Deliverable 10: EU FAB

RECAPI

Technical Support Instrument

Supporting reforms in 27 Member States

Funded by
the European Union

GOBIERNO DE ESPAÑA
MINISTERIO DE INDUSTRIA, COMERCIO Y TURISMO

This document was produced with the financial assistance of the European Union. Its content is the sole responsibility of the author(s). The views expressed herein can in no way be taken to reflect the official opinion of the European Union.

The project is funded by the European Union via the Technical Support Instrument, managed by the European Commission Directorate-General for Structural Reform Support.

This report has been delivered in June 2023, under the EC Contract No. REFORM/2021/OP/0006. It has been delivered as part of the project “Strategic Reserve of essential and strategic resources based on Industrial Capabilities (RECAPI)”.

Directorate-General for Structural Reform Support
REFORM@ec.europa.eu
+32 2 299 11 11 (Commission switchboard)
European Commission
Rue de la Loi 170 / Wetstraat 170
1049 Brussels, Belgium

1. Overview – EU FAB

DRAFT - PRELIMINARY

Context

EU FAB is an **EU mechanism** created to ensure that **manufacturing capacities for vaccines** are operational and can be **activated quickly** in case of a **public health emergency**

Based on the **experience** of the **COVID-19 pandemic**, it was created to **better prepare Europe** for future **health emergencies**

EU FAB is created as part of **HERA** and was published with an overall budget of **160 M€** for **700 million doses** annually

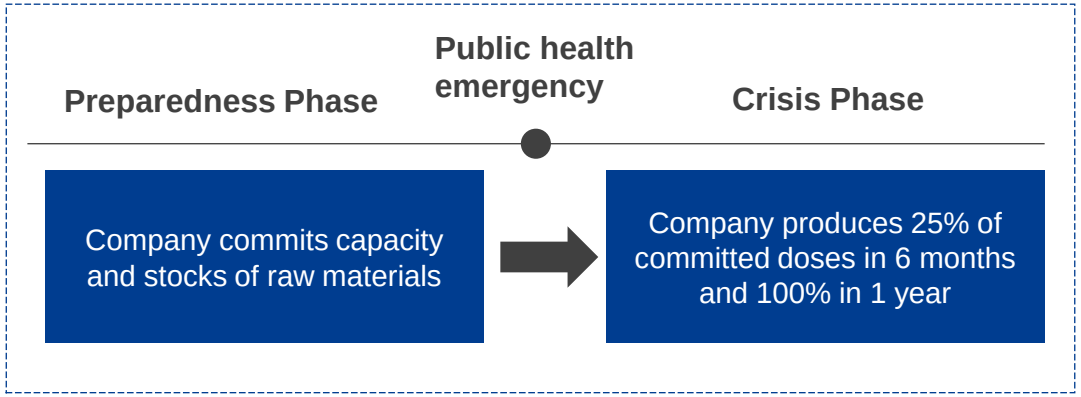
Objectives

1. Reserve manufacturing capacities

2. Obtain a priority right for manufacturing of vaccines in case of a future public health emergency

How does it work?

Detailed next



What is included?

mRNA-based vaccines

vector-based vaccines

protein-based vaccines

2. How it works – 2 phase approach

DRAFT - PRELIMINARY

Functioning of EU FAB:

When?

There is **no crisis,** reservation of manufacturing capacity

Public health emergency declared

Activation of crisis phase and **start of manufacturing**

Actions by participating company

Alternatives

1. Ensure **sufficient stock** of necessary **raw materials** and **vials** to **ramp-up capacity** to produce 25% of committed # of doses in 6 months

2. Have **preferential supply agreements** with **suppliers in the EU** or that have stocks in the EU

3. Conduct a **monitoring process** to detect **possible shortages** in time

4. **Train personnel** in the **manufacture** of this **type of vaccines**

5. Submit to an **auditing process** in the **first 4 months of the contract**

1. **Produce 25%** of the committed capacity in **6 months**

2. **Produce 100%** of the committed capacity in **1 year**

3. Contracting mechanisms – key features

DRAFT - PRELIMINARY

Cost structure included in back-up

1 EU FAB tender

Process

- **EU FAB** published **call for tender** in **April-June 2022** for **700 million annual doses** of vaccines with an overall **budget** of **160 M€**
- **Companies** proactively **submitted tenders**
- EU FAB and companies had a **negotiations** and **evaluation phase**
- EU FAB **awarded successful companies**

Participants

- **Pharmaceutical companies**
- **Contract manufacturing organizations** (CMOs) that provide manufacturing services to other companies in the **pharmaceutical industry**

Requirements

- Be **based** in the **EU or EEA countries**
- Have **manufacturing sites** in the **EU or EEA**
- Have a **sufficient manufacturing capacity** to guarantee the number of doses reserved/to be manufactured

2 Contract

Contract duration

- **From signature of contract** to **end of contracted period** (**4 years renewable** yearly **up to 8 years**)
  - **End of Preparedness phase:** declaration of **public health emergency** and entry into force of **crisis phase**

Payment terms

- **Annual payment** from EU FAB to company: **number of agreed # doses x “readiness cost” per dose**
- Payment periods:
  i. **50%** paid upon completion of **annual auditing process**
  ii. **50%** at the **end of the year**

Award criteria

- **70% quality**
- **30% price**

4. Main lessons from EU FAB experience

DRAFT - PRELIMINARY

Clear mechanism

The EU FAB established a mechanism with two clear phases (preparedness & crisis)

Defined timeline

The duration of the mechanism and timeline of the commitments is well defined

Established commitments

The commitments and expectations from all parties are well established in all phases

Committed budget

EU HERA dedicated a specific budget to the EU FAB mechanism

5. Potential areas to strengthen and proposed approach

DRAFT - PRELIMINARY

Most pronounced in pharmaceutical industry – potentially not applicable to other sectors/ products

Area to strengthen	Description	Proposed approach
1 **Ensure specificity in documentation/requirements**	**Clearly define** the list of **supporting documentation** and **requirements** in the application to the capacity reservation contract, as it is a **time-intensive** application process and may be **difficult to navigate** for first-time applicants	• Provide a **detailed list** of **required documents** complemented by **templates/examples** • Establish a **point of contact** to **guide companies** during the **application process**
2 **Reduce uncertainty about purpose of capabilities**	Provide visibility to participating **companies** on the **purpose/ conditions** – technology, context, use, price – under which they **commit capacity.** A lack of clarity may lead to **reluctance** to adhere to a **legally binding contract**	• Maintain a **partnership approach** rather than a "procurement contract" approach • Maintain **open dialogue / communication channel** to **engage with companies** both **before the tender** and **during the contractual** relationship • Include **risk sharing** provisions in the contract with participating companies to **define responsibilities during crises**
3 **Increase flexibility in ramp-up conditions given uncertainty**	**Participating companies** need to meet **ramp-up timings regardless** of other parts of the **productive process** on which **they have no control**	
4 **Increase visibility on commercial terms during crisis phase**	**Provide clarity** on the expected **final sale price** or **price structure** of the **vaccines** in the **crisis phase**	• Establish a **clear/ specific price structure** in the contract that is **foreseeable** and **set in advance** as much as possible, e.g. price is at market value, fixed % profit margin, etc.
5 **Reduce uncertainty on intellectual property**	**Define mechanism** by which one of the parties– participating companies or RECAPI – will **negotiate** and **obtain** the **IP rights to manufacture** the committed capacity	• Provide a **clear framework/process** for **negotiating and obtaining** the **IP rights** in the contract with the participating companies
6 **Address protection against takeovers**	Define mechanism in case of **takeover by a company outside EU/EEA** to avoid **control of production being relocated** outside EU and jeopardizing the **validity of the contract**	• Include a **legal provision** on this situation in the contract; or • **Include companies** in **RECAPI scheme** as **strategic** to be **protected** under **FDI Screening Mechanism regulations**
7 **Define crisis declaration process and conditions**	**Define** specifics of **the conditions under which the crisis phase may be triggered**, incl. **responsible party**, **conditions** to be met, etc.	• Include a **provision** in the **contract** to **define the requirements** and **conditions** for a public health emergency declaration
8 **Leverage diversification of participating companies**	**Prioritize diversification** of participating companies in RECAPI to: i) achieve **geographical distribution** as a **mitigant to localized crises** and ii) **minimize dependence** on a small number of "controlling" companies for **supply and prices**	• During **tender selection process,** aim to achieve **wide distribution of awards** to participating companies

Back-up – Cost structure of contract

DRAFT - PRELIMINARY

Suppliers in EU FAB scheme	# of committed doses		Readiness cost, € / dose		Total cost
Supplier 1	N of doses 1	x	€ / dose 1	=	**Total cost supplier 1**
Supplier 2	N of doses 2	x	€ / dose 2	=	**Total cost supplier 2**
Supplier 3	N of doses 3	x	€ / dose 3	=	**Total cost supplier 3**
Supplier 4	N of doses 4	x	€ / dose 4	=	**Total cost supplier 4**
Supplier 5	N of doses 5	x	€ / dose 5	=	**Total cost supplier 5**
Total suppliers				=	**Total cost of contract**

1. Estimate of unitary cost for 160M€ budget dedicated to readiness effort for 700 million doses
2. Estimate of # of doses based on EU FAB dose/population ratio (700M doses/ 447 M population) applied to Spanish population (47 M population)
3. Estimate based on EU FAB estimated unitary cost applied to estimated # of doses in Spain

Example: vaccines (based on EU FAB)

EU FAB	
Total # of doses	700 M
Total budget	160 M€
Estimated “readiness cost” per dose[1]	0,23 €
Spain – RECAPI	
Total estimated # of doses[2]	74 M
Estimated “readiness cost” per dose (EU FAB)	0,23 €
Total estimated budget[3]	17 M€

Visit our website:

Find out more
about the Technical
Support Instrument:

Funded by
the European Union