

## CASE STUDY

# Partnering in Global Health Market Development

## Pharmaceutical Partner Introducing New Sterile Vaccine Product

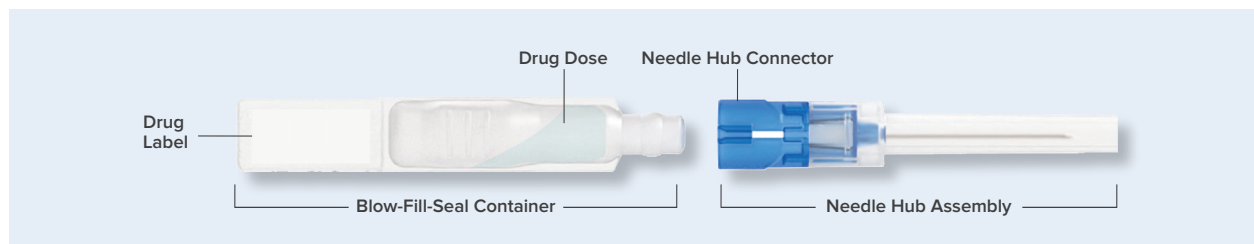
HIPRA, EU-based biotech pharmaceutical company, was developing a recombinant protein vaccine against SARS-COV-2 and was looking for an experienced partner to work with in order to improve the adoption of its vaccine in global markets.

## Project Description

HIPRA engaged with ApiJect to strategize the best path toward to achieving global market acceptance and penetration. HIPRA chose to work with ApiJect because our history, technology, and expertise were the right match for their two primary challenges:

- (1) Developing a scalable, cost-effective injection device that combined with their recombinant protein vaccine could overcome the major barriers for vaccine uptake and would be suitable for global health authorities and markets.
- (2) Accessing these markets in an efficient and timely manner.

## The Prefilled ApiJect Injector System\*



## Strategic Plan

In 2023, ApiJect's device, manufacturing, and global health teams worked onsite at HIPRA's facility in Spain to identify the best path forward. Fareva, a French pharmaceutical and outsourcing company, who is the manufacturer of this product for HIPRA, was also a key partner. This device was the right path forward for global health markets because:

- Operational and manufacturing cost-savings due to efficient BFS process.
- Compact and reliable supply chain since BFS relies on only two raw materials.
- Fast startup manufacturing of BFS allows for rapid response to sudden increase in vaccine demand.
- Provides attractive product differentiation over traditional vial and syringe options.
- Prefilled format enables desirable ease-of-use administration at same cost as single dose vial+ syringe.
- Single-use design ensures a high level of safety while realizing cost savings.

To achieve market access, ApiJect's global health team worked with HIPRA to identify the right stakeholders to engage, the right ways to approach them, and how HIPRA's product served their market needs. One of the complexities with global health is that different stakeholders need to be engaged in the correct order. ApiJect identified this process for HIPRA and how our team could assist with introductions that would start them on the right path.

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## Result

While program is still ongoing, all project objectives have been met or are on track to being achieved.

- A prefilled injector has been designed, accepted, and taken through frontline user focus testing. While testing remains ongoing, the product has remained on its agreed development schedule.
- Key stakeholders at WHO, UNICEF, GAVI, and multiple global health markets have been actively engaged and are encouraging HIPRA to submit the final product for regulatory approval once it is ready.
- Helped define go-to-market strategy by understanding the order tender process that most of the global health markets use to purchase pharmaceuticals.
- Important cost and manufacturing agreements have been identified and committed to which achieve all parties' financial and growth goals.
- Joined important global health events and commissions (e.g., HIPRA became a member of the EU FAB project of the European Commission as a strategic partner for the development and production of vaccines).

Overall, HIPRA's product has been well received by many of the important constituents in their targeted global health markets, both because of its testing results as well as its prefilled presentation.

## Conclusion

While the development process is not complete, this partnership has shown the range of high-quality technical assets that ApiJect can bring to any future drug development partnership to global markets and their patients with more access to the medicines and vaccines they need.

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## ApiJect's Global Health Team

Led by former WHO officers Ed Kelley, PhD and Paul Rutter, MD, ApiJect has a growing global health team focused on designing devices for global markets to enable more injectables to reach more patients that need them.

Our team works with frontline patient organizations to get feedback from health professionals on device reactions and human factors usage. The global health team also works with local health ministries and healthcare funding organizations on how ApiJect's device platform can overcome their challenges of injection access, supply chain, and safety.

This highly-experienced and growing team at ApiJect can be an invaluable asset for companies developing injectable products for global markets.

### Ed Kelley, PhD



Dr. Kelley is the chief global health officer at ApiJect. Previously, he served as the WHO Director of Integrated Health Services, creating WHO's first public-private collaboration working directly with the pharmaceutical and medical device industry to improve health services and patient safety.

### Paul Rutter, MD



Dr. Rutter is the SVP of Clinical Affairs at ApiJect. A British public health physician, he previously served as WHO's Chief Operating Officer for the Polio Eradication Program, as UNICEF's Regional Health Adviser for Southeast Asia, and as clinical adviser to England's Chief Medical Officer.

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