IFPMA International Federation of Pharmaceutical Manufacturers & Associations | Fédération Internationale de l'Industrie du Médicament | Federación Internacional de la Industria del Medicamento | FIIM

Considerations for Primary Vaccine Containers

IFPMA Perspectives: What are the issues?

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On behalf of the IFPMA Vaccines Committee

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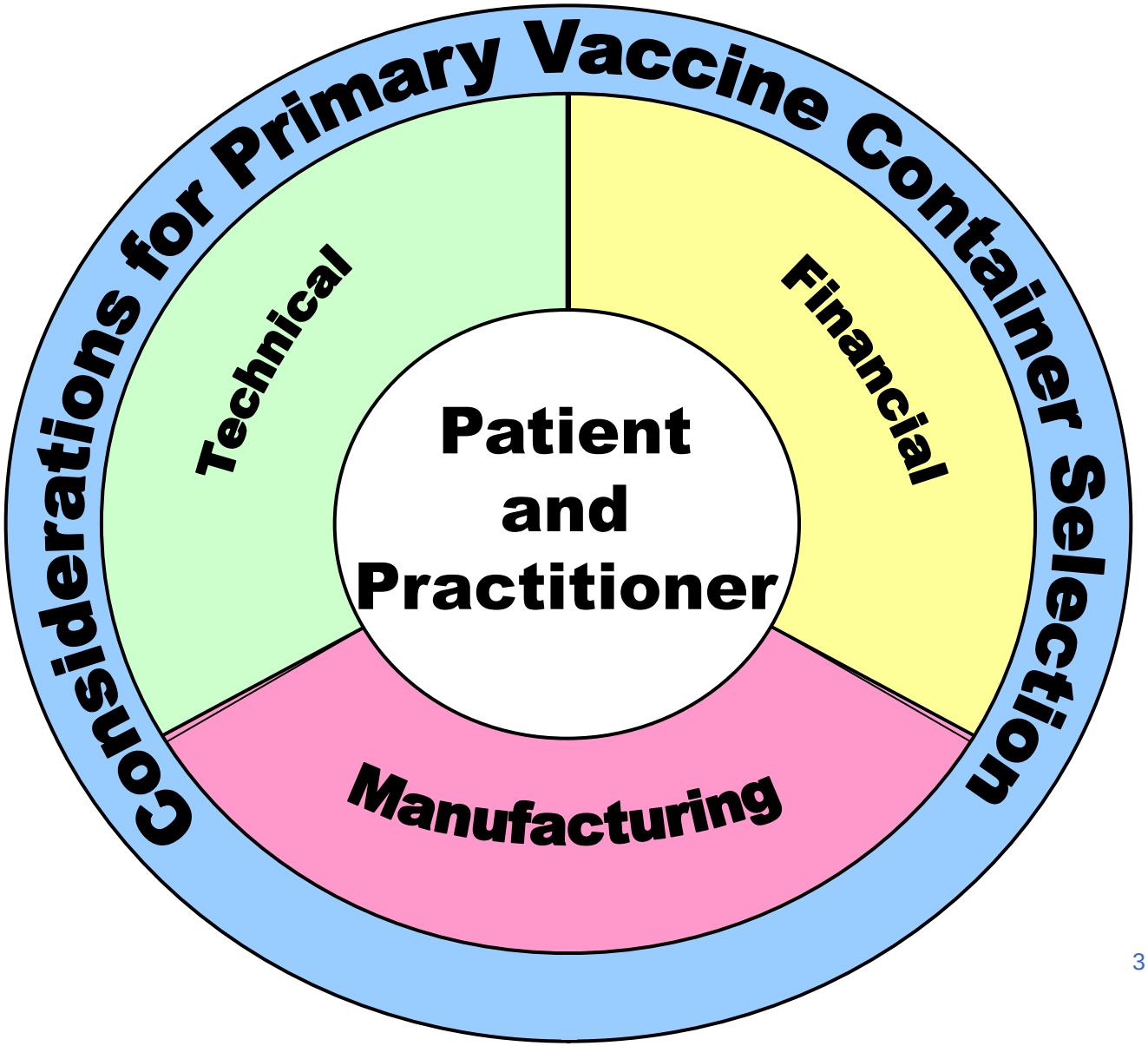
The IFPMA in brief

- Non-profit NGO represents the research-based pharmaceutical industry worldwide
- Membership
  - R&D-based biopharmaceutical companies in Europe, India, Japan & USA
  - National Industry Associations, from all 5 continents
- Official observer status with UN in Geneva, including the World Health Organization, WIPO, WTO, etc.
- Advocates policies supporting innovation, high quality standards and sustainable access to medicines for patients around the world
- Provides the Secretariat for the International Conference on Harmonisation (ICH)

General Considerations



Manufacturing Considerations

- **Machinability** (How the components run on the line)
- **Supply chain**
  - Assurance of reliable supply of components
  - Standard v. unique components
- **Fill volume**
  - Residual volumes and overfill
  - Splashing for high fill products
- **Validation requirements**
  - Materials, Process, Shipping, Cleaning and Sterilization
- **Compatibility with vision inspection systems**
- **Compatibility with secondary packaging lines**

Technical Considerations

- **Stability studies**
- **Material compatibility**
- **Container closure integrity**
- **Extractables and leachables**
- **Moisture vapor transmission rate in some cases**
- **Functional performance**
- **Common issues**
  - Coated vs. uncoated stoppers
  - Impact of silicone
  - Thermal stability performance
- **Transportation**

Financial Considerations

- **Direct component costs**
- **Development costs**
  - Stability studies, Container closure integrity, Machinability, Extractables/ leachables, Antigen sparing
- **Manufacturing costs**
  - Capital cost for manufacturing line modification
  - Ongoing line changeover costs to switch between images
  - Geographical / siting
  - Fill volume and overage
- **Quality failure financial liability**
- **Lifecycle Management**
  - Suppliers (siting, material, etc), Vaccine manufacturers (standardization, etc), Regulatory mandate

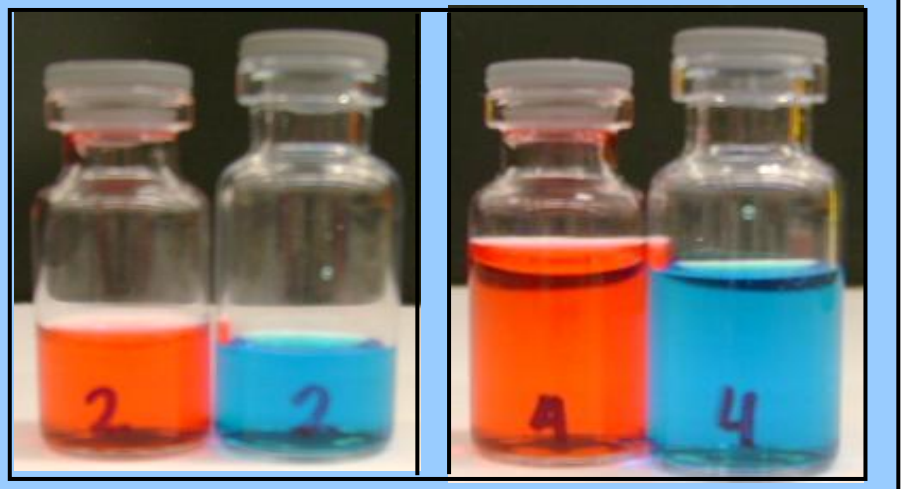
Evaluating technical and manufacturing considerations costs time and money!

Financial Considerations

- **Primary container changes**
  - Similar to new development
  - Stability studies, Container closure integrity, Machinability, Extractables/ leachables
  - $1-3MM USD, 1-2 years to market in some cases
- **Syringe vs. vial unit costs**
  - Pre-filled syringe may cost up to 20 times vial cost per single dose
- **Glass vs. plastic vial**
  - "Plastic" tube vials may cost 10 times glass cost per single dose
  - Blow fill seal vials may cost 2 times glass cost per single dose

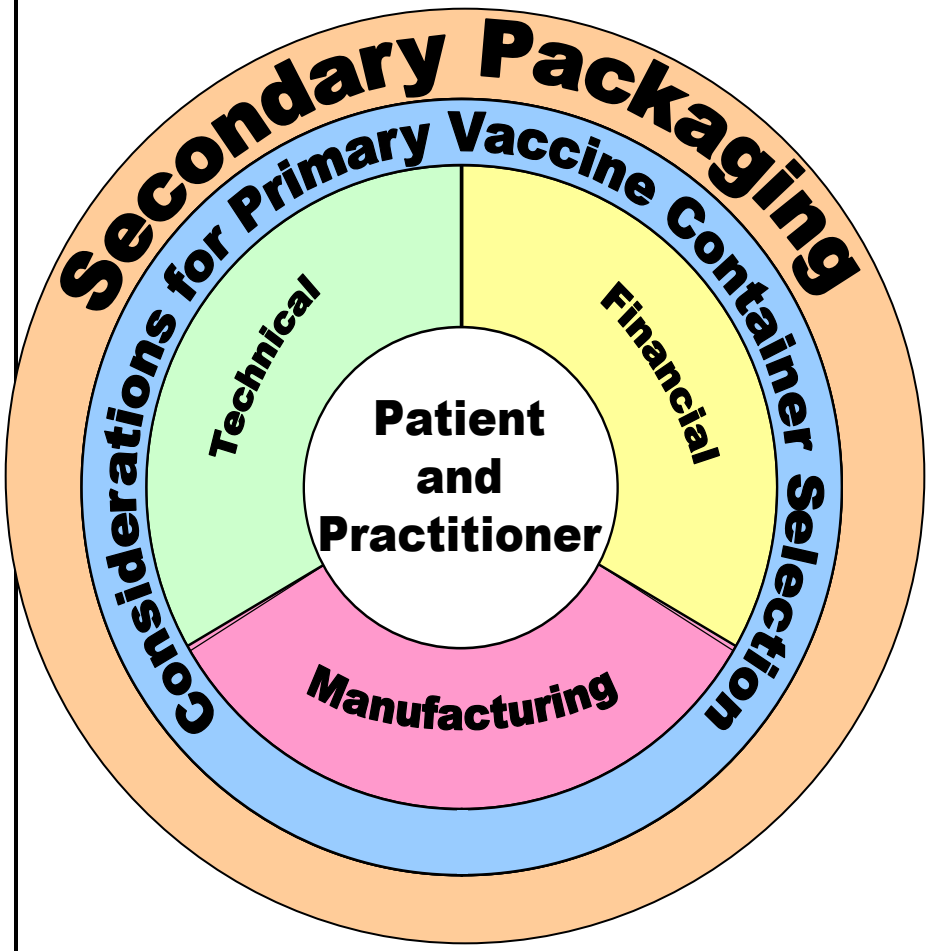
Patient/Practitioner Considerations

- **Product Differentiation**
- **Counterfeit risk**
- **Patient safety including injection safety**
- **Product cost**
- **Wastage**
- **Stability performance (expiry / VVM)**
- **Dose density (cold chain footprint)**
- **Open vial & storage policies**



2 vs 4 doses in 2 different vials

Secondary Packaging Considerations



- **Protect the primary and product**
  - Impact, vibration, light, moisture
- **Communicate / facilitate use**
  - Space for required text
- **Labeling**
- **Overall footprint**
- **Dose density (# doses per volume)**
- **Counterfeit risk / security measures**
- **Machinability**
- **Sustainability of materials**
- **Development time & cost**

Conclusions

- Complexity and multiplicity of parameters to consider for primary container selection
- Patients and provider's are the main consideration that drives the decision
- Manufacturing, Technical and Financial viability remain important
- Secondary container requirements are as rigorous as primary