

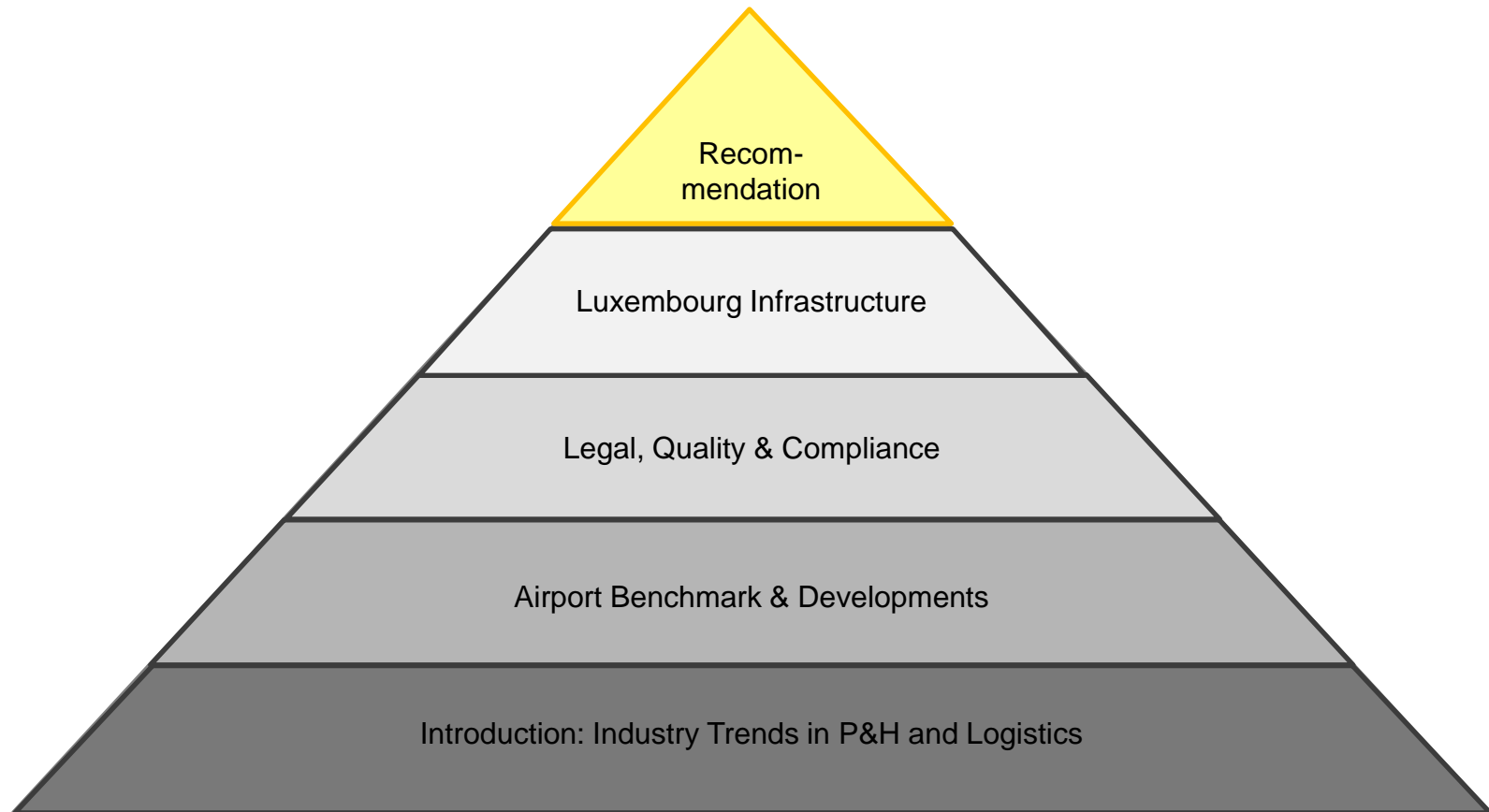


Pharma & Healthcare Logistics Development Roadmap for Luxembourg

There is something
going on in LUX

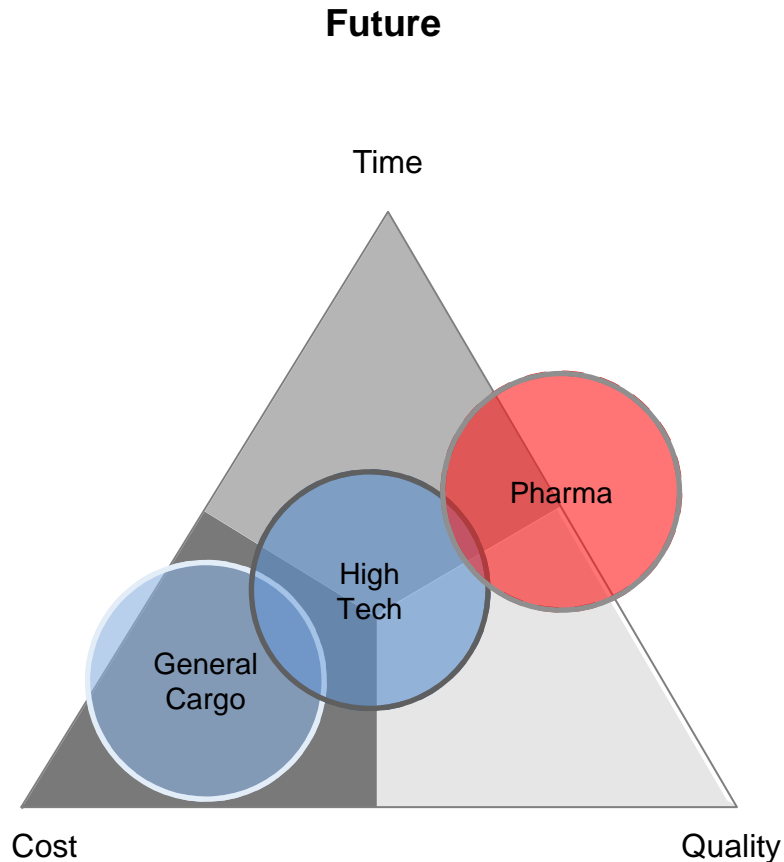


1. Gradually shrinking Cargo volume handled at Lux Airport between 2007 – 2011: **(30%)**
2. Lux's increasing success & attractiveness in global Pharma supply chain activities..
3. Drastically changes in Pharmaceuticals Industry environment, trends & globalization..
4. New Global and EU-Directives: from **Cold chain** to **Good Storage and Distribution Practices**..
5. Customer's 'demand' : **Fully compliant e-2-e temperature controlled supply chain solutions**..

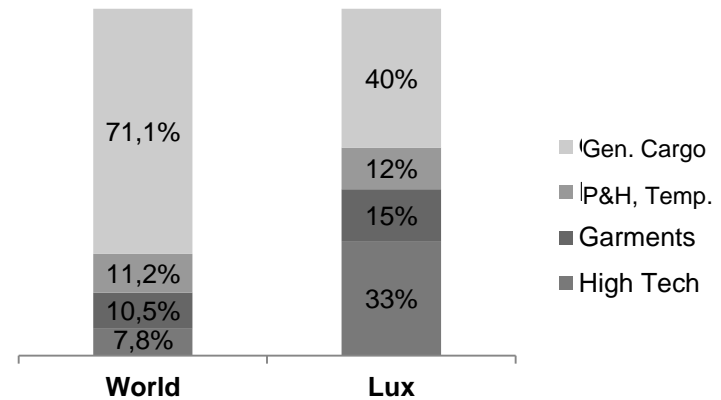




Pharma logistics requires dedication to highest quality norms:



Luxembourg's Cargo Split



General cargo & high-tech goods:

=> will move quickly to other cheaper airports
(commodity volume volatility)

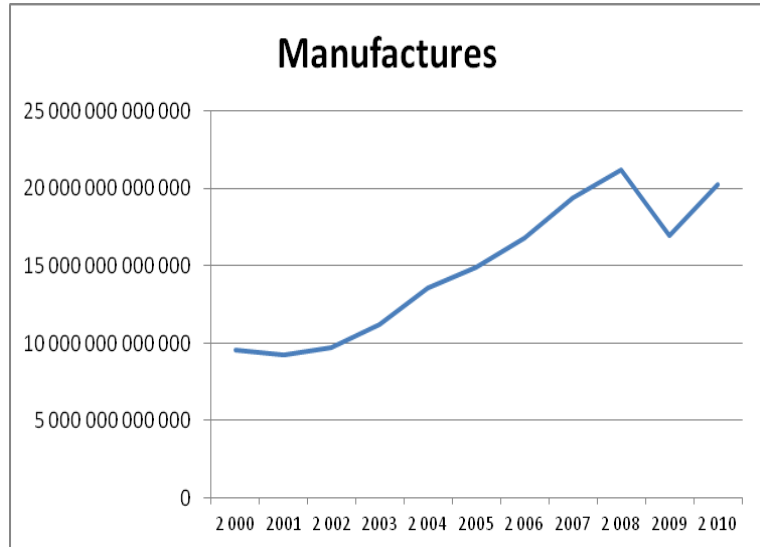
Increasing **Risk** of losing substantial freight volumes to low-cost cargo airports!



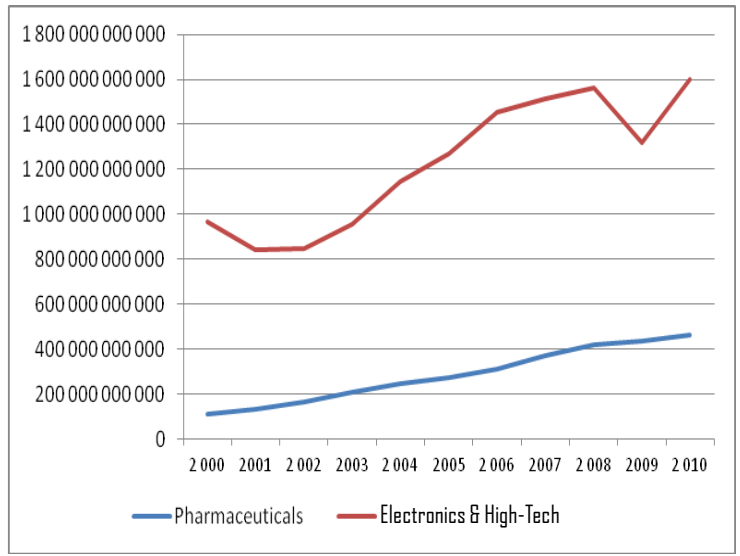
Implications from Crisis on Commodities:

Some commodities less than others are affected by crises*

Pharmaceuticals > High-Tech-Products



*Source: WTO





Main challenges of the Pharmaceutical companies ?

- ⇒ Time to market / reduce lead times
- ⇒ Product life cycle shrinkage
- ⇒ Regulations are tightening up
- ⇒ Counterfeiting
- ⇒ Increasing Total Cost of Ownership
- ⇒ Portfolio of Pharma companies are changing / Biotech drugs become more important
- ⇒ More capacity needed
- ⇒ Monitoring
- ⇒ Not only +2°C to +8°C but especially +15°C up to +25°C.
- ⇒ Increase complexity in relation to compliance



❑ Complex situations:

- Large Governmental public healthcare deficits >> budget restrictions >> force to reduce spendings
- Expiration of drugs patents: 5 of top 10 blockbuster drugs
- Lack of new innovative products
- Increasing competition
- Need to generate profits

❑ Generic drugs will increase market shares of drug sales

- Global market share for branded medicines: 70% (2005) ↘ 64% (2010) ↘ 53% (2015e)
- Global generic drug spending: \$124bn (2005) ↗ \$234bn (2010) ↗ \$400-430bn (2015e)
(70% will be outside developed markets)

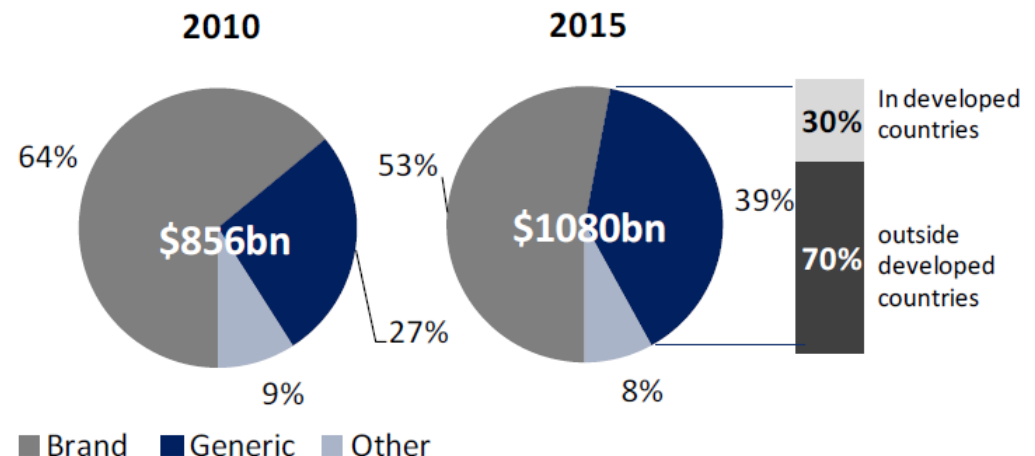
❑ Different therapy classes + size

- Indicators for future market structures: →

❑ Overcoming the past:

- No flexible & cost effective supply chain
efficiency of supply chain due to financial

Figure 2: Spending on pharmaceuticals by segment





- **Patent protection:** 5 of 10 top10 globally sold losing patent protection in 2011/2012.
- **Coming off-patent products:** approx. 30%: will be produced by Indian companies
- **Biotech drugs:** Steadily increasing market share (from 19 > 23%)
Most of global spending currently in USA
Till 2015, biotech drugs worth than USD80bn losing patent protection
- **Follow-up products:** **biosimilars**, most attractive markets are US, Germany
..due to market size & generally high substitution by generics
- **Strong market positions:** European Pharma companies (in biotech and biosimilars drugs)
..and increasing focus in temperature sensitivities products

&

➔ **Leading into rising/increasing demand for Good Storage and Distribution Practices.. especially for those highly temperature sensitive drugs!!**



➤ Spending on Pharmaceuticals by segment : from USD 856bn in 2010 to USD 1.080bn in 2015

- Branded medicines losing from.. 64% >> 61%
- Generics in 2010 growing from.. 27% to 39%
➔ spending on Generics: will especially grow outside developed markets, representing 70% of total sales
- Other med. products from.. 9 % to 8%

➤ Most important therapy classes and sales forecasts 2011 > 2015:

- Oncology: till 2015, 20 mio new cases of cancer : increase from USD 60,8bn > USD69bn
- Diabetes: increase by 69% in developing countries, 20% in developed countries USD 36,8bn>USD41bn
- Astma+COPD: from USD 37,6bn in 2011 to 43,1bn in 2015

➤ **Biotech drugs:**, Steadily increasing, frequently targeted for counterfeiting due to high values:

- From 19% in 2011 >> to 23% in 2016
- Share among the top 100 products increasing from 31% in 2015 >> 45% in 2016

➤ **Summery:**

- Market share of **Generics** will increase by 12% p.a. till 2015 **from 27% to 39%**
- Oncology is and will be the most important therapy class till 2015 in sales
- Loss of patent protection and increasing Generics competition will drive globalization



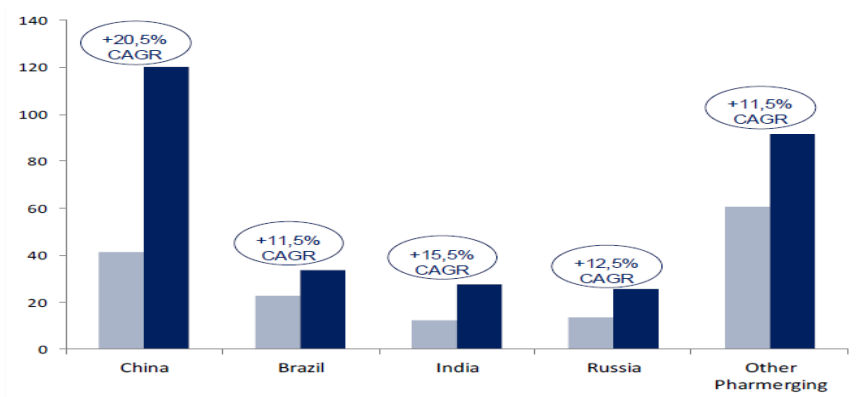
- Acc. to study by IMS, **17 so-called “pharmerging” countries will contribute 50% of Pharma growth by 2014**
Comprising: China, Brazil, India, Russia, Venezuela, Poland, Argentina, Turkey, Mexico, Vietnam, S.-Africa, Thailand, Indonesia, Romania, Egypt, Pakistan and Ukraine.
- Together, spending will **double** from USD150bn to USD300bn by 2015,
→ thereof, approx. **80%** of spending on **generics**

China: improving healthcare infrastructure, spending predicted to grow by 19-22% p.a./ aging population / rising diseases → **Largest growing market**

Brazil: spending predicted to grow by 10-13% p.a.

India: by **14 – 17%** p.a. till 2015

Figure 8: Predicted growth of spending of pharmerging countries in \$USbn in 2010 and 2015



(Own illustration; data adapted from IMS Institute 2011)

1. Sea freight transportation of Pharmaceutical products:

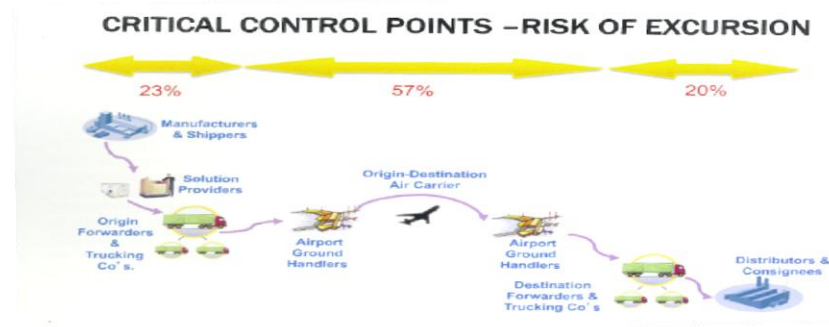
⇒ are unlikely due to their values, capital return, risks & limitations in liabilities of carriers

2. Airports are seen as the most sensitive critical control points (57%) in the supply chain:

⇒ due to all different actors involved (e.g. LSP, air carrier, handling agent, customs, health inspections)

⇒ **Recent Pharma-Analysis:**

⇒ 57% of ALL SIGNIFICATE non-compliance cases / irregularities happen during Airports



3. Pharmaceutical Industries' Expectations:

⇒ Major initiatives for securing their trade lanes

⇒ *How-fare-you-willing-to-go-with-us..???**

⇒ In-future, only fully Pharma compliant LSP and S/C-concept will be qualified and forming the basis of Pharma Industries' global supply chain activities.

* Heike Falkenhagen Head of Global Quality Boeringer , Ingelheim during IQPC Basel 2012



⇒ **The pharmaceutical supply chain is under attack:**

- Thefts
- Counterfeiting
- Quality of raw materials

⇒ **New GDP-Requirements to put into place a Quality Management Systems**

- Training
- Standard Operating procedures
- Service level Agreements

⇒ **All this is even more important for biotech-drugs as:**

- Higher and increasing product sensitive : >50% need for temperature controlled supply chains!!
- Over proportion high values
- Longer manufacturing cycle
- increase need for clinical trials

⇒ **P&H Industry expectations from their future LSPs:**

➔ **Fully compliance with e-2-e integrity:**

➔ **GDP - compliancy became simply a MUST...**

...and not any more a nice-to-have or good-signal.



- ❑ **Growing wealth of emerging countries:** > better healthcare coverage
 - ..but also spending on diseases
 - ➔ Opening of new markets for products in developing countries.

- ❑ **Little changes of top selling blockbusters:** > high dependency of products
 - Loss of patent protections: > increase market dynamics
 - Generics will likely moving to and into > growing emerging markets
 - ➔ Consequence: More products and exports of generics > from and into emerging countries

- ❑ **Rising demand for top 3 therapy classes** effecting logistics > *ALL temperature sensitive products!!*

- ❑ **All in all:** Pharma & Healthcare markets will continue growing, *especially in generics*
 - Constant spending in existing markets
 - Rising demand in emerging markets.