

# Production of major therapeutic interest drugs: example of pancuronium bromide

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## Introduction

- COVID pandemic has deeply affected the efficiency of the production and distribution capacity of drugs.
- The increase in use of certain drugs causes **supply tensions**, particularly for drugs of major therapeutic interest (DMTIs), as it happened for **curares**.
- Possible drug shortage : The COMEDIMS, the Direction & the College of Specialties have requested the unit to produce **injectable curare preparations**.

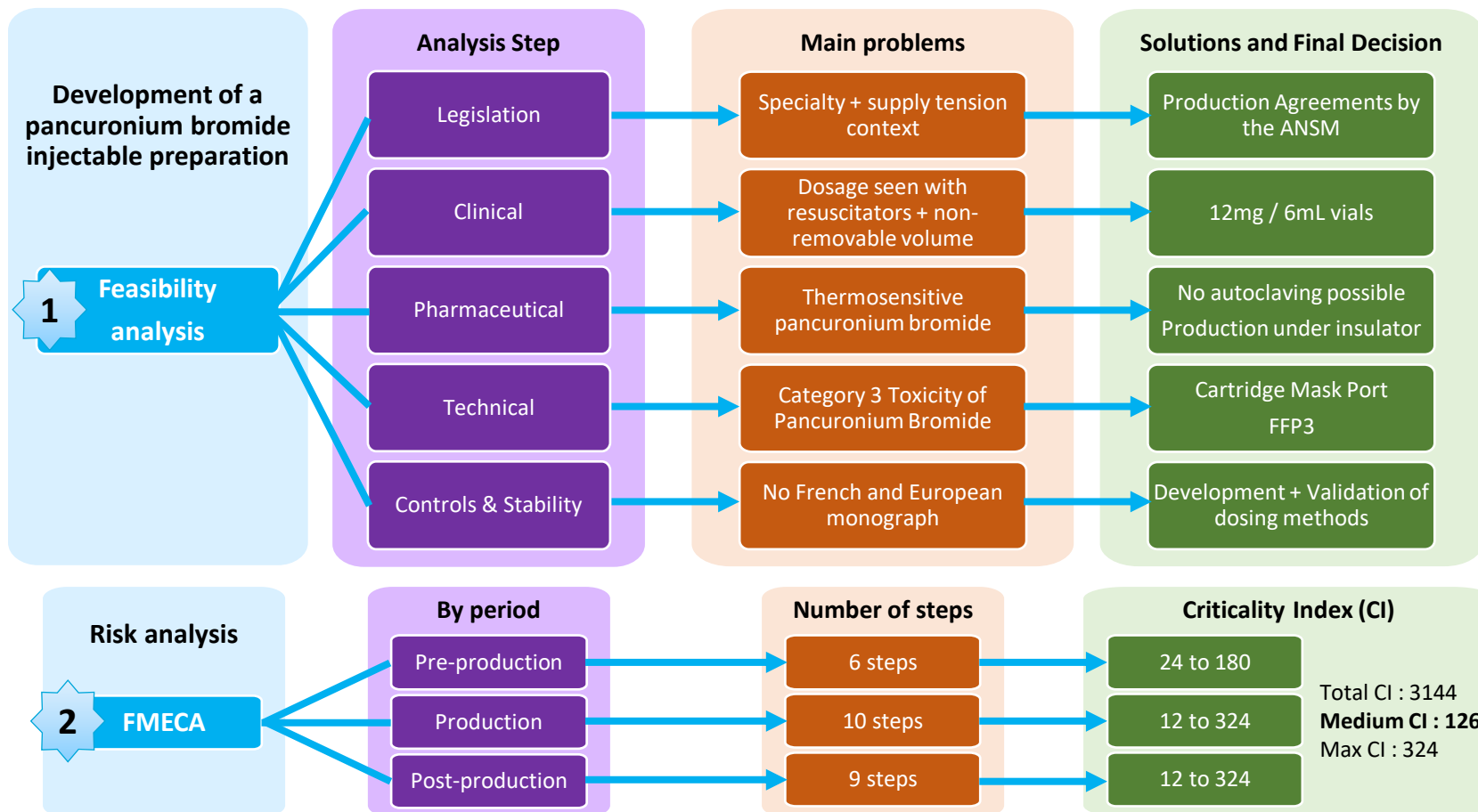
## Objective

Develop the production of an injectable pancuronium bromide solution

## Materials & Methods

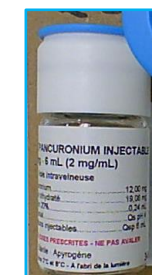
## Results

## Discussion & Conclusion



✓ Feasibility & risk analysis were favorable

📌 Formulation developed → From an existing specialty



**FAB step** → weighing under a laminar flow hood, mixing step in class B, filtration in class A and distribution with filtration and capping/sealing under an isolator. Vial control with the candling method, labelled, packaged and stored between 2 and 8°C.  
→ Batches contained between 545 to 1090 vials, with a volume of 6 mL each.

🔬 **Physico-chemical CTRL** → macroscopic aspect, vial leakage test, pH, osmolality, invisible particle count, preparation uniformity and content testing by high performance liquid chromatography.

**Microbiologic CTRL** → bacterial endotoxins, sterility testing and "Bact/alert" vial inoculation

→ 5000 units were produced and controlled, 100% were found to be conformed.

⚠️ → The production carried out between April 23<sup>rd</sup> and May 14<sup>th</sup>, 2020, allowed the formation of a preventive stock.