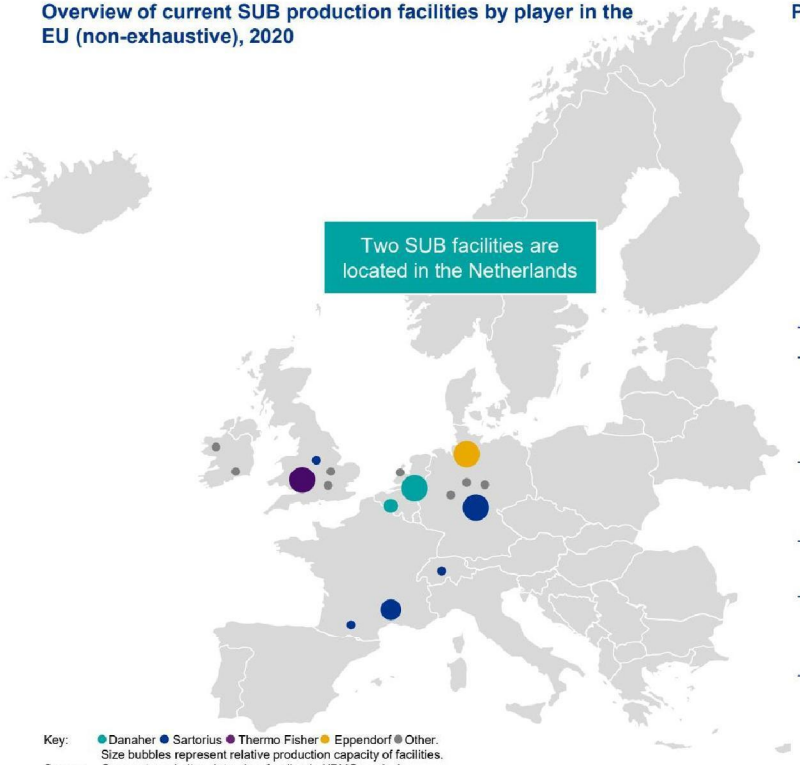


Note: (a) Other COVID-19 demand is related to production of vaccines in EU destined for other parts of the world, stocking across the industry and ongoing R&D efforts.
Source: KPMG analysis.

Supply

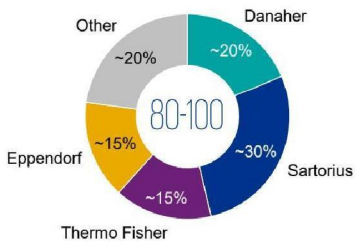
Majority of SUB production capacity is accounted for by the top-4 players, with most facilities located in North-Western Europe

Overview of current SUB production facilities by player in the EU (non-exhaustive), 2020

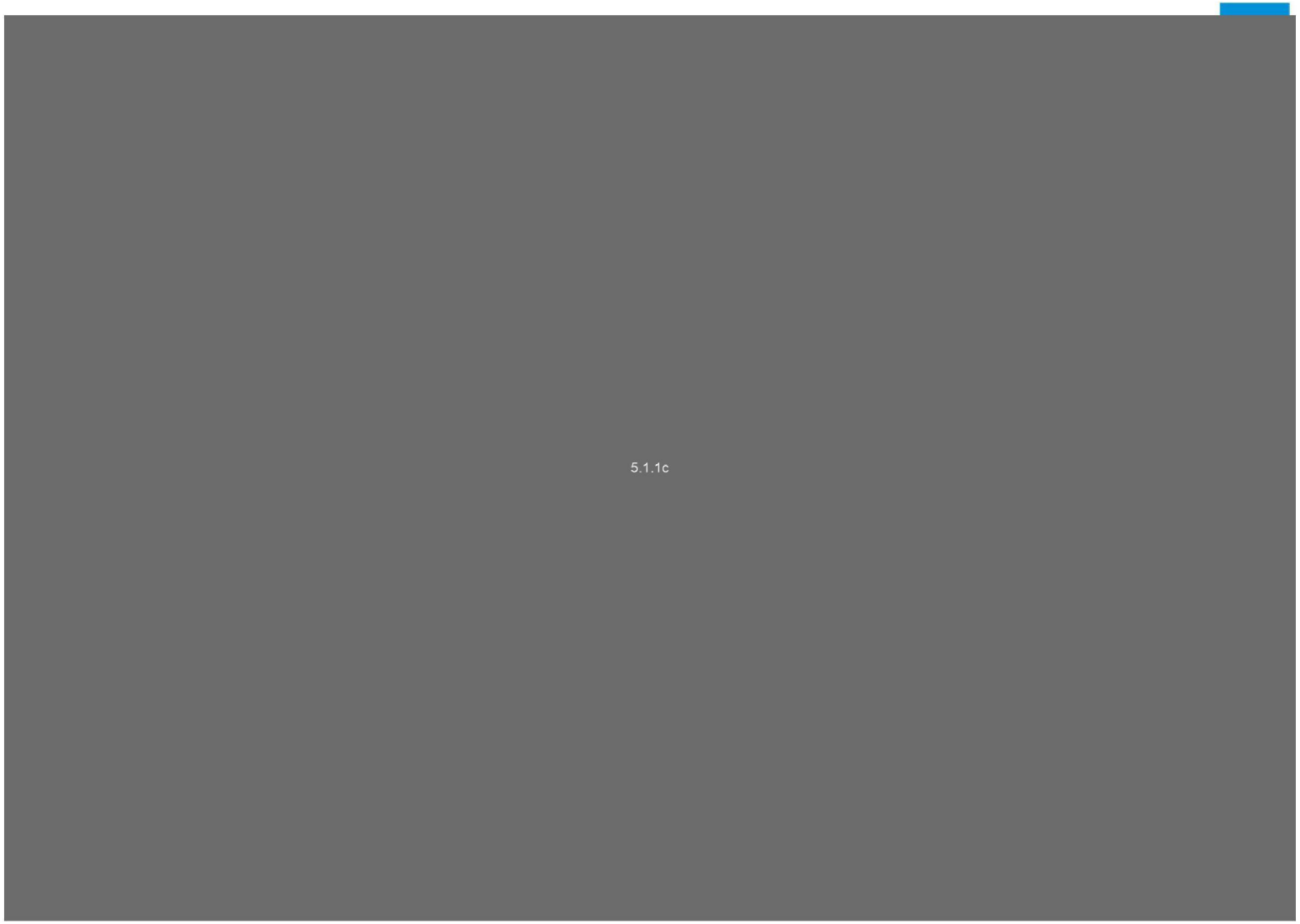


Key: Danaher Sartorius Thermo Fisher Eppendorf Other. Size bubbles represent relative production capacity of facilities.
Source: Corporate websites, Interview feedback, KPMG analysis.

Production capacity in the EU by player, 2020, %, #000



- In the EU 15 facilities are identified that are operated by ~10 players
- Merck is one of the largest global players active in the SUB segment, but currently has no EU production capacity. A new facility will be opened by Merck in France at the end of 2021 in order to serve its EU customers locally
- Danaher is the holding company of Pall, Xcellerex and Cytiva. The latter does not produce SUBs locally, while Pall also appears to import mostly from the US
- Smaller players include Repligen, Cellexus, Celltainer, Parker, Meissner, Hegewald and ABEC
- Capacity expansion is not capital intensive as SUB production is an assembly process, and requires only light investment in clean room (<€10m) and potentially the building (€10-20m) for a typical plant
- Because SUB production is economically attractive, major capacity additions are expected. Interviews suggest that due to current shortages and high demand growth there is limited risk that SUB producers will repurpose their existing or planned SUB production capacity for the production of other products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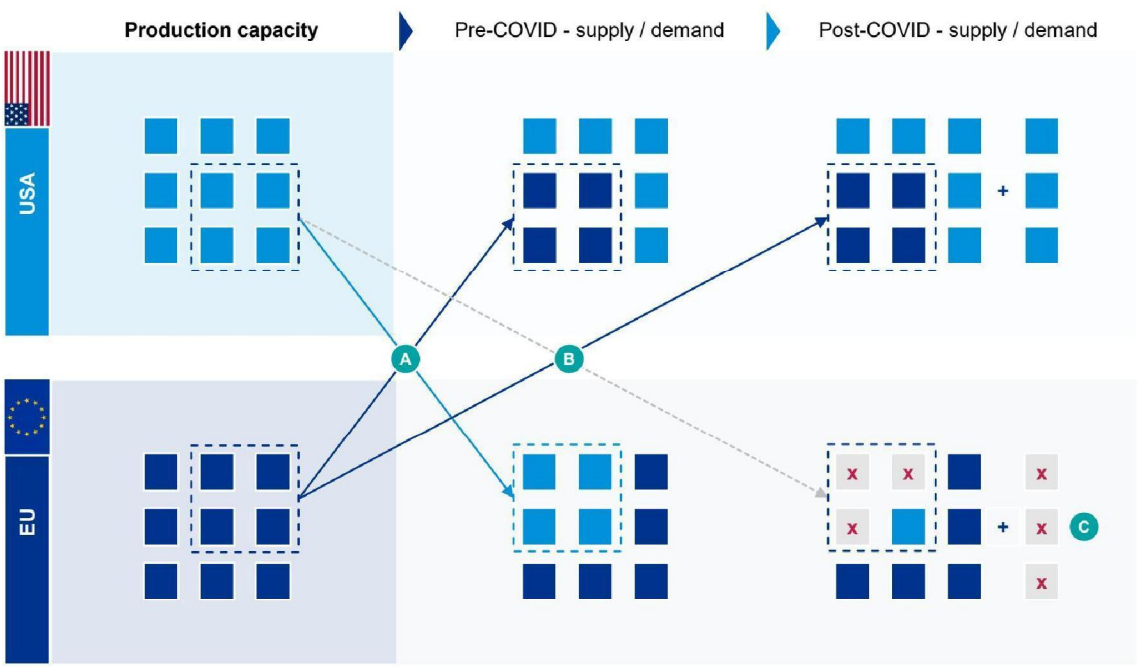
Supply

The US Defence Act has contributed to the current SUB shortages in EU due to increased local (COVID) demand, as import from the US is restricted

Conceptual explanation of the impact of COVID and the Defence Act



Note: Sizes of the effects are not in proportion to reality, and are used for illustration purposes only.
Source: Interviews feedback, KPMG analysis.

Highlights

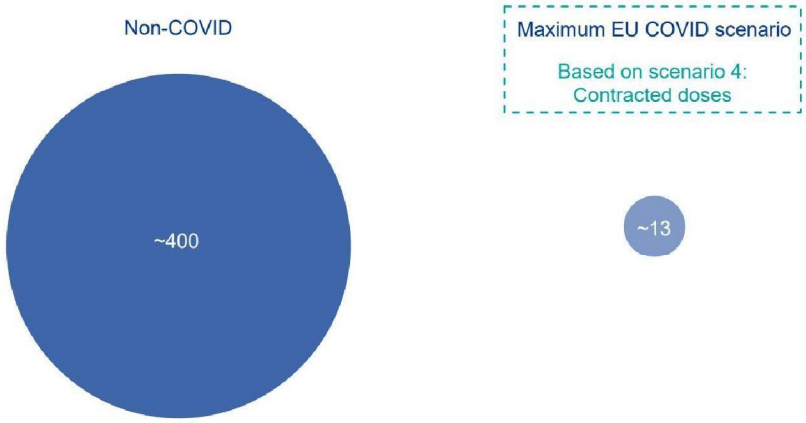
- **A** Historically a significant share of EU's SUBs were produced in the US and vice versa
- **B** Due to COVID and the US Defence Act export to EU from the US is limited, while export from EU to the US is mostly continued
- **C** As a result of the additional COVID demand in combination with the US Defence Act, most of the additional capacity will be added in EU - as confirmed by interviews with SUB producers and suppliers of SUB components

"Capacity additions in the US are limited relative to those in the EU, as recently SUB producers aim to produce 'in region for region' partly due to the Defence Act" – SUB producer

Demand

SUB demand from COVID vaccine production accounts for less than 3% of total demand over the 2021-2023 period

Cumulative non-COVID demand of SUBs in EU compared to COVID related demand[(a)], 2021-2023FC, #000



- Biologics are primarily used for treatment of conditions such as cancer, anaemia and other autoimmune diseases
- Monoclonal antibodies represent the main type of application in the biologics segment due to its ability to target unhealthy cells without harming healthy cells

- Impact of the maximum EU COVID scenario is relatively limited compared to the total underlying demand for SUBs
- Also, according to interview feedback even with COVID related orders being prioritised majority of customers are being serviced. Only customers in veterinary medicine or non healthcare related upstream or downstream processing might suffer from current shortage (very long lead times)
- As such, local supply is more than sufficient to meet COVID related and other SUB demand within EU

"Most SUB demand is coming from other non-COVID applications such a gen and cell therapy. New personalised medicines also increase demand for flexible small scale production – ideally produced with single use reactors! COVID vaccines production really is just one of many applications for SUBs." – SUB producer

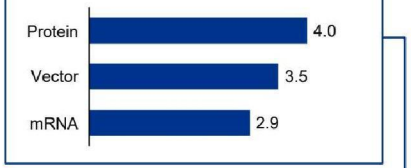
"COVID has only increased our revenue slightly by around 10-20% globally in 2021, though this unexpected uptake did contribute to longer delivery times" – SUB producer

Note: (a) Number of SUBs for COVID includes scale-up of cultivation process, failed batches, spillage and R&D activities.
Source: MPDI research institute, Businesswire, Interview feedback, KPMG analysis.

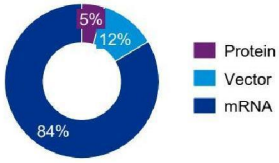
Demand

Close to 13,000 SUBs are required for vaccine production in maximum COVID demand scenario over the years 2021-2023

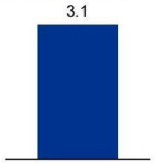
Number of SUBs per 1 million vaccines per type, #[(a)]



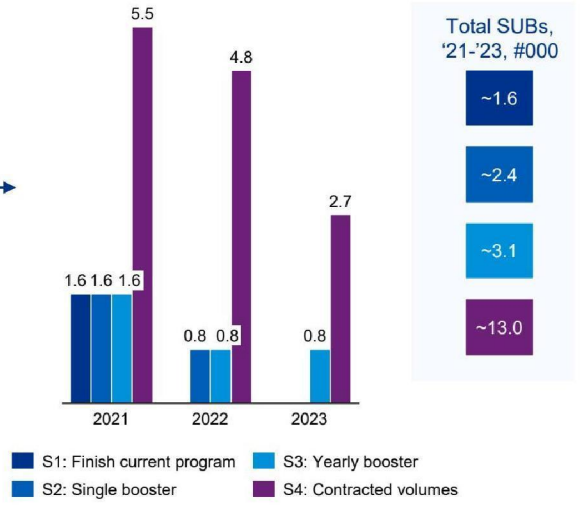
Relative share of contracted vaccines, 2021-2023, %



Weighted average number of SUBs per 1 million vaccines, #



SUBs required for COVID vaccine production per scenario, 2021-2023, #000



Total SUBs, '21-'23, #000

- ~1.6
- ~2.4
- ~3.1
- ~13.0

Number of SUBs required among the various vaccine production processes is relatively comparable driven by an implied optimal number of vaccines per batch and the number of bioreactors needed to scale up to production size. Refer to the appendix for further detail

"Even though mRNA vaccines could be produced at massive scale due to the low volume per dose, it is economically viable to produce these vaccines at small scale. If a 30 litre batch fails you lose millions, while a 1,000 litre batch failure could put you out of business. Other vaccine types are produced at larger scales." – SUB producer

Note: (a) Number of SUBs per 1 million vaccines per type includes scale-up of cultivation process, failed batches, spillage and R&D activities.
Source: MPDI research institute, Interview feedback, KPMG analysis.

Demand

Four demand scenarios are determined together with VWS to estimate the impact of COVID on SUB demand in the EU

COVID demand scenarios	Description per scenario	Impact on EU single use bioreactor (SUB) demand: Vaccines, '21-'23, #bn
1 Finish the current vaccination campaign	In this scenario only the current vaccination program will be completed: all willing EU citizens (est. 70% of adult population) will receive both a first and second dose. Afterwards the COVID vaccine production will be stopped	~0.5
2 Additional single booster	All willing EU citizens (est. 70% of adult population) will, on top of the double vaccinations that are part of the current program, receive an additional single booster in 2022, after which no further COVID vaccines will be produced for EU	~0.8
3 Yearly booster	All willing EU citizens (est. 70% of adult population) will receive a yearly booster from 2022 onwards, after completion of the current vaccination program. Production in EU will continue in this scenario	~1.0
4 Contracted doses	In this scenario the number of estimated EU vaccine demand equals the volumes contracted for by the European Commission (i.e. Pfizer, Moderna, AstraZeneca, Johnson & Johnson, Sanofi and CureVac)	~4.3

Low

High

This scenario is used in our calculations as it implies the highest number of vaccines and therefore has the largest impact on SUB demand

Assumptions per scenario are described in detail on the next page.

Source: COVID EU Vaccination Tracker, European Commission: EU Vaccine Strategy for Authorized Vaccines, KPMG analysis.

Demand

Each demand scenario is underpinned by several assumptions and datapoints

COVID demand scenarios	Assumptions
General assumptions	— Willingness to vaccinate is estimated to be 70% based on current vaccination roll-out (i.e. willingness to receive first dose) and the EU target vaccination rate — The future split of vaccines by brand in the EU (%) is assumed to follow the split of contracted vaccines by the European Commission (see table below in S4) in all scenarios — For simplicity it is assumed that all vaccines require 2 doses, as the share (%) of the Janssen vaccine is limited relative to the total vaccine volume and may be discontinued — Total adult population in EU consists of 372m individuals
1 Finish current campaign	— No additional assumptions
2 Additional single booster	— The willingness to receive a 2022 booster will equal the current willingness to be vaccinated (i.e. 70% of adult population)
3 Yearly booster	— The willingness to receive a 2022 and 2023 booster will equal the current willingness to be vaccinated (i.e. 70% of adult population)
4 Contracted doses	— EU demand equals the number of contracted doses by the European Commission — Volumes are distributed equally over time per contract based on contracting terms (i.e. delivery dates). Please find below a breakdown of volumes by year:

Contracted vaccines, 2021-2023 by type

#m	2021	2022	2023	Total
BionTech-Pfizer				2,400
Moderna				460
AstraZeneca [a]		5.1.1c		300
J&J [a]				200
CureVac				405
Sanofi-GSK				300
Novavax				200
Total	1,787	1,580	898	4,265

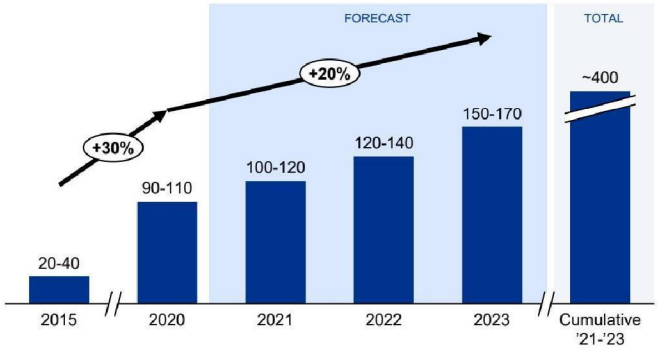
Note: (a) AZ and J&J contracted vaccination volumes have been adjusted downwards (to include only non-optional volumes) based on recent statements from the European Commission to discontinue the relationship with J&J and AZ, prioritizing mRNA vaccines Data collected by 2 August 2021. Not all contracting terms are publicly available.

Source: COVID EU Vaccination Tracker, European Commission: EU Vaccine Strategy for Authorized Vaccines, KPMG analysis.

Demand

SUB market volume is estimated at ~100k in 2021 (or ~400k in 2021-23) mainly driven by an increasing adoption rate and growth of the biopharma industry

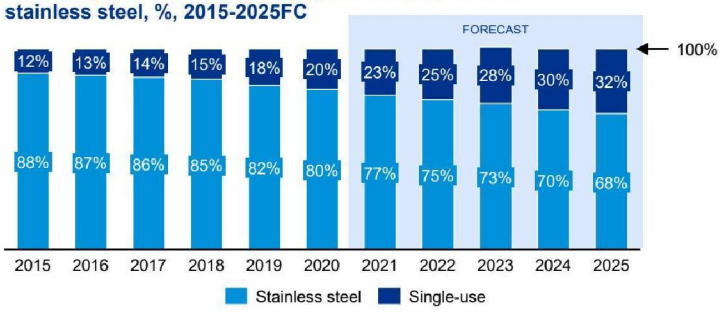
Underlying EU market development SUBs, #000, 2015-2023FC



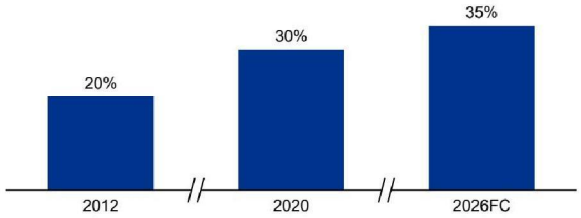
— Key reasons for the shift towards single-use over stainless steel are reduced risk of cross contamination, greater production flexibility and cost savings associated with prevention not having to clean the stainless steel set-ups

— At the same time, usage of single-use systems by existing users is increasing driven by the general market growth of the biopharmaceutical industry, primarily as the share of biologics within the global pharmaceutical market has been increasing rapidly and is forecast to continue

Relative global market share single-use equipment vs stainless steel, %, 2015-2025FC



Share of biologics in global pharmaceutical market, %, 2012-2026FC

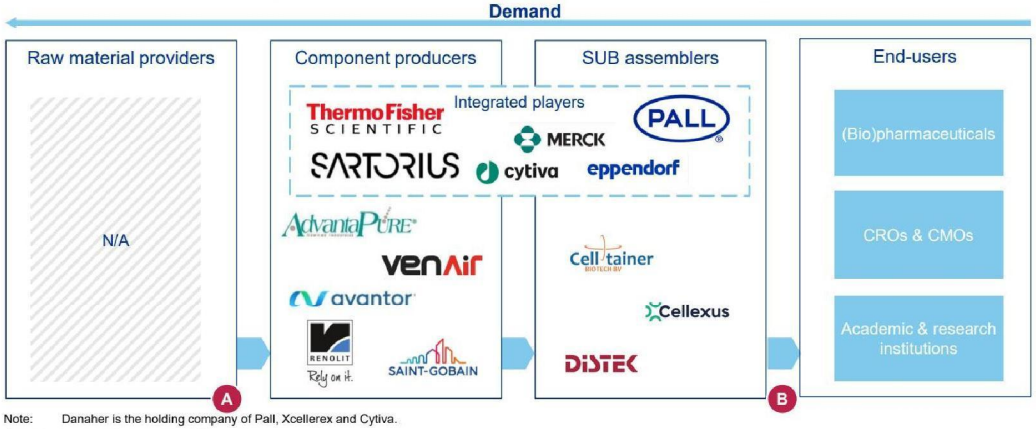


Source: Interview feedback, KPMG analysis, Exane BNP Paribas Research Report on Imaging & Diagnostics, Bioplan annual survey, EvaluatePharma June 2020.

Other bottlenecks for SUB production include waiting times due to stocking and slow upstream upscaling

Simplified value chain of SUB production, including selected players

Raw material providers	Component producers	SUB assemblers	End-users
Key materials required for the production of SUBs concern high quality plastic resins (LDPE, PP, PVA, PVC) and electronics (sensors, chips) Raw material providers generally serve a multitude of markets as biopharma accounts for just a small share of global plastic demand (<5%)	Majority of the components used by the main SUB assemblers are produced in-house Non-integrated component producers often supply both the main (integrated) players and smaller assemblers	Largest SUB assemblers mainly comprise integrated players with a strong footprint in the market of (bio)pharmaceutical equipment Smaller players are often less diversified in terms of footprint and product range	Biopharmaceutical companies represent the lion share of the end-user market



Note: Danaher is the holding company of Pall, Xcellerex and Cytiva.
Source: Interview feedback, KPMG analysis.

Other value chain bottlenecks

A Demand growth drives a capacity-addition 'ripple' effect which can take up to 1.5 year to settle upstream, especially due to the 100+ required components – *see page 22 for more details*

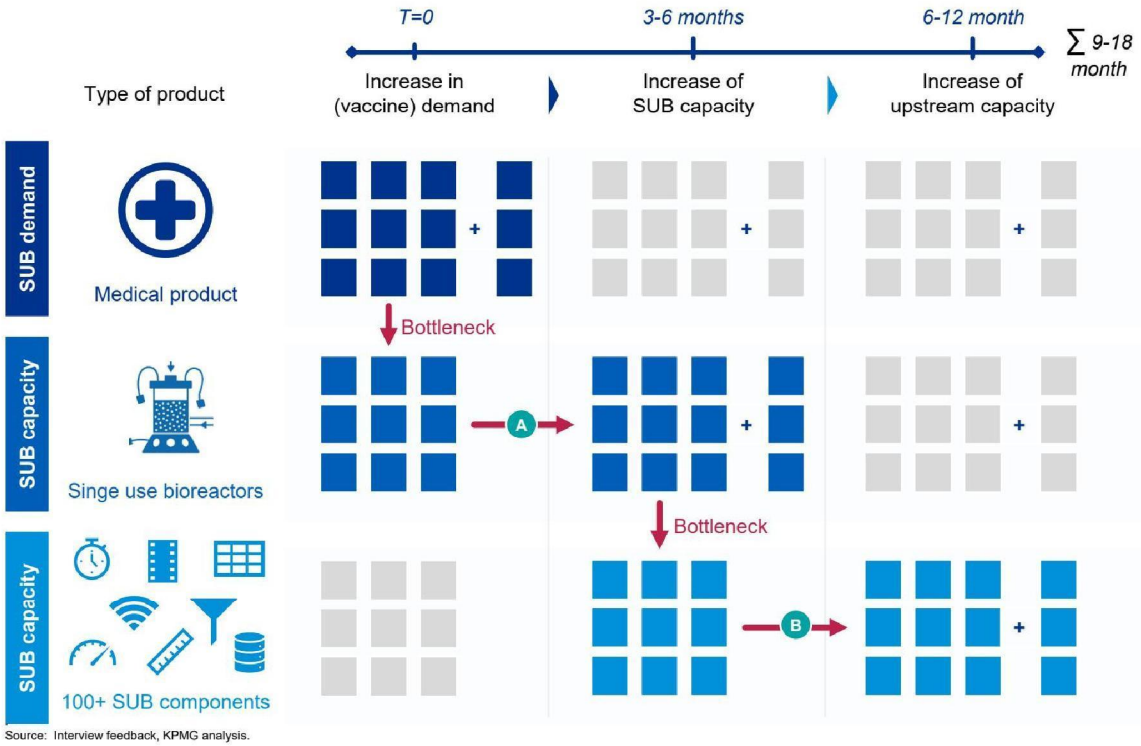
B Interview feedback suggests that waiting times are gradually decreasing as capacity additions are completed – *see page 23 for more details*

"It takes a while for our suppliers to scale up, which is why also components are now scarce in the US and Europe. Many components now have long delivery times." – SUB producer

Other bottlenecks

Demand growth drives a capacity-addition 'ripple' effect in the value chain which can take up to 1.5 year to settle upstream

Conceptual explanation of upscaling of (upstream) capacity

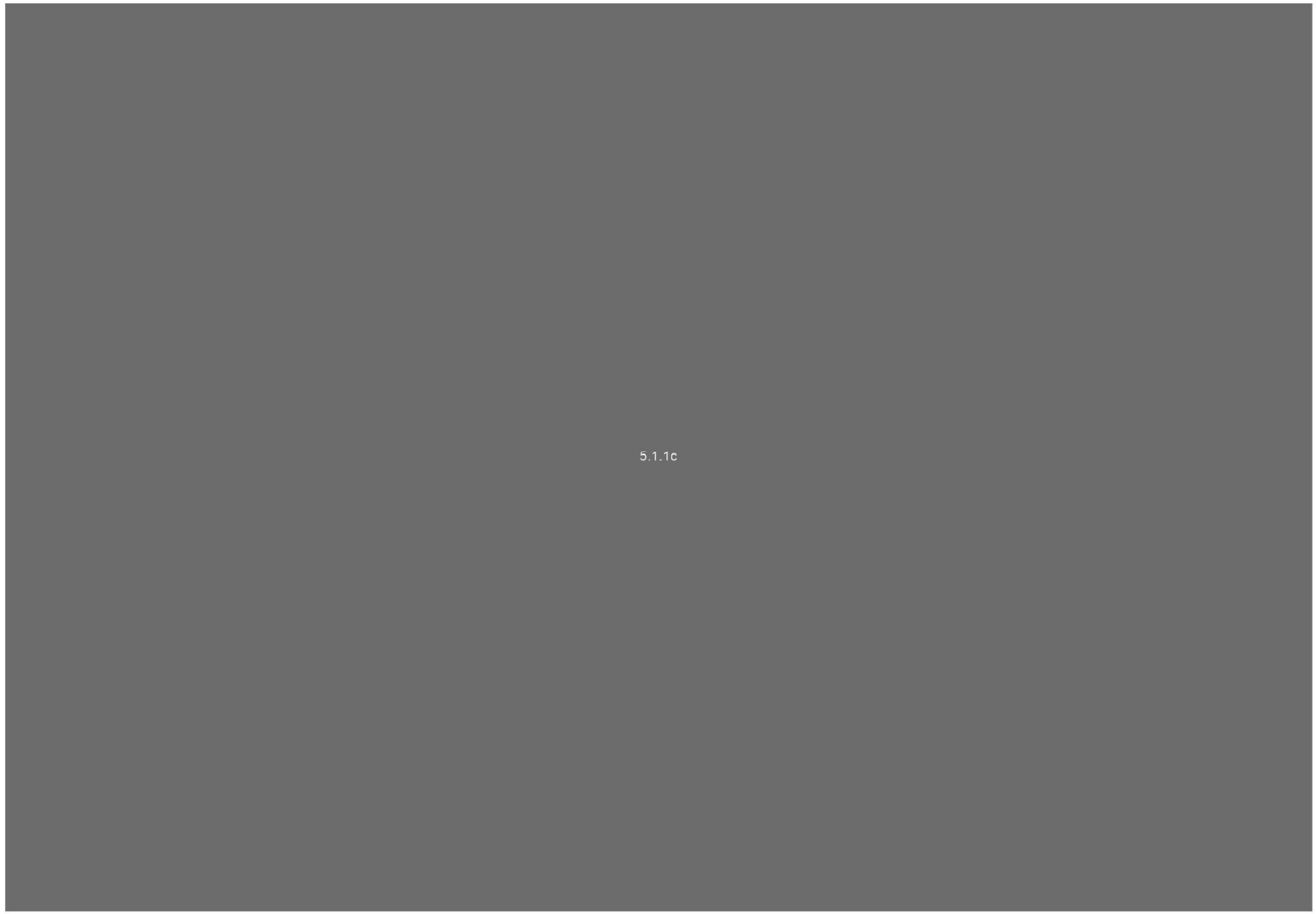


Source: Interview feedback, KPMG analysis.

A After an unexpected demand increase it generally takes only 3-6 months for SUB producers to expand their capacity volumes, limited amongst others by attracting the right personnel and by the validation of the new facility and product

B Especially the upstream adjustment of capacity can take time due to the large number (100+) components required in an SUB that are sourced from various producers. Suppliers will typically scale up *after* demand has increased, and due to COVID backlogs scale-up can take time

Total scale up time can amount to 9-18 months as SUB production is highly dependent on its components: if one component is delayed the full product delivery will be delayed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Other bottlenecks

Sector participants made several 'other' remarks on potential barriers for future vaccine and broader pharmaceutical production

Overview of 'other' recommendations to the (Dutch) government that can help protect and enable SUB production

Headline	Description and consolidated interview feedback
Finding qualified personnel has been identified as major barrier in scaling-up production	— Besides a lack of qualified 'pharmaceutical' personnel, the training of new staff is also challenging given the international nature of the market and the current COVID travel restrictions — Potential mitigation could lie in supporting training initiatives, relieving (business) travel restrictions on EU level short-term and investing in educational systems for pharmaceutical personnel in the long-term
Validation processes slow down or hamper market efficiency according to both suppliers and end-users	— Approval process for new components in the pharmaceutical production process are considered very lengthy and costly. Even for the slightest change in production set-ups or materials, often without any impact on production output, new approvals are required. This has also contributed to many interdependencies throughout the value chain from end-users to raw material providers (i.e. limited flexibility or incentive to switch or work with multiple suppliers) — Market participants have indicated that the EU (or Dutch) government can contribute to the streamlining of this validation process. For instance, by developing a common standard for certain types of components or SUBs
The US Defence Act has been indicated to amplify supply shortages	— Many players in the EU SUB market faced delivery problems due to a decrease of exports from the US, resulting from the US Defence Act that prioritises US over EU demand — Overall, trade barriers on a global level should be mitigated as much as possible by the EU or local governments
Unwillingness not to change of plastic providers negatively impacts supply of high spec plastics	— For raw material providers, especially for plastics, the biopharmaceutical market is only a relatively small share of revenues (<5%), while the quality demands are high and the overall flexibility is deemed very low. When specifications are altered this often requires new validations of the derived components, thereby imposing large delays in production — Interviews have requested regulations that for example would place key materials (with specific compositions) under a general duty to supply for a certain period, or would prioritise medical uses

Source: Interview feedback.

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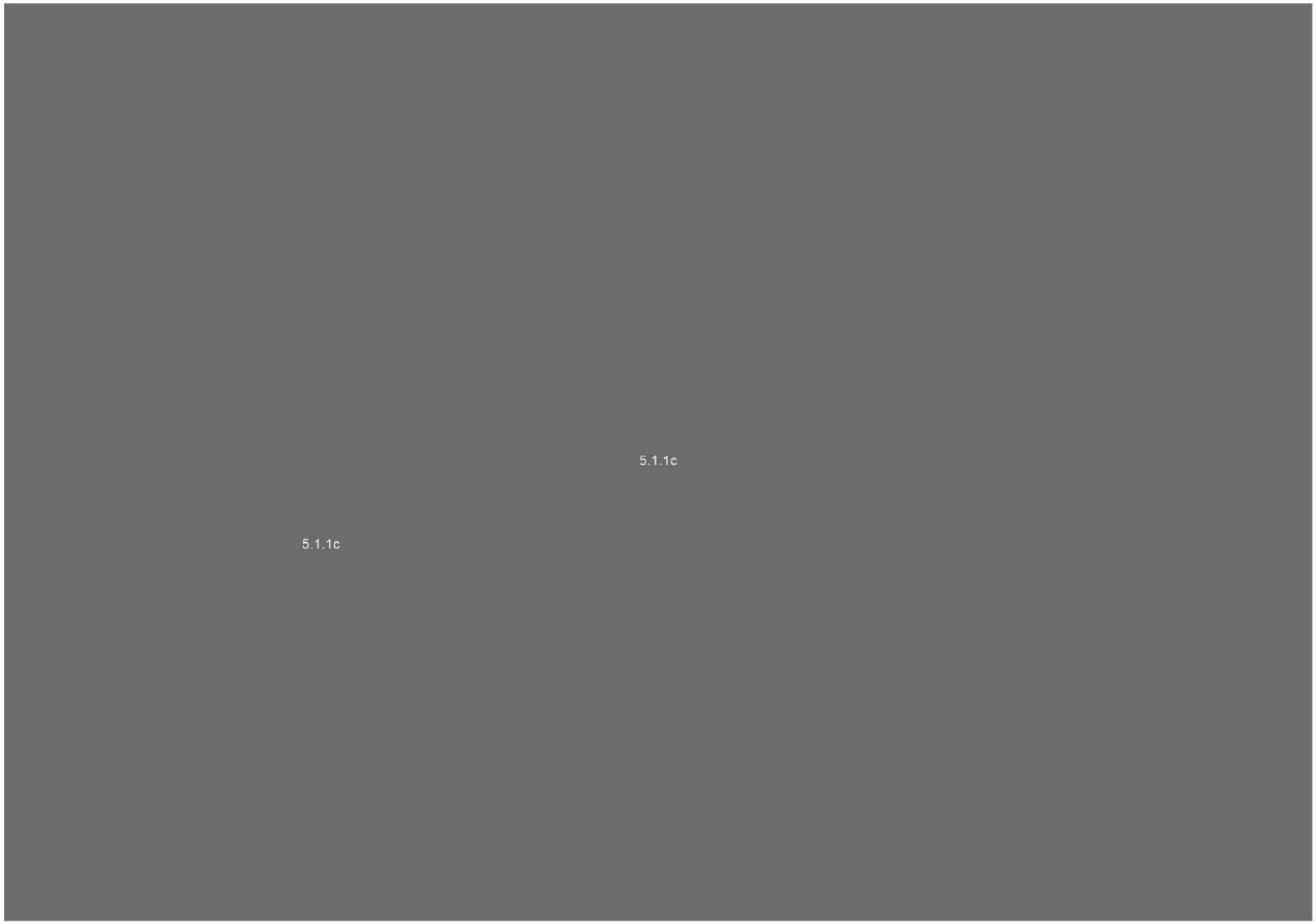
Appendix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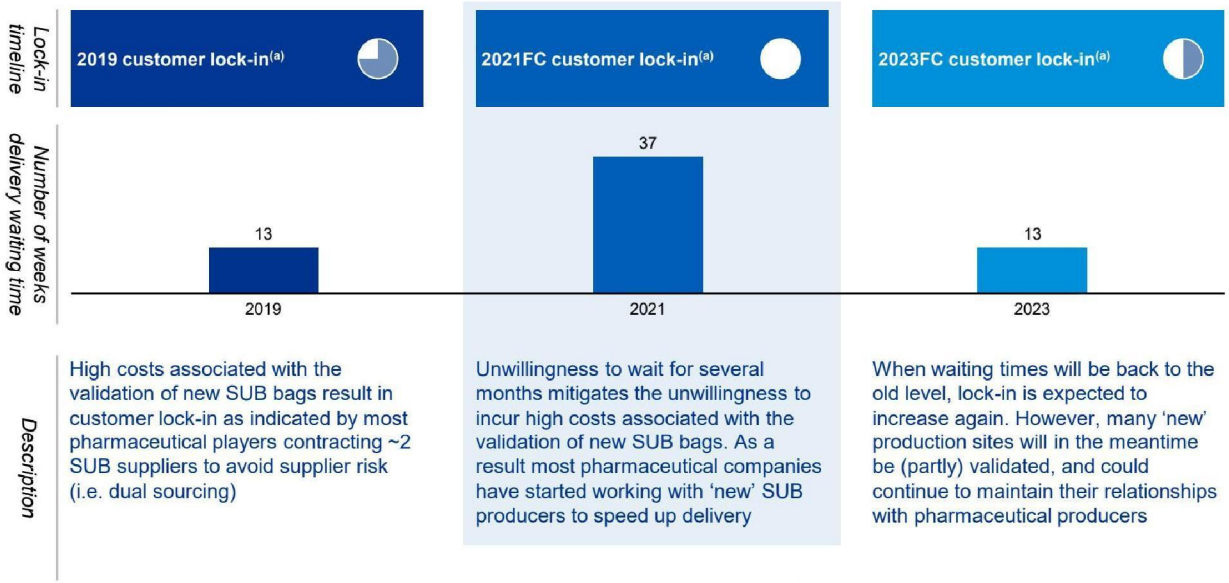
Appendix

Customer lock-in today is mitigated by opportunity costs associated with high waiting times, though lock-in might increase when waiting times decrease

Explanation of lock-in of pharmaceutical customers by SUB producers, 2019-2023FC



"The opportunity costs of not being able to produce or develop vaccines is much higher than the cost of validation, so many new SUB producers players have found their way into the big pharma." – *Market expert*

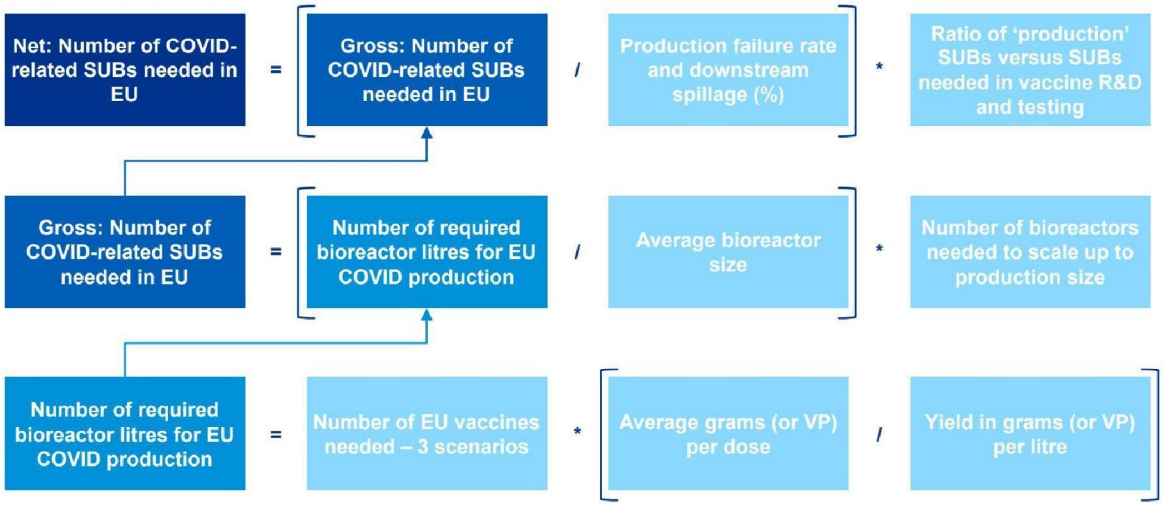
"Yes, validating a new production site is very costly and time-consuming. But with these waiting times pharmaceutical producers are willing to do anything." – SUB producers

Key: High lock-in / Low lock-in
Note: (a) Lock-in refers to the inability or unwillingness of a pharmaceutical company to switch to a new SUB provider.
Source: Interview feedback, KPMG analysis.

Appendix

Calculation of COVID SUB demand is based on expected vaccine volume/SUB applying several scientific parameters such as yield and failure rate

Overview of calculation steps



Note: Differences between mRNA, Vector and Protein vaccines have been accounted for.
Source: MPDI research institute, Interview feedback, KPMG analysis.

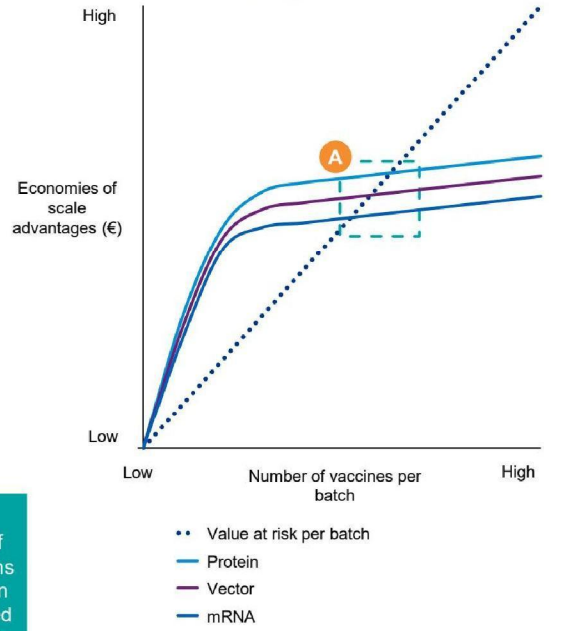
Appendix

The size of SUBs (L) per vaccine type can vary strongly but the number of vaccines per batch is in the same order of magnitude

Overview of main vaccine types

Type	Description	A Size of SUB (L)	COVID vaccine producers
mRNA	Novel technology focused on spike protein production by human body	30L-50L Most common bag size	— Pfizer — Moderna — CureVac — Sanofi-GSk
Vector	Concerns an inactivated cold virus as vessel to produce spike proteins	100-250L	— AstraZeneca — Janssen
Protein	Employs recombinant versions of the spike protein	~500L(+)	— Novavax

Simplified, conceptual economics of vaccine production per type[a], €, #



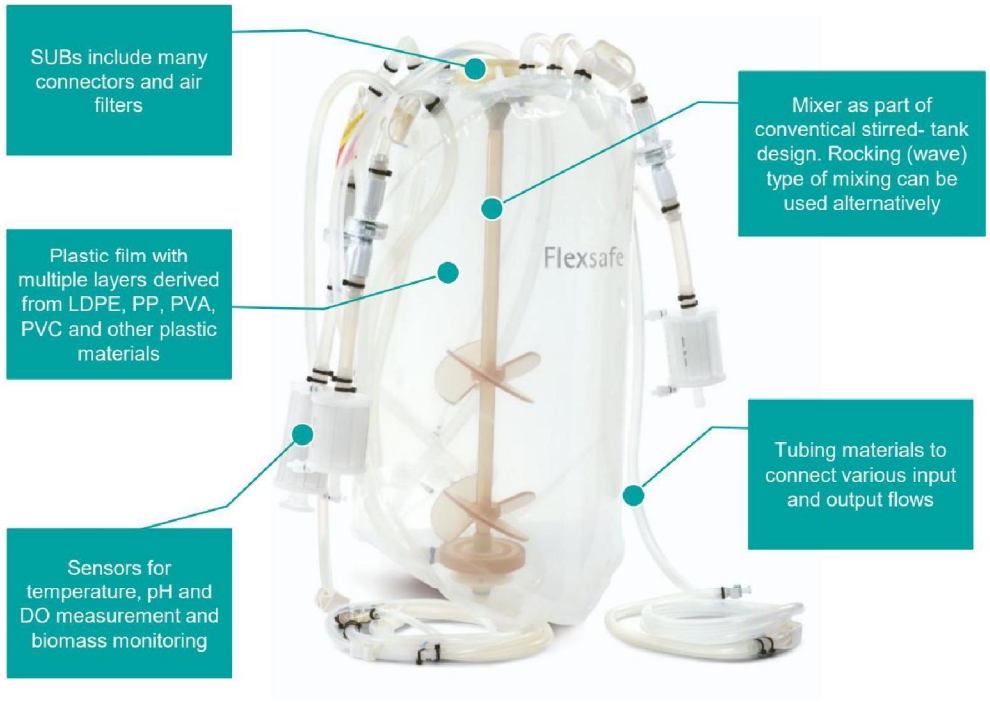
A Each type of vaccine production process exhibits very different yields (g/l) and required doses per vaccine (mg), however there appears to be an optimal point of production size per batch. This point is driven by a reducing marginal return in terms of scale advantages relative to a linear value at risk per batch (economic loss upon batch failure). As such, the size of SUBs used in each production process is implied by the optimal number of vaccines per batch (c. 2m-5m however depending on the production process additional scaling (additional SUBs) need to be incorporated)

Note: (a) Concerns a conceptual explanation, hence excludes specific price and costs components.
Source: Interview feedback, KPMG analysis.

Appendix

SUBs are complex products assembled under very strict conditions and used in a broad range of biopharmaceutical applications

Example of a SUB and its key components (Sartorius BIOSTAT STR)



Source: Corporate websites, Interview feedback, KPMG analysis.

- Type of cells which can be cultivated in SUBs mainly include CHO, NS0, SF9, E.coli, stem cells and CAR-T cells. These cells are used for a broad range of applications such as monoclonal anti body production (MAB), vaccine production and other biologics production
- Size of these bags varies depending on the specific application, however the size typically ranges from 250ml up to 2,000L. Some producers, such as ABEC, have been developing larger SUBs with volumes up to 6,000L
- Note that SUBs are produced under strict conditions in special clean rooms. To ensure sterility of the SUBs its components are often treated with gamma irradiation
- Depending on the specifications SUB prices can range from €1,000 up to even €20,000 per unit. Average price is ~ €7,000
- In addition, the SUBs are placed in holders with a broad range of connectors and sensors and with an integrated software system as well, costing easily over €100,000

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