Expression of Interest:

Vaccine Drug Products in alternative primary packaging and delivery devices

CEPI is requesting information from vaccine developers and their vaccine manufacturers, who are looking to establish additional primary packaging and fill/finish capacity, and/or are interested in a novel delivery device that facilitates mass vaccination. An associated vaccine candidate may be in development for use in the current COVID-19 pandemic, or for another disease that requires immunisation at large scale.

This document describes the scope, requirements and process for submission of information. The Expression of Interest (EOI) will remain open while the delivery device development progresses, and we will review applications on a rolling basis for their fit with the project. Information gathered through this EOI will be the basis for a potential partnership to develop the vaccine drug product in the novel container or device and bring this to market in collaboration.

1. Introduction

The COVID-19 pandemic is a global humanitarian and economic crisis - unprecedented in modern times. Developing safe and effective vaccines is our best chance of an exit strategy and the best hope of saving lives and getting the world's economy back on its feet. CEPI has moved quickly and urgently to catalyse and accelerate vaccine development, working with vaccine development partners to make investments where they can have most impact. Built on the principles of speed, scale, and access, CEPI has created the world's largest COVID-19 vaccine portfolio to date, supporting the development of nine COVID-19 vaccine candidates. CEPI is also co-leading COVAX, the vaccine pillar of the Access to COVID-19 Tools (ACT) Accelerator to develop, manufacture, and distribute 2 billion doses of COVID-19 vaccine by the end of 2021 to end the acute phase of the pandemic.

In addition to developing its own portfolio, CEPI is supporting programmes to benefit other vaccine developers, including through its centralised laboratory network, assessment of vaccine manufacturing capacity, and primary packaging for the storage and delivery of future COVID-19 vaccines

As part of this broader effort, CEPI is exploring advancement of a novel multidose Drug Product presentation, the 200-dose bag developed by INTACT Solutions, a subsidiary of MEDInstill. These bags are made from multilayer film with proven biological and chemical compatibility and freeze/thaw stability, and contain ports for sterile closed filling and dispensing, either via a multiuse pre-metered syringe or via a luer lock port. Both contain a one-way anti-retro-contamination valve that ensures container-closure integrity and sterility are maintained during dispensing of the 200 doses. The

sterility and integrity of the bag designs are being validated in different conditions by microbial challenge experiments.

An innovative, passive auto-disable, sharps-injury-prevention, intra-muscular metal needle fits with the multidose syringe bag, and completes the device as a fast, high-capacity, low-cost solution for mass vaccination, with the ease of use of a prefilled syringe. More information is provided in videos that explain the use of the technology for outbreak response (https://youtu.be/AsaEladCEG8), compare vaccination procedures from a vial, the luer pouch and the multidose syringe pouch (https://youtu.be/wihmbPZNqWk), and demonstrate the possibility of a socially-distanced vaccination campaign (https://youtu.be/NE1gjtX72as).

CEPI and INTACT Solutions are exploring this delivery device from the technical, regulatory and usability points of view. The aim of this Expression of Interest is to identify vaccine developers and manufacturers who are interested in deploying this solution for their vaccine candidates, for COVID-19 or other pathogens requiring mass vaccination campaigns. The planned solution can substantially increase Drug Product capacity, decrease cold chain footprint and cost of goods, and differentiate the vaccine in the market by offering the user experience of a prefilled syringe.

2. Objectives and scope of this Expression of Interest (EOI)

The objective of this EOI is to identify organisations and their manufacturing partners with capability and interest to develop their vaccine candidate Drug Product in one of the INTACT Solutions presentations (multidose bag with multiuse syringe or with luer lock port). The vaccine candidate may target COVID-19 or another disease requiring vaccination campaigns at large scale.

Once a partnership has been established, CEPI, INTACT and the vaccine developer and their manufacturers will work together to take the necessary technical, regulatory, manufacturing, and implementation steps to develop the vaccine in this presentation and get it deployed. CEPI and INTACT will advance the device development from the technical and manufacturing sides, and perform generic studies into e.g. the container-closure integrity and sterility under challenging conditions. The vaccine developer will perform product-specific studies such as: long-term and in-use stability, and leachables studies. Regulatory and user acceptance will be a joint effort, potentially with additional partners.

3. What kind of organisations does CEPI request information from?

The vaccine developer may be a non-profit or for-profit organisation, product development partnership, government research organisation or intergovernmental organisation. We are looking for developers that have a COVID-19 vaccine in development, or another vaccine candidate or marketed vaccine for which large-scale vaccination campaigns are foreseen; all technology platforms are in scope. The vaccine candidate is preferably in clinical development, or a clear rapid chemistry, manufacturing and controls (CMC), clinical and regulatory plan for taking the vaccine forward is provided.

The bags are an ideal solution for developers who wish to solve one or more of the below issues.

- Drug Product capacity: Because of the 200-dose format and rapid fill/finish process, the INTACT Solutions bags provide a substantial increase in Drug Product capacity. Developers with an excess Drug Substance capacity can thus increase their overall dose volume using this solution.
- Cold chain capacity: The cold chain footprint is about half that of a 10-dose vial, which allows larger numbers of doses to be shipped and stored in a wider geographical area, at reduced costs. This is an advantage especially for vaccines stored at (ultra)low temperatures.
- Mass vaccination: Because of the increased capacity as well as the fast immunization process, the INTACT Solutions bags facilitate mass vaccination.

- Costs of goods: The primary packaging costs are ca. $0.02 – 0.04/dose, or $0.14 – 0.16/dose including the auto-disable, sharps-injury prevention needle, making this a very attractive solution from a costs perspective.
- Differentiation by ease of use: The first wave of COVID-19 vaccines will mostly be in non-preserved multidose vials, delivered by separate single-use syringes and needles, with leftovers discarded at the end of the session. The INTACT Solutions bags provide a differentiation in presentation, combining the ease of use of a prefilled syringe with the capacity of large multidose presentations. Because of the retained sterility, leftovers do not have to be discarded and wastage is reduced.
- Bedside mixing or dilution of drug product: Some vaccines may require mixing, for example of an antigen and adjuvant, or dilution in the case of a concentrated Drug Product. The INTACT Solutions bags can be divided into two compartments, allowing easy and sterile mixing or dilution in the field.

4. Information requested

To submit your EOI, please provide information on the following:

- Your vaccine candidate and targeted pathogen;
- The clinical phase of your project and high-level clinical development plan with timelines;
- Currently intended Drug Product presentation and storage temperature;
- Estimated annual Drug Substance and Drug Product manufacturing capacity and partner if applicable;
- Any specific issues you are aiming to solve, as listed under (3);
- Existing stability data of your product in contact with multilayer plastic film.

5. Submission of information

Please submit information in PDF format within max three pages, covering the questions above to eoi@cepi.net. Applications will be reviewed on a rolling basis.

All information submitted will be stored in a restricted access repository.

6. Technical and administrative questions

Technical and administrative questions about this EOI should be directed to the CEPI Secretariat (**eoi@cepi.net**).