

# Emerging Trends for Generic Markets

November 15-16, 2005 Amsterdam

## „Opportunities for FOB’s in Europe - A Risk Benefit Analysis with EPO“

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# Agenda

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- **EPO**

- **Indications, Therapy and treated Patients**

- **EPO-Market**

- **Market Dynamics**

- **European Market**

- **Market Forecast**

- **EPO Development-Aspects**

- **Patent Situation**

- **Regulatory Aspects**

## Indications

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- **Anemia:**

- **Chronic Renal Failure:**

- Anemia is the consequence of renal failure and occurs because of erythropoietin deficiency.

- **Cancer:**

- Anemia can develop as a result of the disease progress and/or treatment with platinum based chemotherapy.

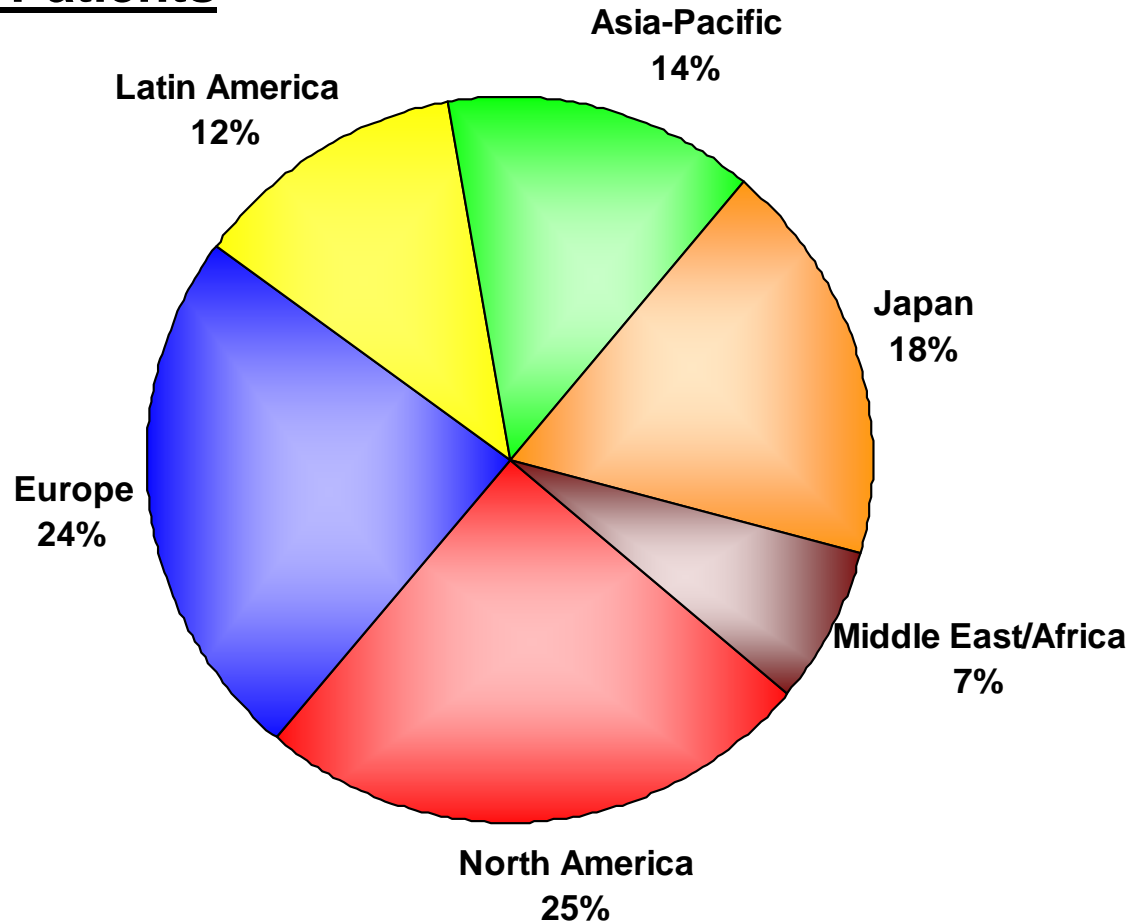
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- **Anemia:**

In anemic patients with chronic renal failure, treatment with recombinant human erythropoietin (rhEPO) is now standard practice and has dramatically reduced (40-50%) the need for blood transfusions.

Treatment of cancer-related anemia is supportive: it reduces symptom severity, improves quality of life and reduces or eliminates the need for transfusion.

**Dialysis Patients**



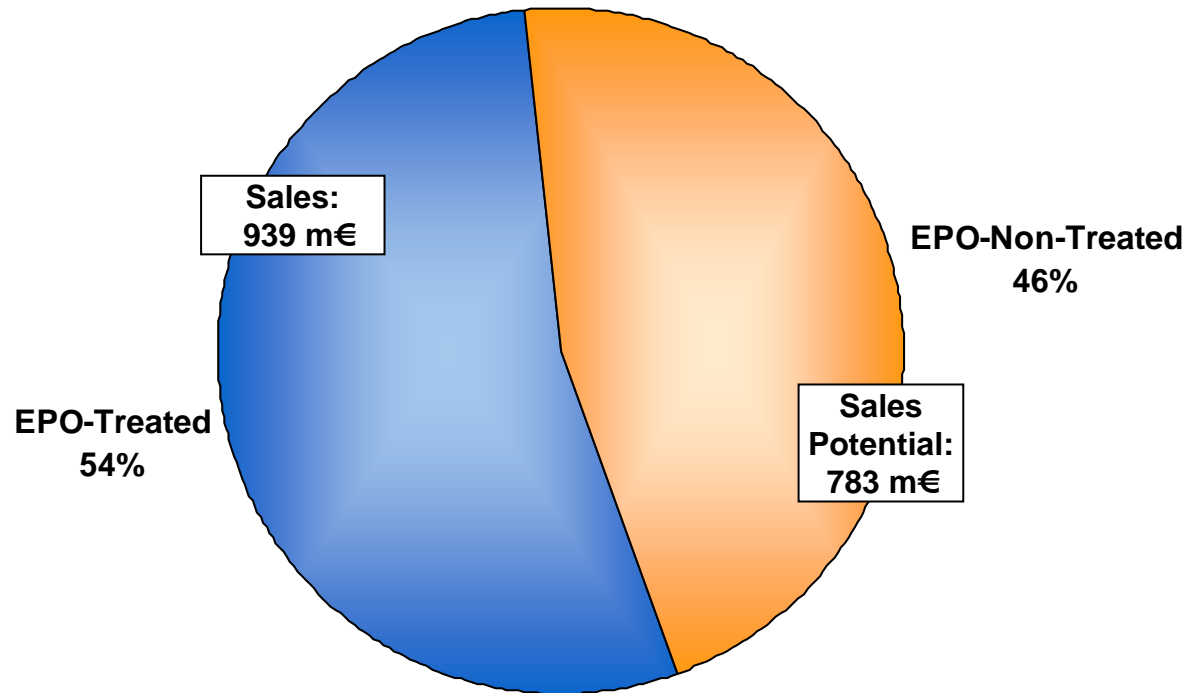
**Global: 1.300.000 Patients (+8%)**

- **Dialysis:**

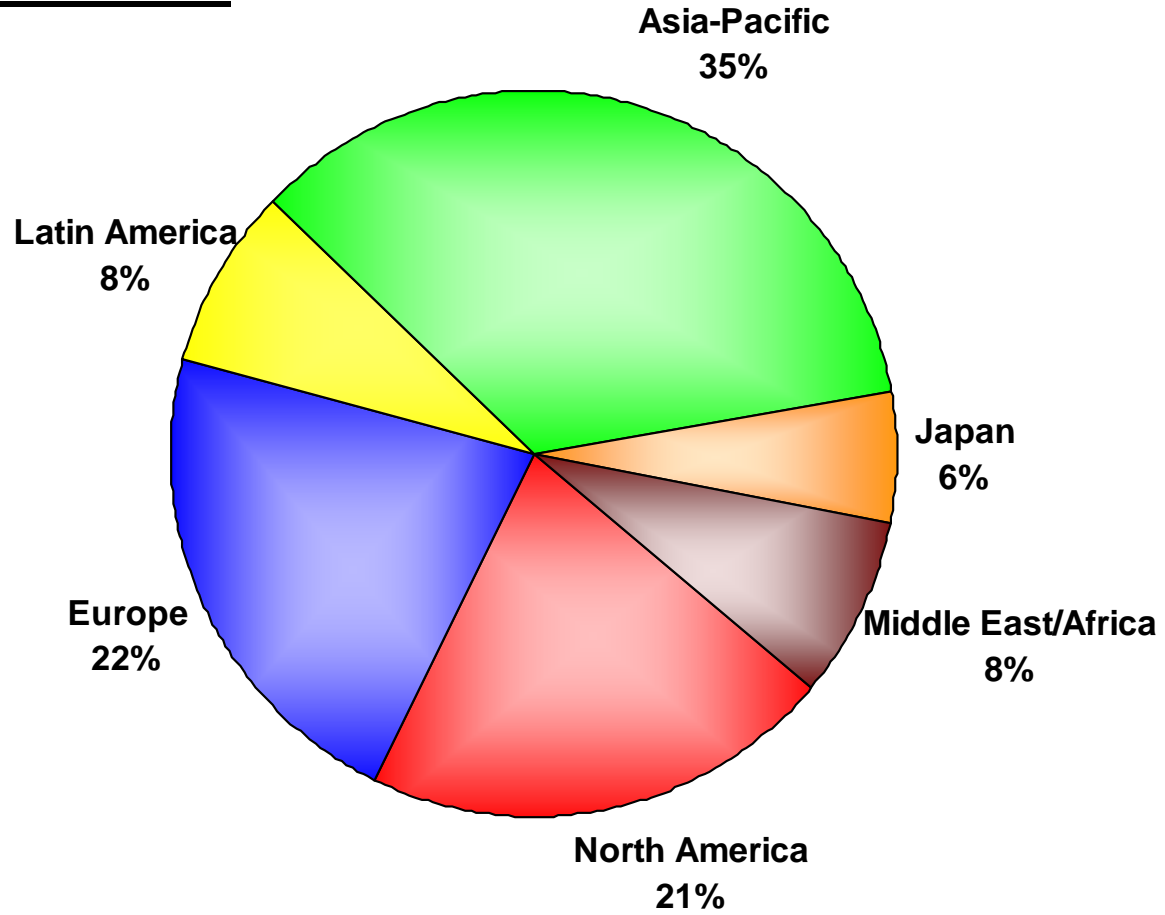
312.000 Patients in Europe (Growth: 5%) – 168.500 treated / 143.500 non-treated

EPO-Sales in Dialysis in 2004: approx. **939 m€**

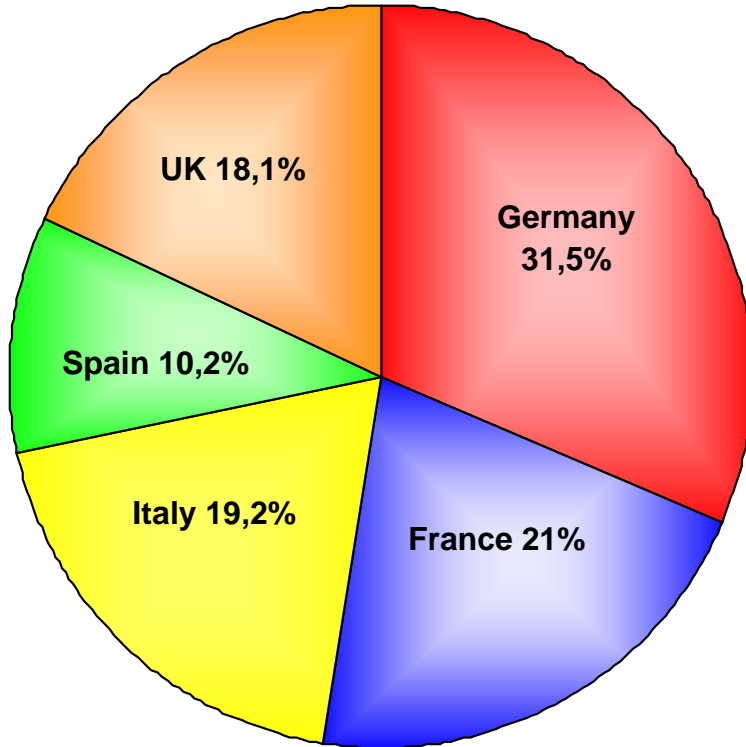
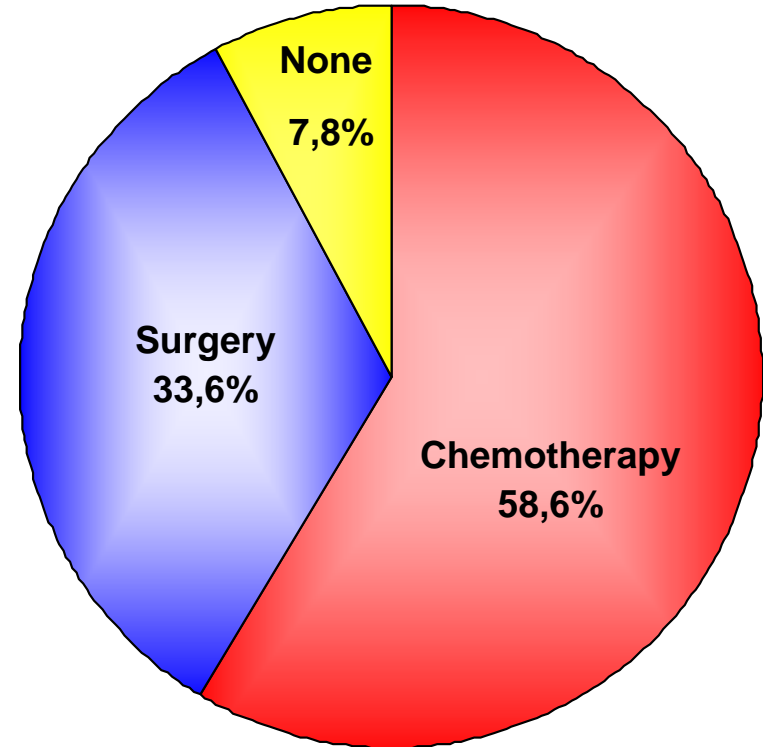
EPO-Potential in Dialysis: approx. **1.722 m€**



**Cancer Patients**



**20.500.000 Patients (+35%)**

Cancer PatientsCancer Therapy

**2.320.000 Patients (+20%)**

- Cancer:**

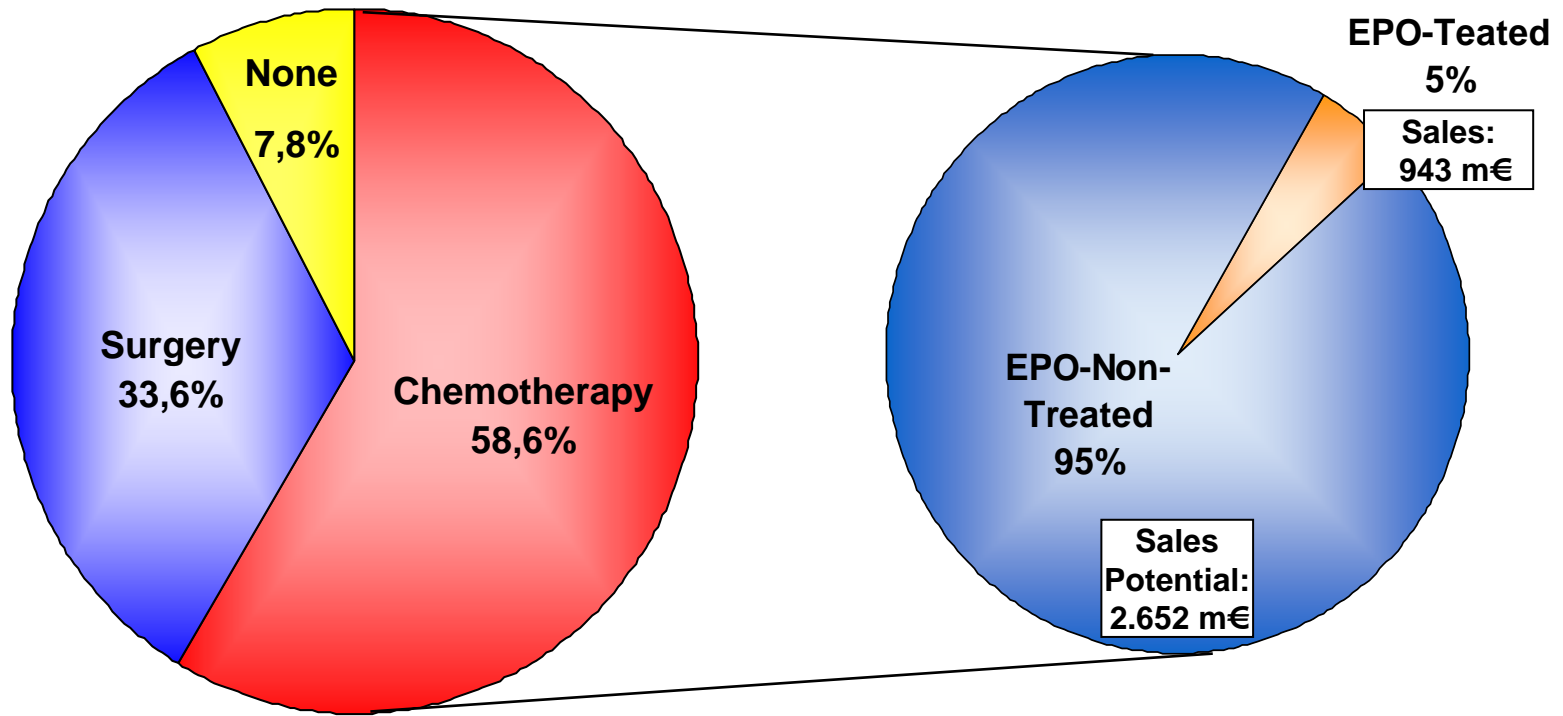
1.360.000 Patients treated by Chemotherapy – only 5% are on EPO

EPO-Sales in Cancer in 2004:

approx. **945 m€**

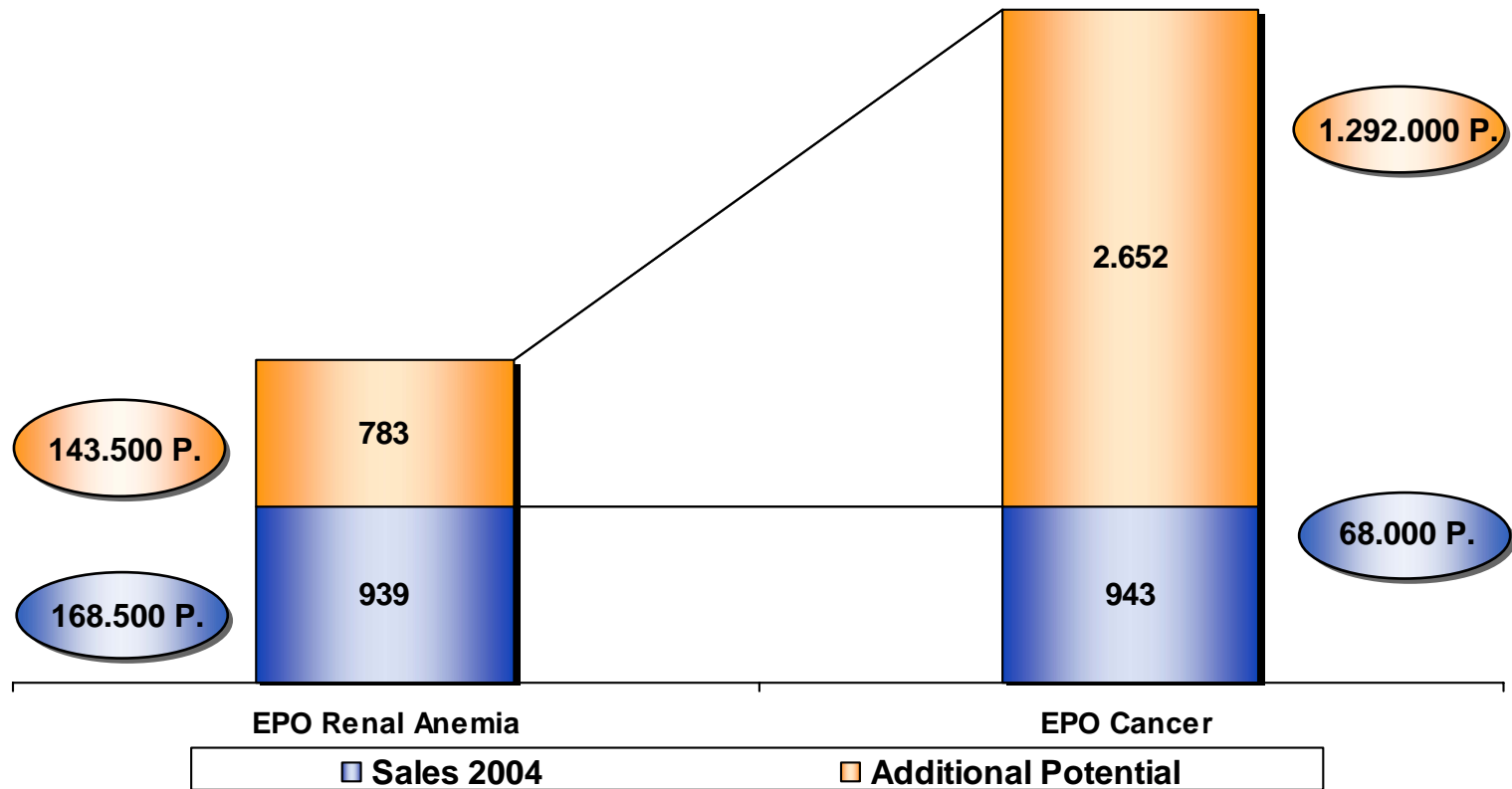
EPO-Potential in Cancer:

approx. **2.655 m€**



## Potential in Europe

- **European Sales 2004 and additional potential due to Patient Prevalence and Treatment Rate (in m€)**

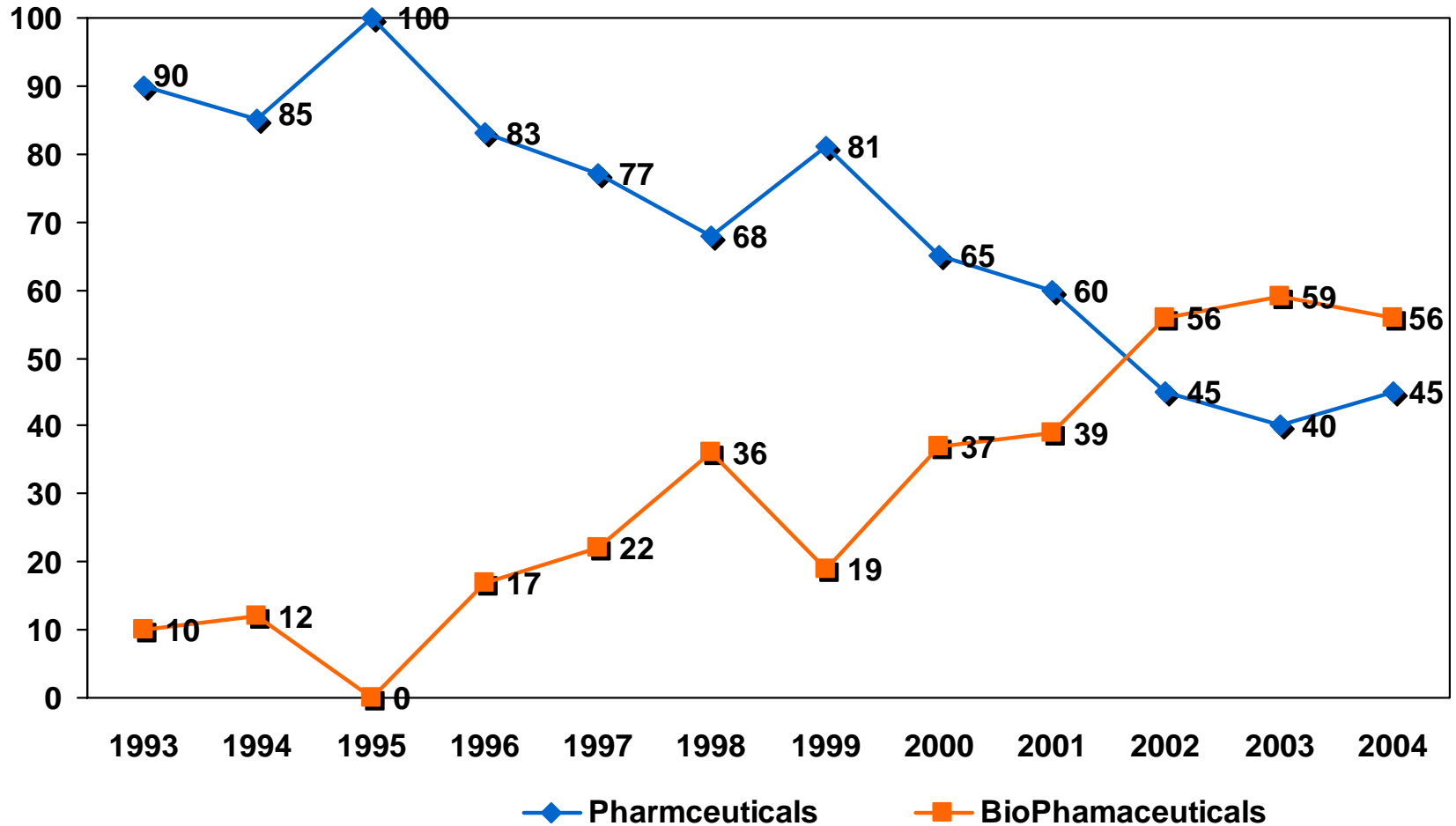


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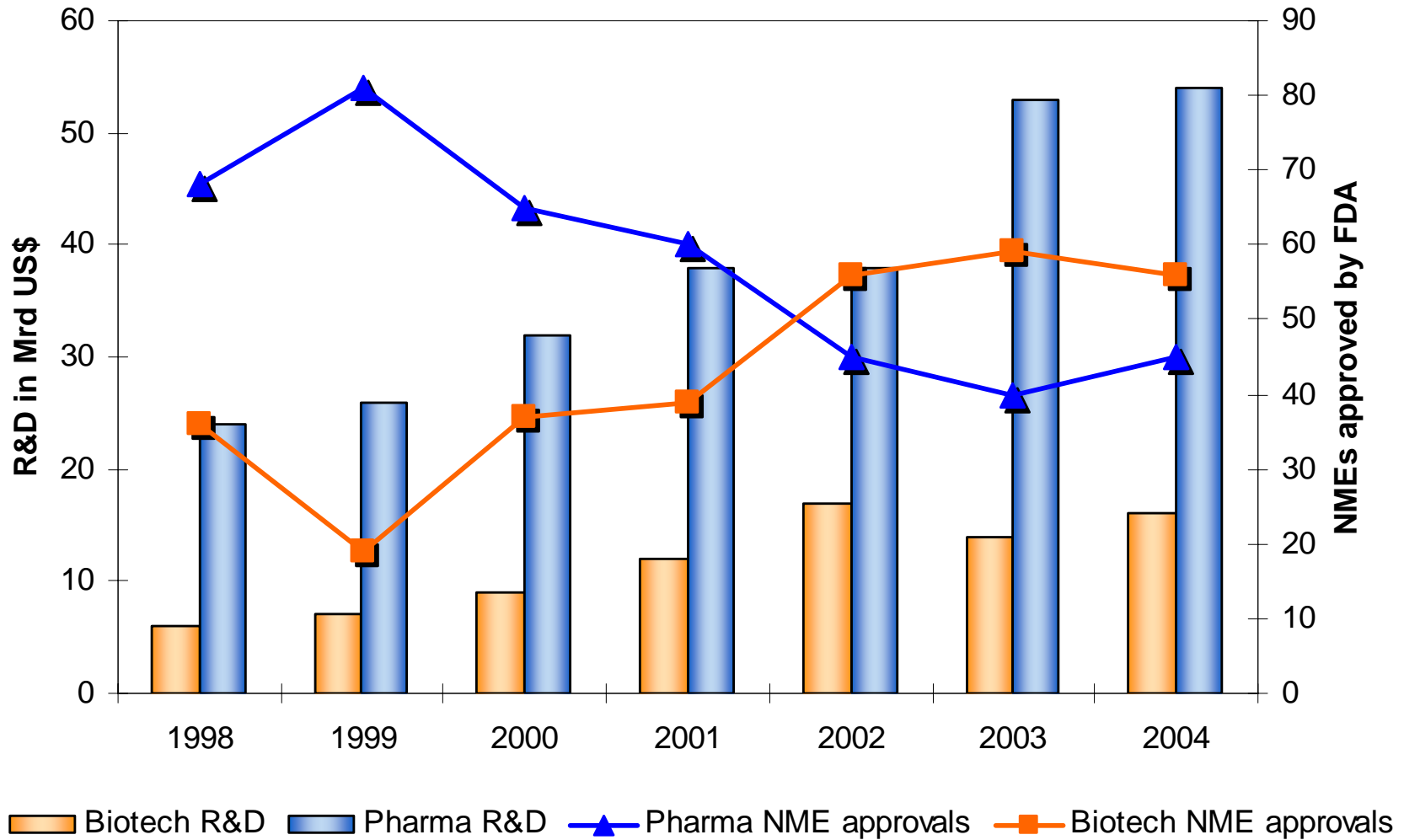
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## Market Dynamics: Share of New Approvals (US)



Source: FDA

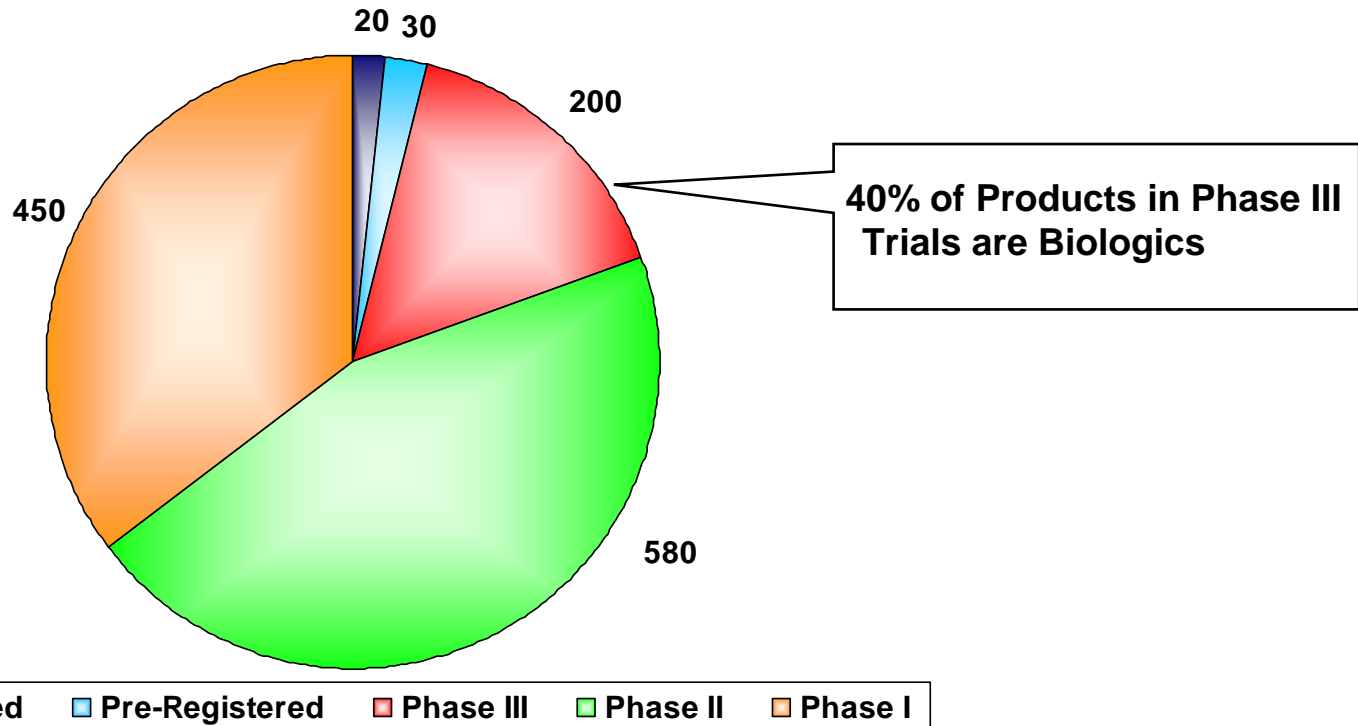
## Market Dynamics: The Innovation Gap (US)



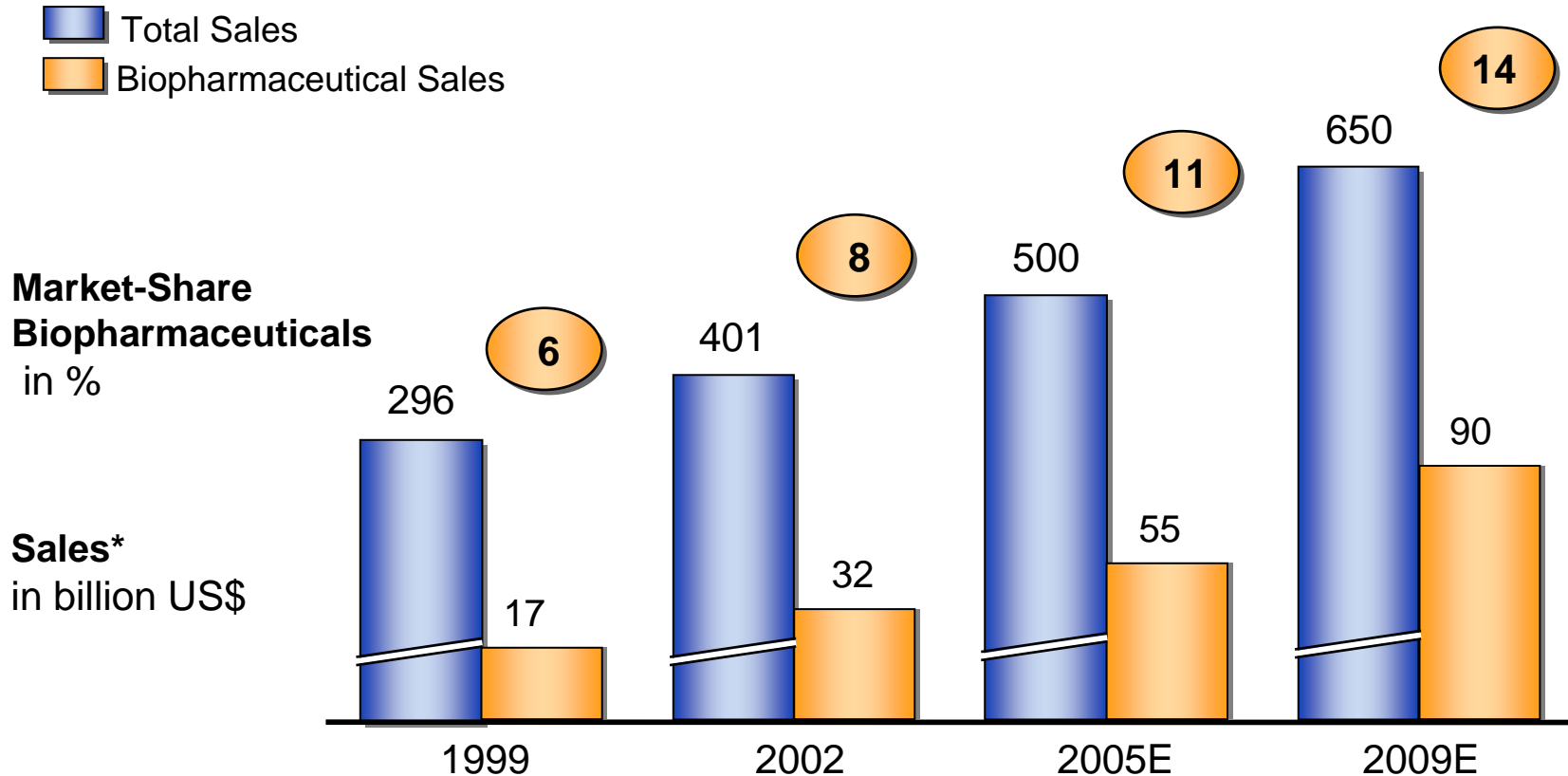
Source: FDA/ Ernst&Young, Global Report 2005

## Market Dynamics: Pipeline-Products

- **Biologics growing at twice the rate of “Small Molecules”**
- **In 2010 nearly 50% of all new approved Pharmaceuticals will be of biotechnological Origin**



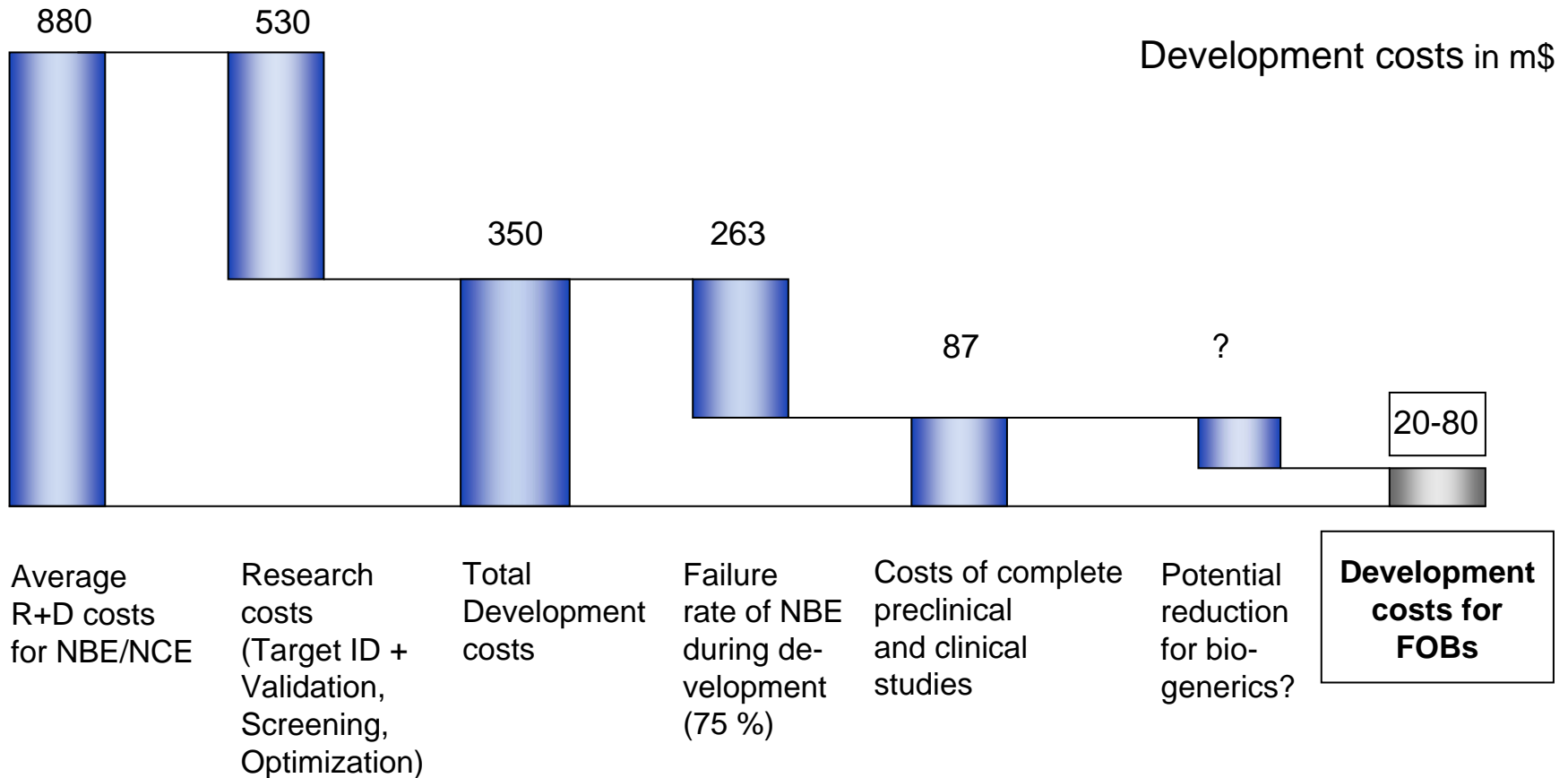
# Market Dynamics: The Global Pharma Market



\*Rx

Source: IMS Health, BioGeneriX Forecast

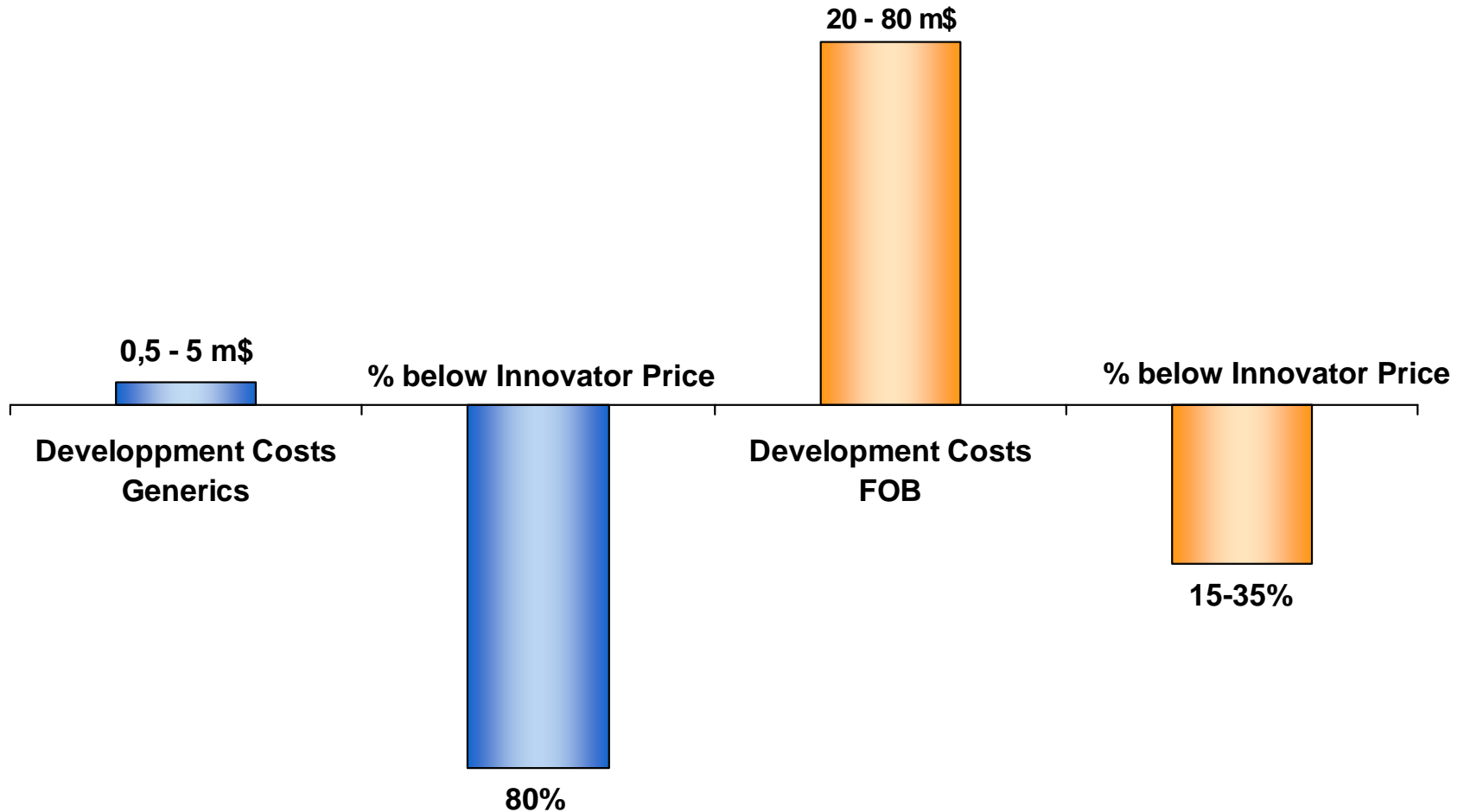
## Market Dynamics: Development Costs



**Due to high development costs, regulatory and GMP-constraints, only few companies will succeed**

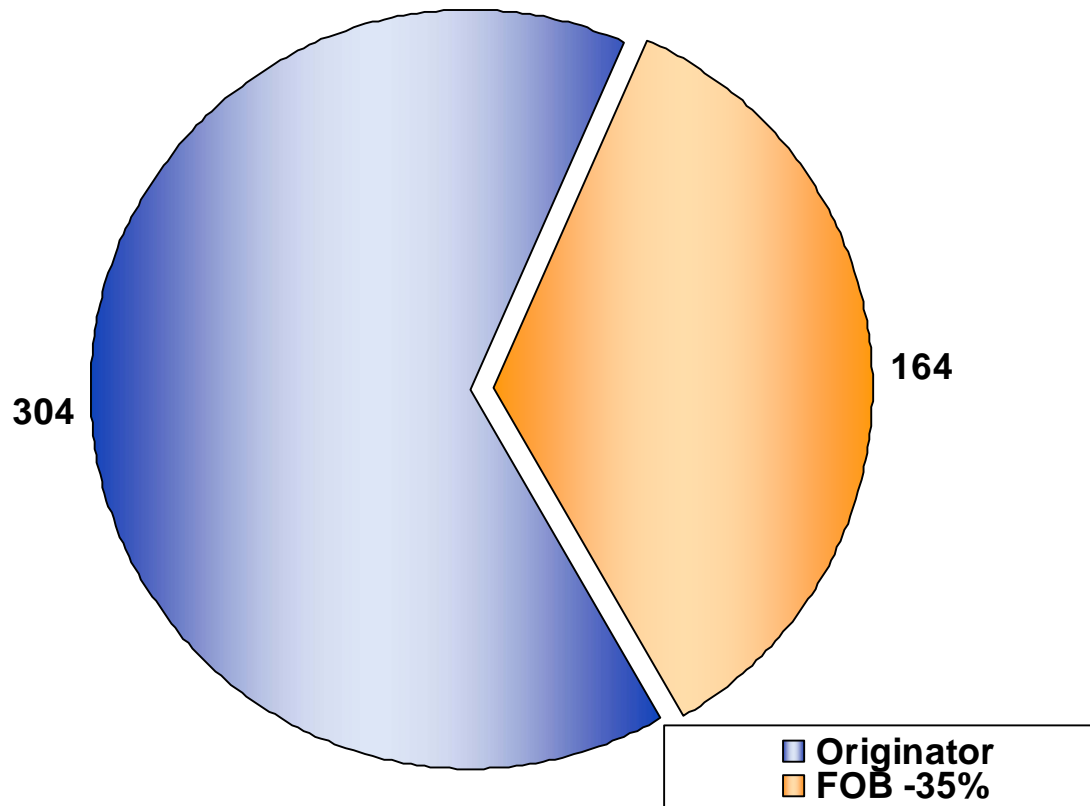
## Market Dynamics: Development Costs and Pricing (in m\$)

- **Development Costs for FOBs can easily be 100 times higher than for Generics**



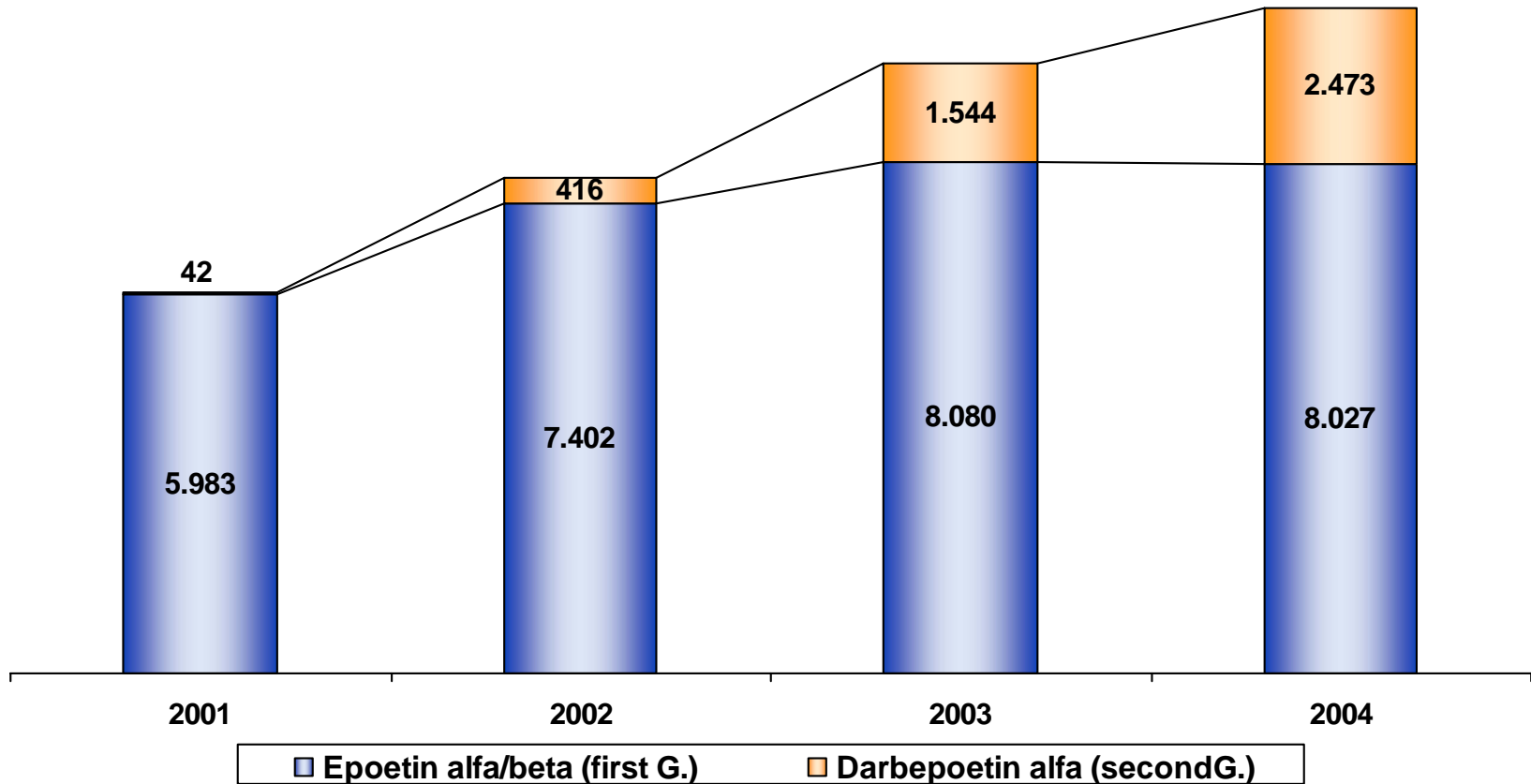
## Market Dynamics: Development Costs and Pricing (in m\$)

- **Possible Cost Savings for Health Care Systems in Germany (based on manufacturer Price)**



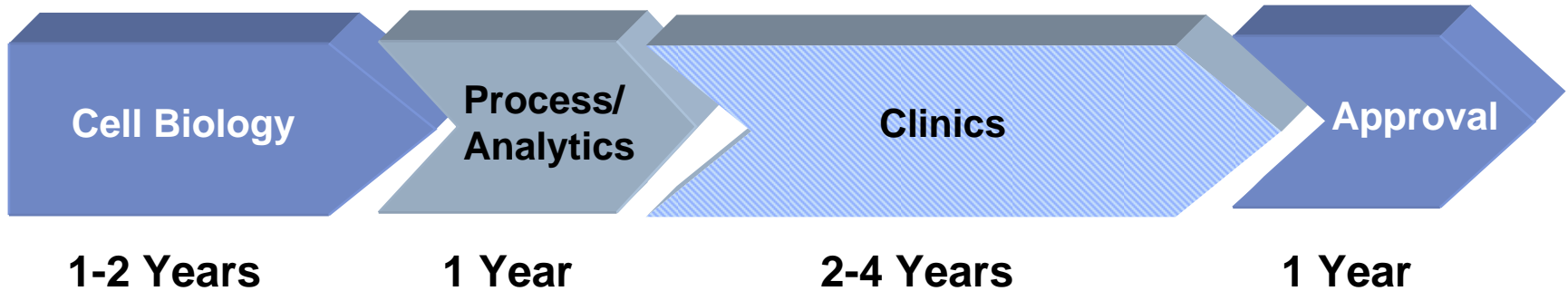
## Market Dynamics: The largest Therapeutic Protein by Sales

- In 2004 the global market recorded sales of 10.5 b\$ (+9.24%)



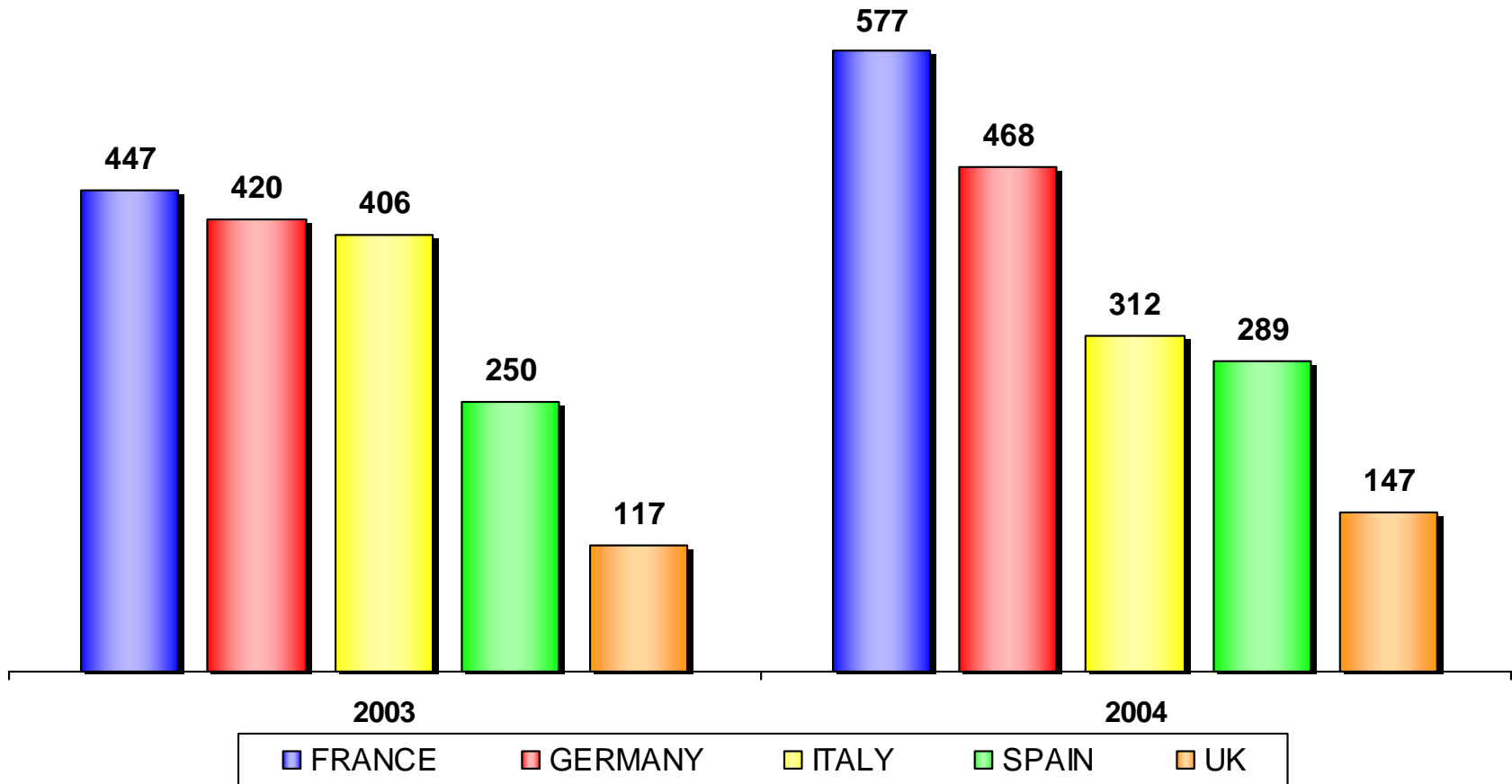
## Market Dynamics: Development Timelines EMEA

- From the first Steps until Launch it could take approx. 5-8 Years



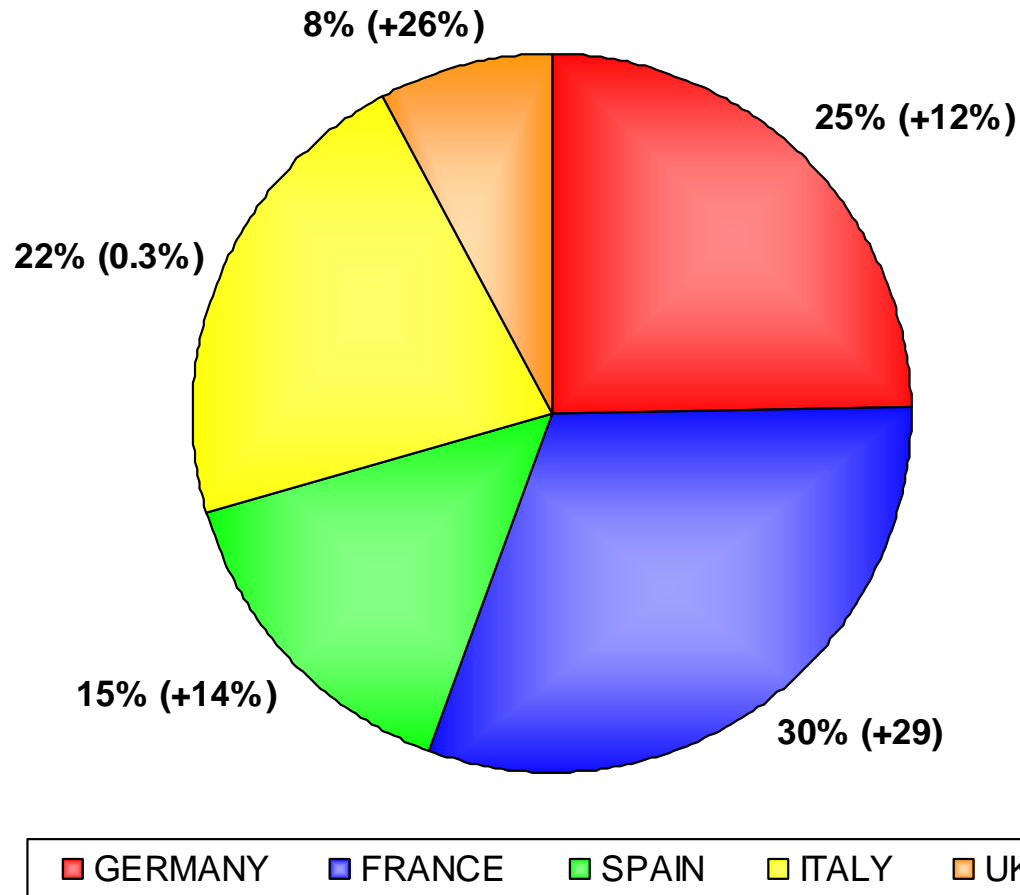
## European Market: Top-5 Countries

- Key-Countries EPO-Market in 2004: 1.8 b\$ (+13%)



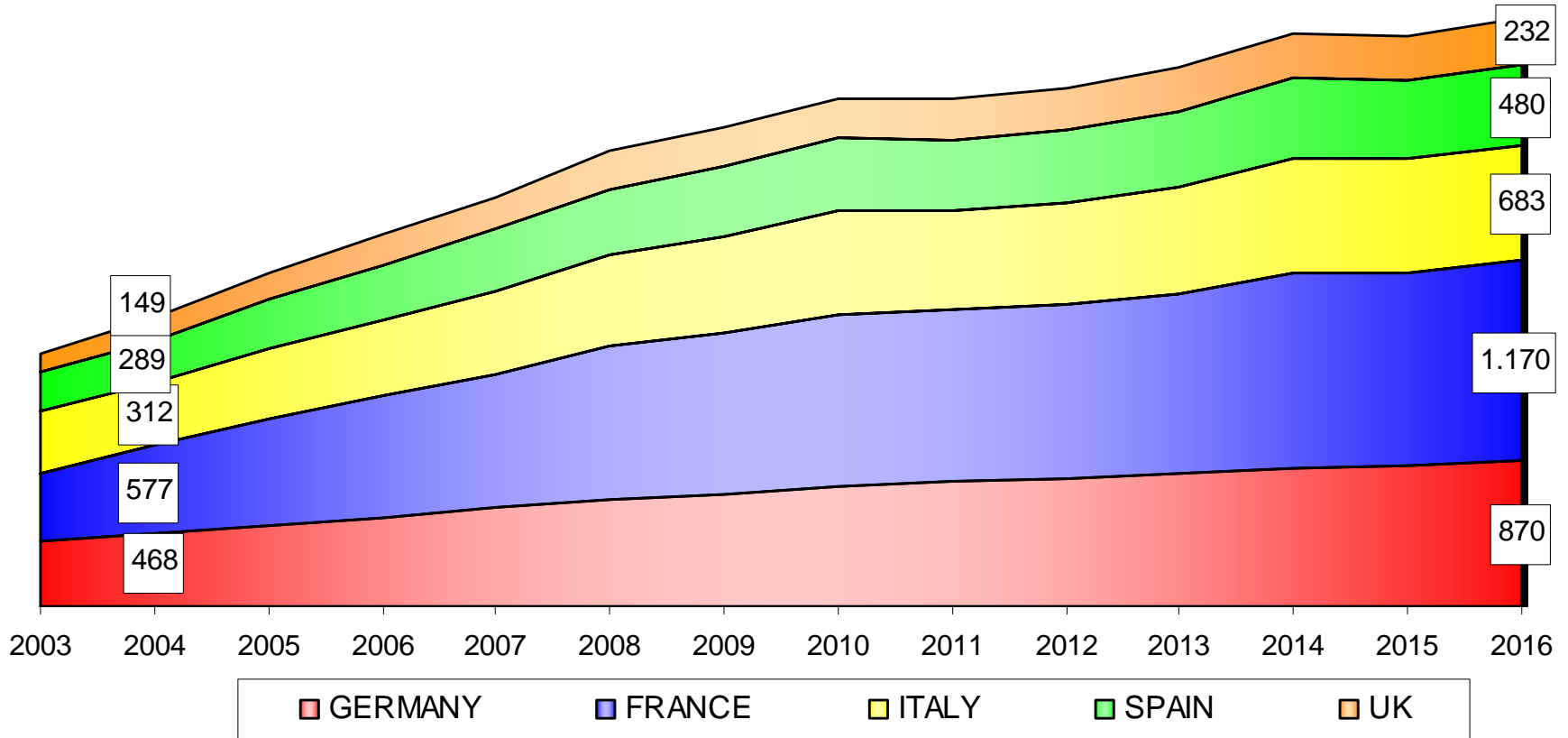
## European Market: Top-5 Countries

- **Key-Countries EPO-Market in 2004: 1.8 b\$ (+13%)**



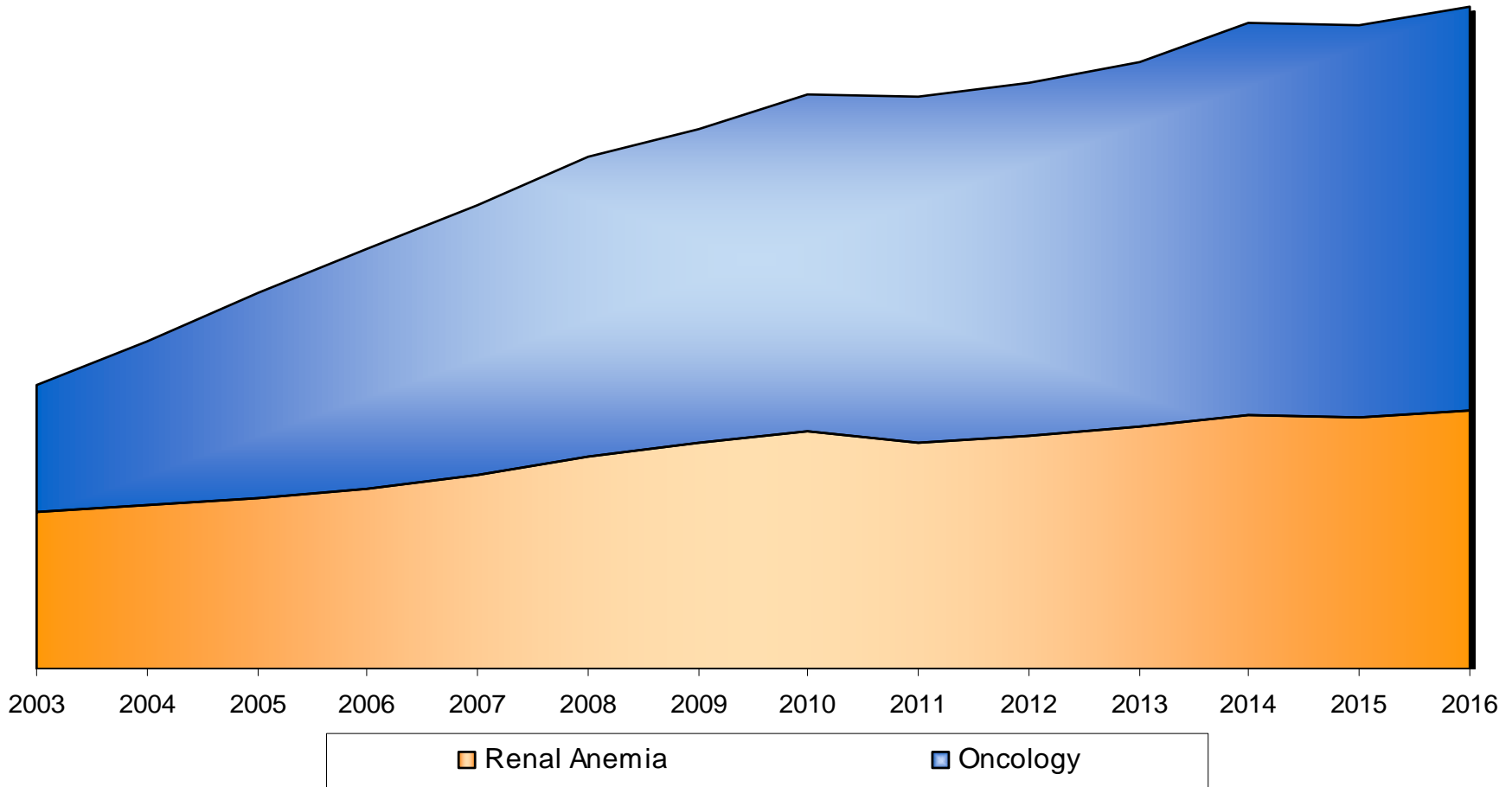
## Market-Forecast: Top-5 European Countries

- Forecast Key-Countries: EPO-Market in 2016: All Indications and Product Generations - approx. 3.4 b\$



## Market-Forecast: Top-5 European Countries Split by Indication

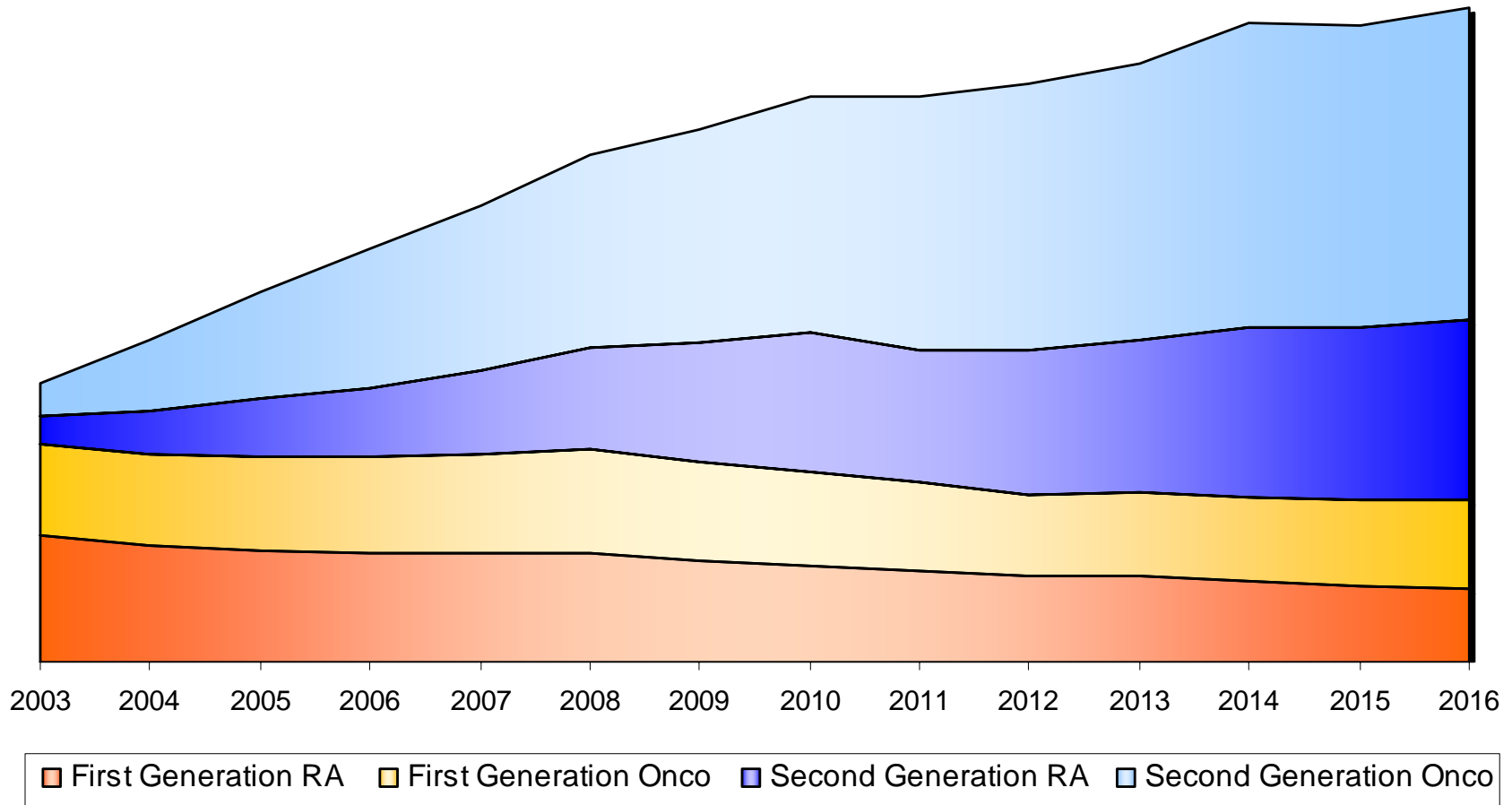
- RA vs Oncology : 45:55% in 2004 - in 2016 38:62%



Source: IMS Health, BioGeneriX

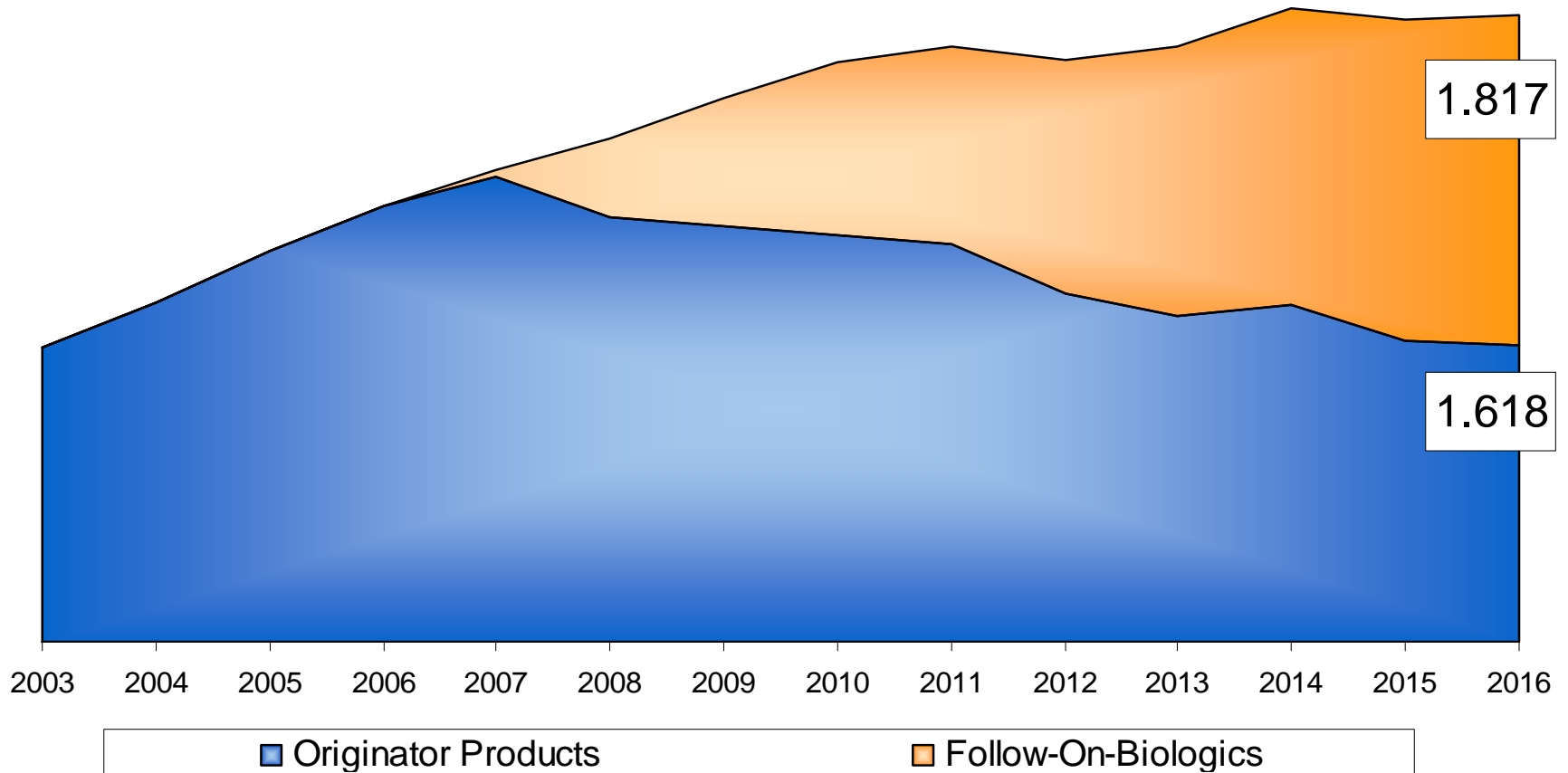
## Market-Forecast: Top-5 European Countries Split by Generation

- The Growth is mainly driven by the Second Generation EPOs



## Market-Forecast: Top-5 European Countries Future of FOB's

- In 2016 50% of total Sales may account for FOB's due to Cost Savings and Product Lifecycle Management

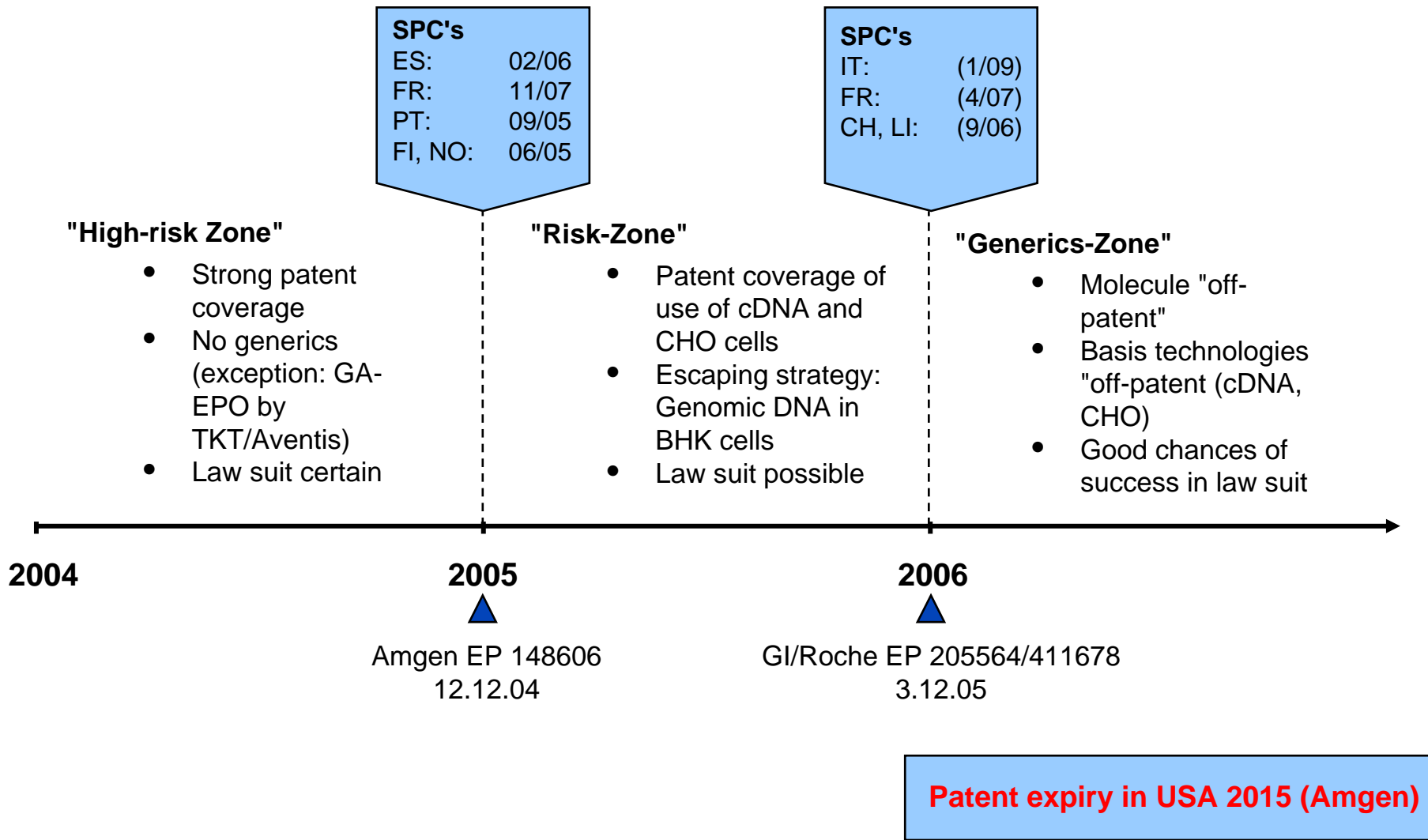


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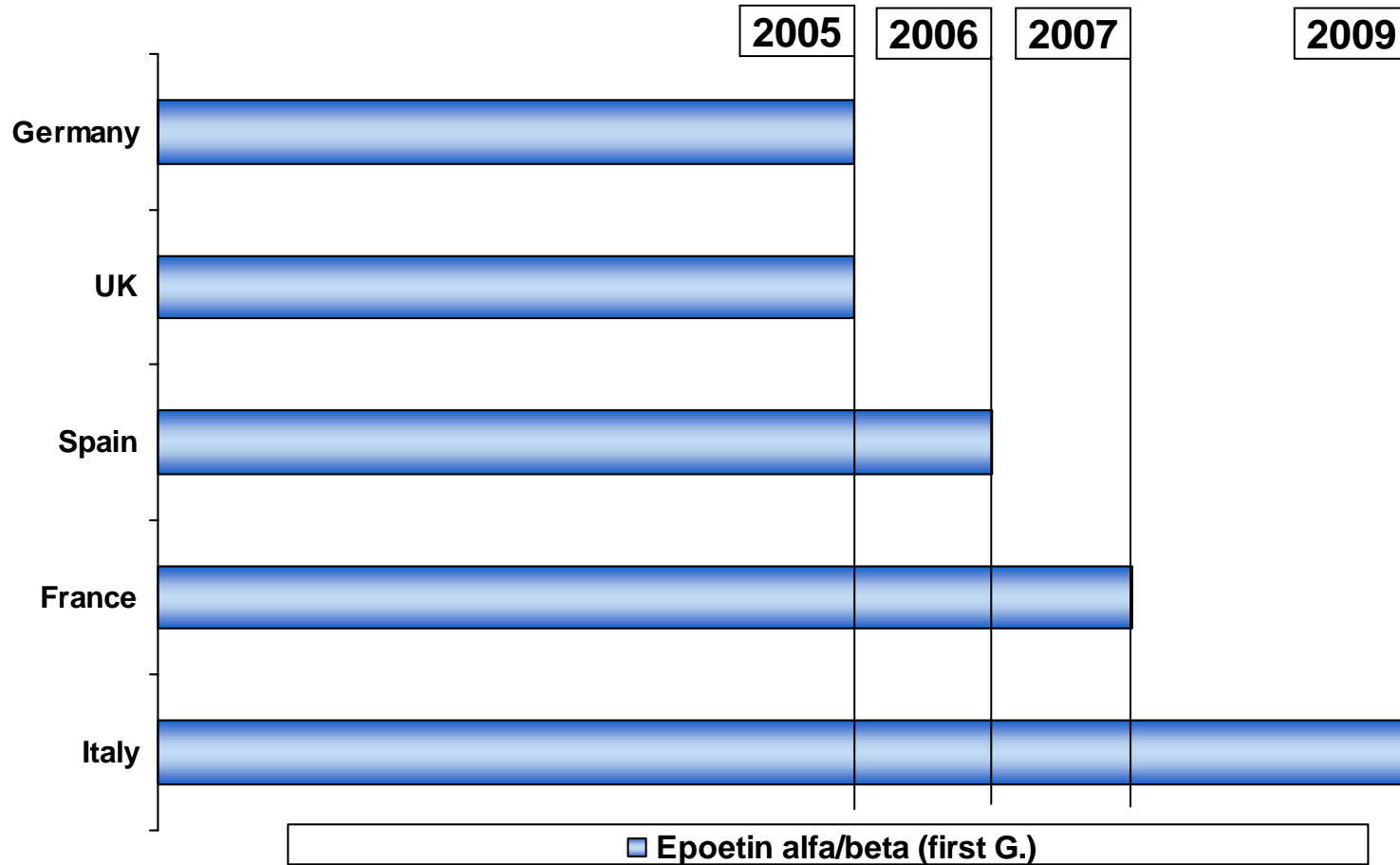
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# Patent Situation



- Patent Expiry including SPC\* :



\* Supplementary Protection Certificate  
Source: BioGeneriX AG/ IMS/ Patent Databases

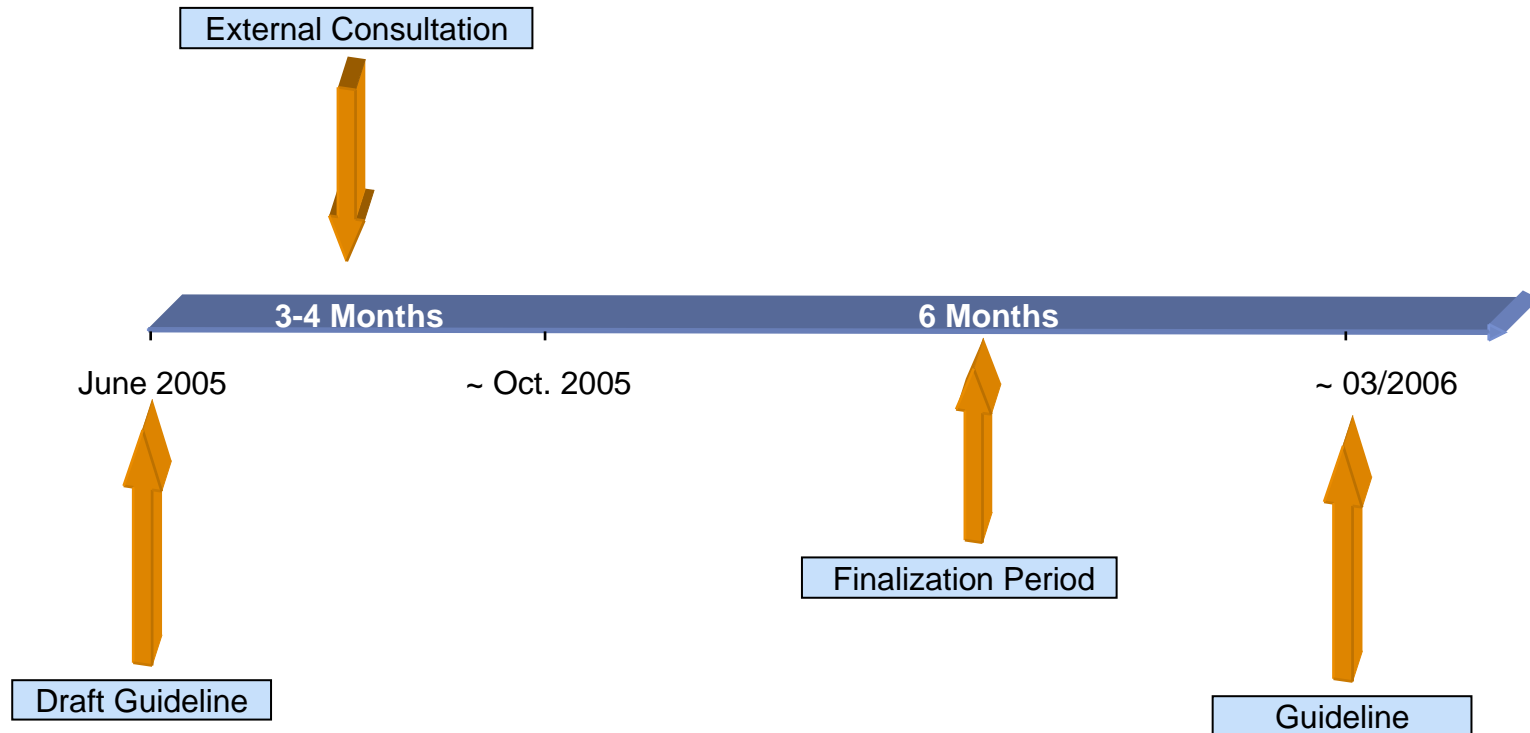
## Regulatory Aspects: Authority Expectations for biosimilar Erythropoietins

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- **Comparative single-dose Pharmacokinetic Study**
- **Equivalence Trials:**
  - **Patients with Renal Anemia**
  - **Titration Phase Study**
  - **Maintenace Phase Study**
  - **Primary Endpoints: Hb-Level and Dosage**
- **One-Year Immunogenicity**
- **Risk Management Plan**
- **Extrapolation to other approved Indications possible**

# Regulatory Aspects: EMA Committee for Medical Products for Human Use (CHMP)

- EPO - Expected Timeline for Guideline:



## Conclusions

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- **Big Growing Market (+9,24% on a global Basis)**
- **High Prevalence, High Number of Untreated Patients (untreated: Dialysis 46% - Cancer 95%)**
- **High Margins**
- **High Investments (20-80 m\$)**
- **High Authority Expectations and Demands**
- **Increasing Regulatory Frame by End 2005**