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Managing indirect taxes in the Life Sciences sector

Global Indirect Tax Advisor webcast series

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Agenda

Introduction
(Vivien Polok)

EU supply chain aspects (*Maite Vilardebo/ Mathias Bopp*)

Chinese Supply Chain aspects (*Harry Zhang/ Jason Yu*)

Distribution License requirements (*Peter Mozerov*)

A client perspective (*Peter Tansey-Dwyer/ Will Gull*)

Administration

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— Polling questions will appear as we proceed through the presentation.

— As mentioned, in order to receive the certificate of attendance, we require participants to take part in at least four of the five polling questions.

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EU Supply Chain aspects

Operational framework

1 Import of the API/drug substance into the EU

The Swiss group company is the owner of the API/drug substance.

2 Manufacturing process in Spain

- The Spanish group company/subsidiary provides manufacturing services to the Swiss entity to produce the finished product (“maquila”).
- The Swiss company is always the owner of the API/drug substance as well as of the finished product.

3 Distribution of finished drug product

Switzerland
Export of the finished product outside the EU

France
Intra-EU supply of the finished product

Spain
Domestic supply of the finished product

The Swiss company supplies the finished product to its customers worldwide.

VAT implications

1 Import of the goods into the EU

- Import of the API/drug substance → super reduced rate applicable to medicines or standard rated because not finished product?
- Who has the right to recover import VAT?
- VAT return reporting and SII?
- Or possibility to apply the Import VAT Deferral Regime in order to mitigate the import VAT financial effect.

2 Manufacturing process in Spain

- B2B service, general place of supply rule (i.e. Switzerland)
- If Swiss company is VAT established in Spain → Possibility to apply 4 percent VAT rate on the medicine manufacturing service
- VAT return reporting and SII?

VAT implications (Cont...)

3 Supply of the finished product

3.1. Export of goods outside the EU

— Spanish VAT exempt export of goods.
— Union Customs Code conditions to act as the of exporter of the goods.
— SAD export document administration

3.2. Intra-EU supply

— Spanish VAT exempt intra-EU supply of goods → EU Sales List (Form 349), Intrastat & VAT return (Form 303).
— Proof of intra-EU transport according to article 45 (a) of the Council Implementing Regulation (EU) Nº 282/2011.

3.3. Domestic supply of goods in Spain

— Reverse charge applicable to the extent the Swiss company is not established in Spain.
— If VAT established in Spain, the Swiss parent company must charge 4 percent VAT.

VAT refund procedure of the Swiss company

— General VAT refund procedure for Spanish companies; or
— Special VAT refund procedure set for entities not established within the EU (13th EU Directive)

Pharma to become Partially Exempted Industry?

- **Advanced therapy medicinal products**
  - Genes, cells, tissue
  - E.g. CAR-T for cancer therapy
- **Tax exemption for**
  - Hospital and medical care (Art. 132 of Directive 2006/112/EG)
  - Delivery of organs and human blood
- **Taxable (potentially reduced rated) pharmaceutical products**

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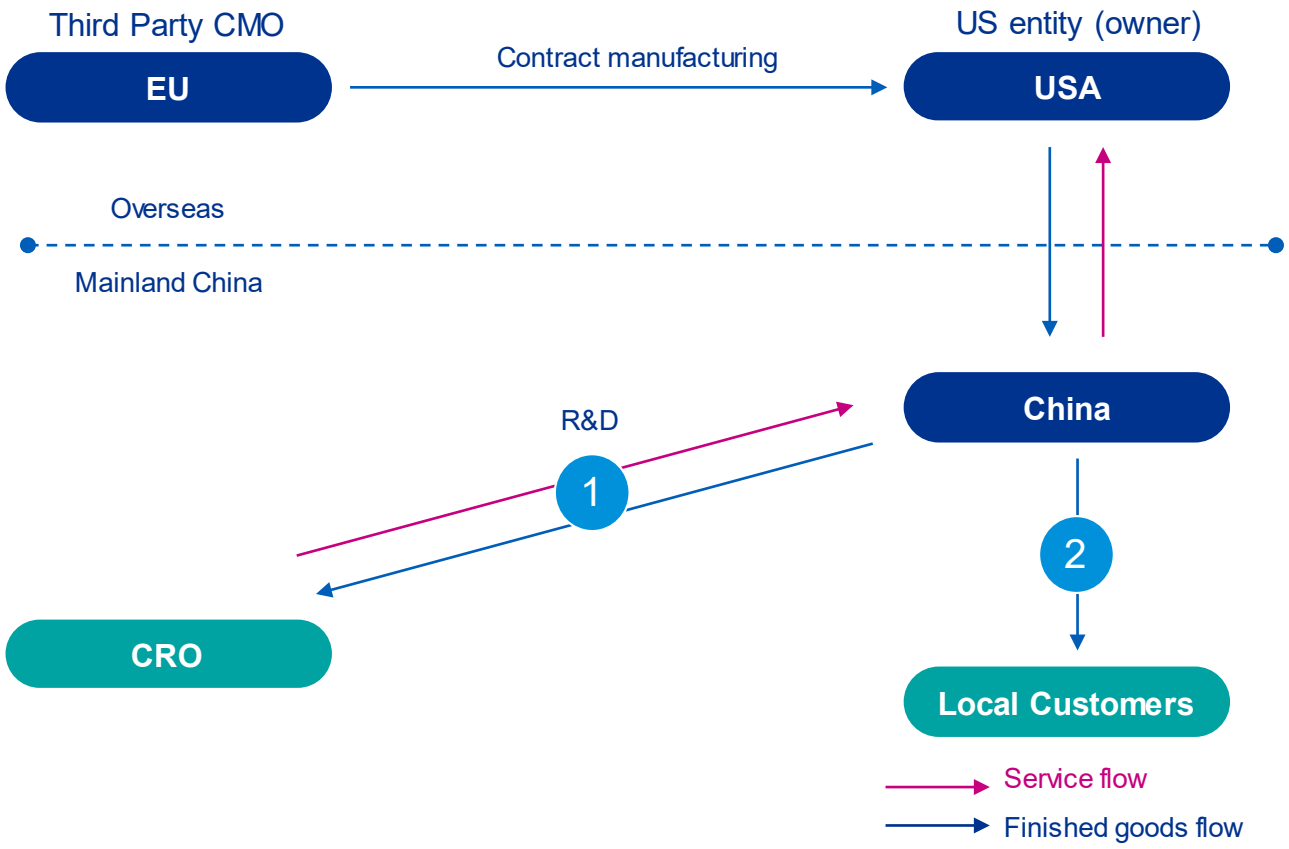
Chinese Supply Chain aspects

Clinical Trials: China Indirect Tax considerations



- Management plans to arrange the R&D outsourcing arrangement between the US entity and PRC entity.
- US Pharma Co consigns the R&D activities to PRC entity, who then further consigns to a local contract research organization ("CRO").

Value Added Tax ("VAT") Perspective

- Import VAT incurred in relation to imported trial drugs could be credited against output VAT for taxable R&D activities, regardless of whether title is passed to PRC entity or not.
- Provision of R&D services to an off shore entity may enjoy the following preferential VAT treatments:
  - zero-rated VAT, which allows credit of input VAT;
  - exempted VAT, which requires the input VAT in relation to VAT exempted services to be transferred out, i.e. constitutes a cost of the company.

Customs valuation for non-commercial product

Background:

— *The Company is a leading medical research and manufacturing enterprise.*

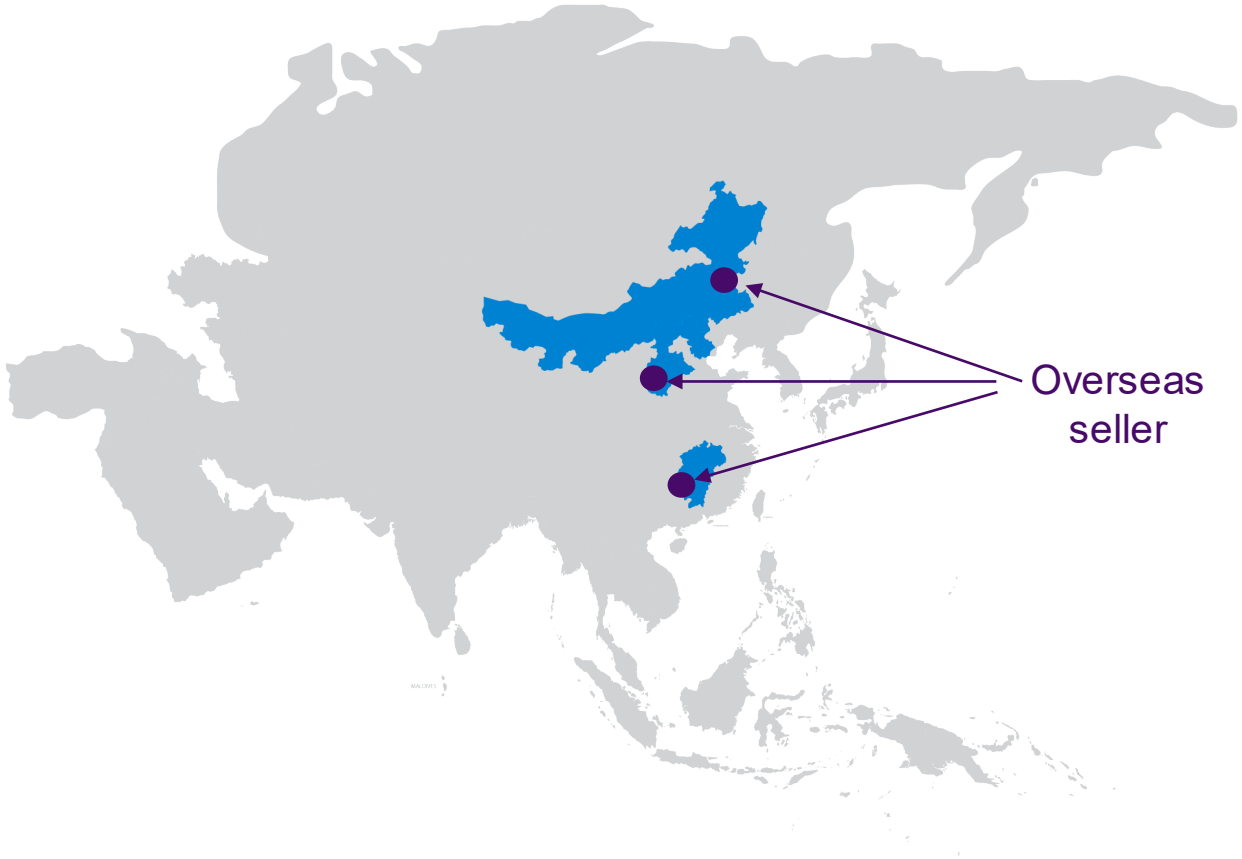
— *Certain clinical trial drugs were imported free of charge from foreign related parties.*

— *No transaction price is available.*

— *For Customs declaration purpose, such drug is valued based on the cost-plus method. Customs recently approached the Company and requested the Company to:*

1. Conduct a lump-sum adjustment to past shipments;
2. Adjust dutiable value for past 3 years;
3. Change the cost-plus method to identical/similar product method, by referring to the resale price of the identical/similar drug upon global NDA approval;
4. For future import, stick to identical/similar product valuation method for experimental drug.

Distribution Network



Centralized Supply Chain Dilemma

DC is located in Shanghai WQG FTZ. DC is mainly responsible for distribution and labelling.

Most customers are located in Beijing, Tianjin, Shanghai, Shenzhen etc., which are mostly first-tier cities;

After labelling is finished, goods are imported into another DC in Shanghai. Upon receiving the order, the Company distributes the order to the customer from Shanghai DC altogether.

01 **Goods are inspected at least two times before delivery to the customer, i.e. one at inbound and one at import;**

02 **The Company is concerned whether labelling operation could be shifted to other FTZ.**

03 **Inventory management is relatively easier, while lead time is comparatively longer.**

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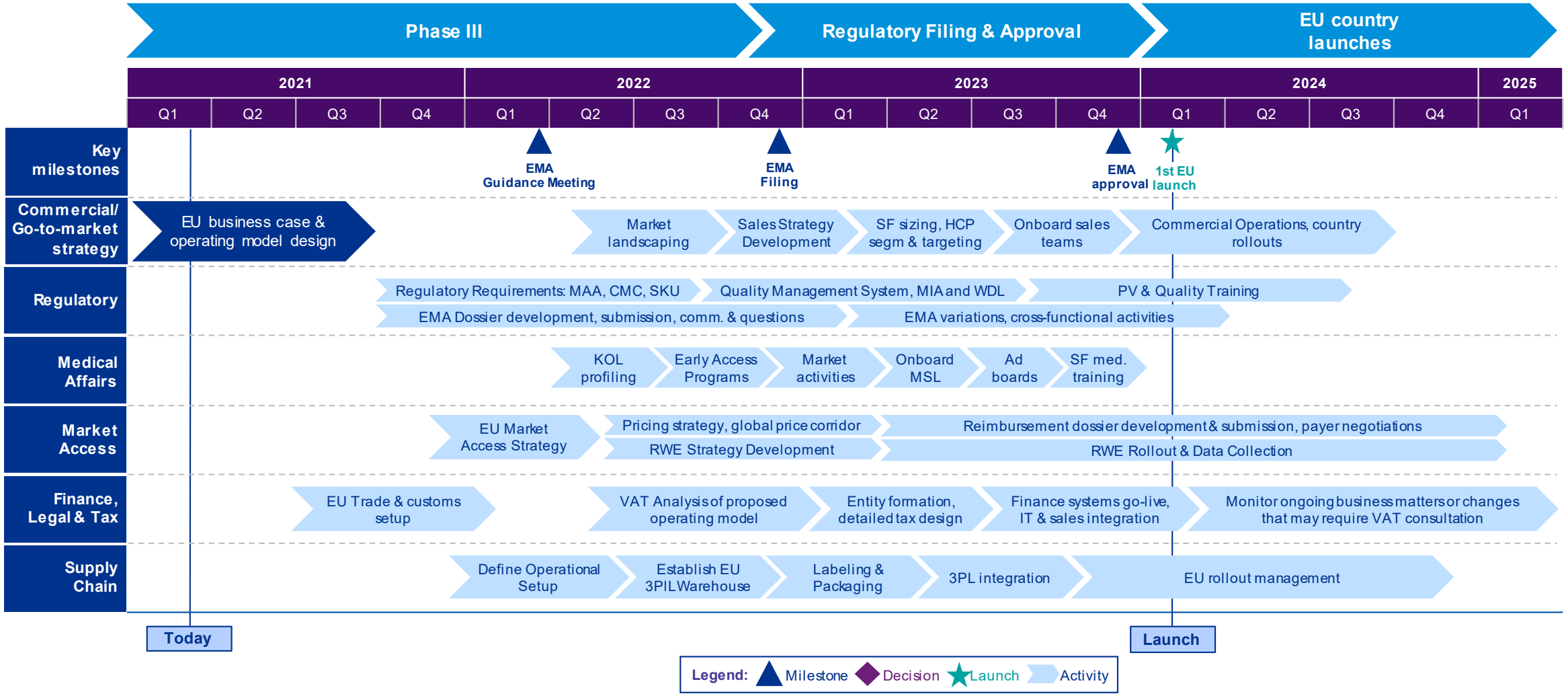
Distribution License requirements

Direct launch in Europe: challenge with a substantial payback

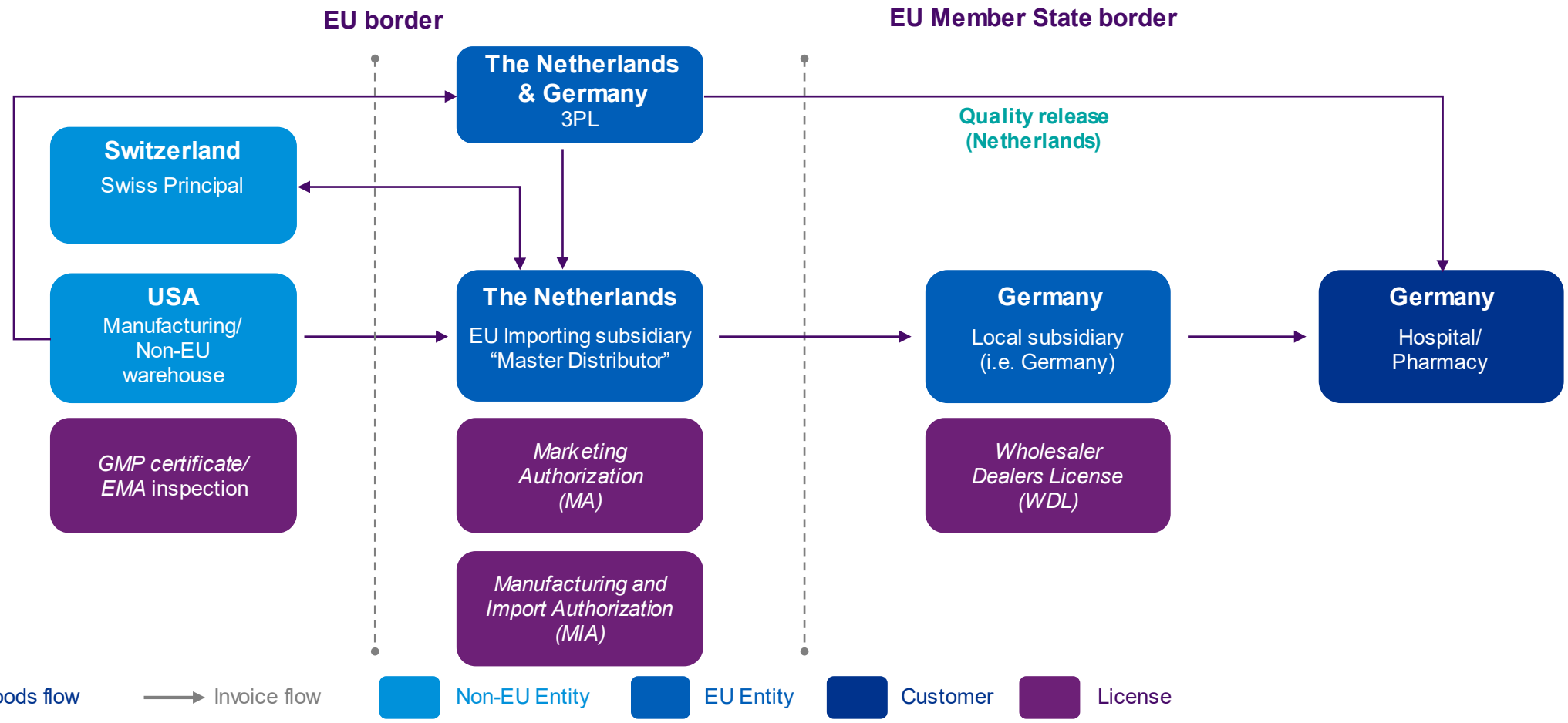
- Increasingly, small biopharmaceutical companies are launching their new drugs themselves rather than relying on large pharma companies to do it for them
- Half of the expected 40 "blockbuster" launches in the next five years will come from first time launchers
- Europe represents an attractive, but complex market with market access environment differing between countries
- While EMA provides marketing authorization valid across the European Union, reimbursement decisions are national
- The buildup of European commercial organization requires a strong commitment, planning, and a substantial investment
- The payoff is however substantial, both in terms of revenues, and in the rationale for M&A
- In Europe, Zug has become the epicenter for US first time launchers (Bluebird, Portola etc.)

EU launch requires advanced preparation



Master distributor: a common compliant distribution model for the EU

Common EU setup: Dutch Master Distributor with Swiss Principal



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A client perspective

Peter Tansey-Dwyer [Gilead Sciences]

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