

Are Biosimilars an Option?



Annual General Meeting

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What am I doing here?

- 28 years in Dutch vaccine institutions (RIVM, NVI, Intravacc)
 - vaccinology training, capacity building and technology transfer to developing countries
 - 2013-2015 with WHO Technology Transfer Team
 - Marie-Paule Kieny / Martin Friede
 - » WHO GAP Influenza
 - » AVMI-initiating meetings at WHO / UNIDO
 - » *Creation of UCAB*
- Now retired, part-time vaccinology consultant
 - advise / consultancy on building networks and partnerships
 - between science & technology and policy
 - public and private
 - national, regional, global



Background

- Biosimilars in general very expensive drugs globally
- Out of reach for many patients in LMICs
 - even when on the WHO's "Essential Medicine List"
- "generic-type" biologics after patent expiry
- only modest cost saving so far with available biosimilars
 - average ~30% price reduction

Source: Slide provided by Prof. Han van den Bosch, Chairperson UCAB Foundation

Difference between cost of manufacture and sales price of monoclonal antibodies

Product	Price (US\$)	Sales Price/g (US\$)	Manufacturing cost* (US\$/g)	COGs as % sales of price
Avastin (bevacizumab)	687.5/100mg	6875	188	2.7%
Enbrel (etanercept)	243/25mg	9706	428	4.4%
Humira (adalizumab)	1816/40mg	45400	308	0.7%
Rituxan (rituximab)	675/100mg	6751	188	2.8%
Herceptin (trastuzumab)	3331/440mg	7570	126	1.7%
Erbitux (cetuximab)	600/100mg	6000	188	3.1%
Soliris (eculizumab)	5122/300mg	17073	135	0.8%
Remicade (infliximab)	784/100mg	7839	188	2.4%
Average		12877	231	2.3%

*Estimated assuming a 2 gr/L yield.

Source: Ronny Gal, Bernstein Research, 2014

Utrecht Centre for Affordable Biotherapeutics

- Non-profit foundation at University of Utrecht
- Under a MoU with WHO in 2014
- **Mission**

Enable sustainable production of high quality and affordable biotherapeutics/biosimilars that are also accessible to patients in LMICs.



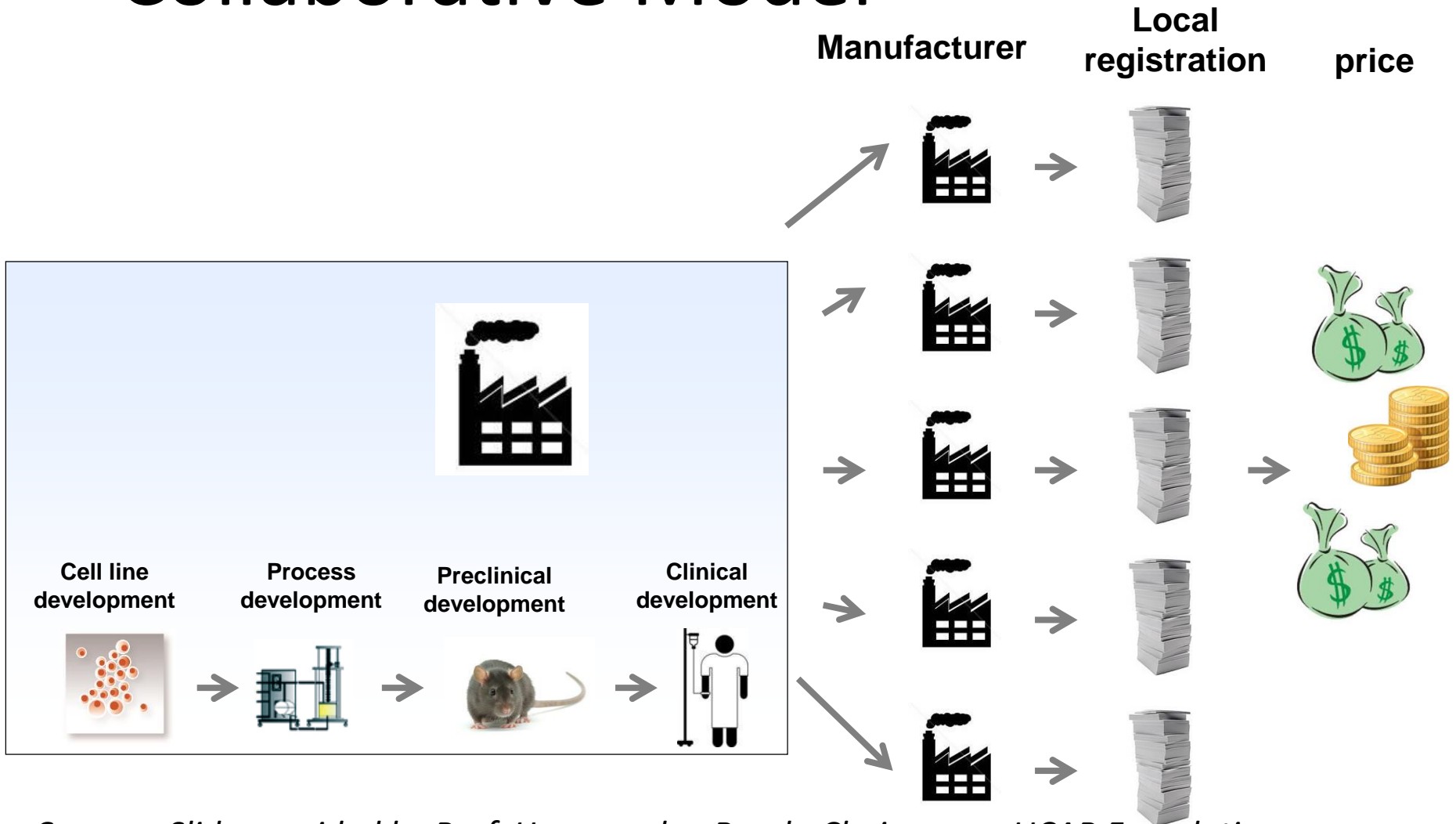
Concept

In order to achieve affordability and sustainability:

- Combine forces with companies in LMICs
- Reduce development costs through central MA dossier
- Reduce production costs by technology transfer to local manufacturing partners
- This will result in a comprehensive central file that will be the basis of local marketing authorization applications

Source: Slide provided by Prof. Han van den Bosch, Chairperson UCAB Foundation

Collaborative Model



Source: Slide provided by Prof. Han van den Bosch, Chairperson UCAB Foundation

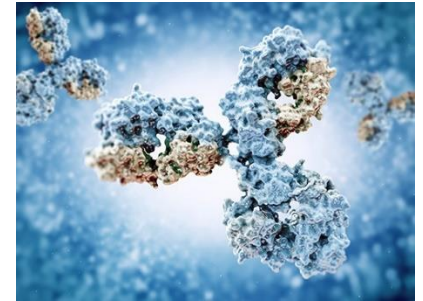
First Project

- 9 March 2016
 - First consortium of local manufacturers to make affordable Paluvizimab available for low income countries
 - **mAbXience** (Arg./Spain) [Lead Manufacturer], **Libbs**(Brazil), **Medigen**(Taiwan) and **SPIMACO** (KSA)



Activities

- Identifying and developing affordable biotherapeutics
 - first product to be marketed in 2023
 - Palivizumab: mAb for prevention RSV in high-risk children but unaffordable for LMIC children due to high costs : US\$ 9600/per season in USA, €5000 in Europe
 - *now actively looking for other projects*
- Research
- Develop/strengthen capabilities of local manufacturers and national regulatory authorities
 - *? creation of AREMAB*)*



*) AREMAB: Association of Regional Emerging Manufacturers of Affordable Biosimilars

April 2018

UCAB reached out to DCVMN...

- Manufacturing of vaccines **and** biologics often done by same companies including some DCVMN members, and using same facilities, technologies and even equipment
- For manufacturers an opportunity to increase flexibility by using these facilities for multiple purposes
- *Let's have a chat.....*

Suggestion to AVMI

- There seems to be interest in biosimilars in particular in the northern part of the African continent
- Consider to include biosimilars/biotherapeutics in AVMI's mandate