


Challenges and Opportunities of the Swiss MedTech Industry

Summary

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Zurich, Summer 2006

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Preliminary note

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- This summary does not allow any conclusion to any specific company

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Abstract (I/II)

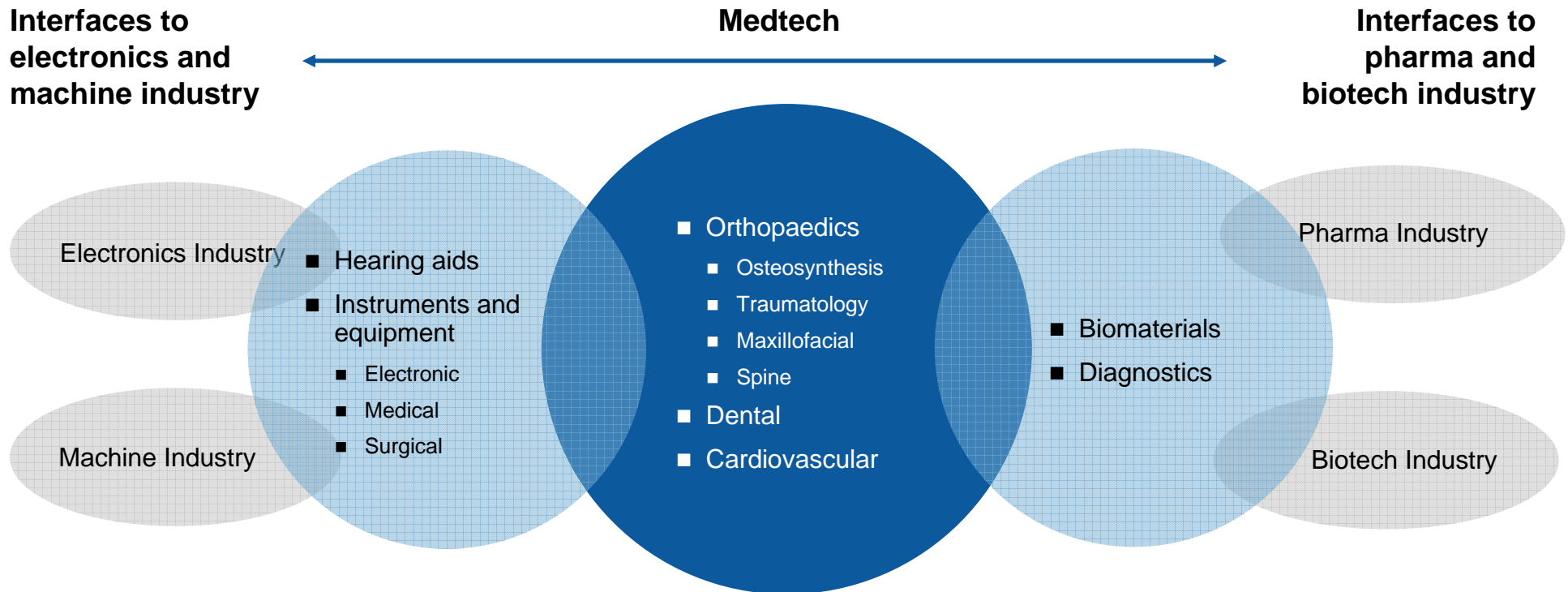
- The turnover of the medtech industry grows above average compared to other industries. In the last two years, the top Swiss medtech companies have shown strong growth rates. This trend is said to hold on as the boost is driven by new and emerging technologies, patient needs, changing social conditions, market conditions, and the regulative environment
- How can the Swiss medtech industry adapt to this conditions, meaning which challenges and opportunities will they be faced with in the future?
- To answer these questions, an investigation including 229 Swiss medical device companies was carried out
- This investigation shall initiate a lively discussion among decision-makers and other interested parties of future needs and possible solutions
- Definition of medtech: It is a cross sectional industry, containing influences from the electronics, machine, pharmaceutical, and biotech industry. It includes products, instruments, and devices that serve for diagnostic purposes, the improvement of the state of health, life expectancy and quality of life
- In this study, a sub-segmentation has been done, dividing medtech into the six segments orthopedics, dental products, cardiovascular, hearing aids, instruments and equipment as well as biomaterials and diagnostics
- The world market for these six segments has an estimated volume of CHF 285 bn. The Swiss market volume for medical devices amounts approx. CHF 4 bn. The average annual growth rate is assumed to be 8%

Abstract (II/II)

- Within the segments mentioned, there exists a high pressure for consolidation. This has already led to numerous M&A activities. The two main reasons are the high importance of gaining market leadership and the focus on realizing economies of scale. Along with that go the high requirements concerning the regulative environment and the rules for marketability. Especially for SMEs these issues are getting increasingly critical to master
- Between the segments only few mergers happen. This is caused by the different demands concerning products and technologies, which do not create any promising synergies
- Adjacent the large, worldwide leading companies, the industrial sector is strongly fragmented in all sub-segments. More than 80% of European medtech companies are SMEs
- In Switzerland, there are 586 medtech companies which employ altogether 35'000 persons. However, more than 90% of the companies are SMEs with staff of less than 250
- In Switzerland there is a considerable amount of well organized regional and local promoting organizations. This emphasizes the huge interest and the high importance of the medtech industry as future business potential. The companies themselves mostly agitate in national and international value chains. Therefore the possibility to further foster this industry remains
- Costs for R&D are on average 14% of the turnover
- More than 70% of the goods manufactured are exported

Medtech has interfaces to many other industries

Our understanding of the medtech industry



Definition of medtech:

Medtech includes non-metabolic products, instruments, and equipment that either serve for diagnostic purposes, the improvement of the general well-being, the life expectancy or the quality of life.

Market structure and segments show differences between medtech, pharma and biotech

Boundaries of medtech

	Medtech	Pharma	Biotech
Market structure	<ul style="list-style-type: none"> ■ Few big companies per segment, numerous small and tiny companies ■ Consolidation process for established uses ■ Heterogeneous products ■ High growth 	<ul style="list-style-type: none"> ■ Few big companies, many SMEs as niche players (specialty pharma) ■ Process of focusing and consolidation under way ■ Relatively homogenous products and segments ■ Gaps in product development 	<ul style="list-style-type: none"> ■ Few big companies, many SMEs ■ Consolidation process with pharma companies under way ■ Products with new mechanisms of action ■ High growth
Segments	<ul style="list-style-type: none"> ■ Orthopaedics <ul style="list-style-type: none"> ■ Osteosynthesis ■ Traumatology ■ Maxillofacial ■ Spine ■ Dental ■ Cardiovascular ■ Hearing aids ■ Instruments and equipment <ul style="list-style-type: none"> ■ Electronic ■ Medical ■ Surgical ■ Biomaterials ■ Diagnostics 	<ul style="list-style-type: none"> ■ On prescription <ul style="list-style-type: none"> ■ Cardiovascular ■ Central nervous system (CNS) ■ Infection ■ Inflammation and autoimmune diseases ■ Metabolism ■ Oncology ■ Respiratory system ■ Transplantation ■ Virology ■ Non-prescription ■ Generic medicaments 	<ul style="list-style-type: none"> ■ Diagnostics and analysis ■ Pharmaceuticals and chemicals ■ Bioinformatics and bioelectronics ■ Genomics and proteomics

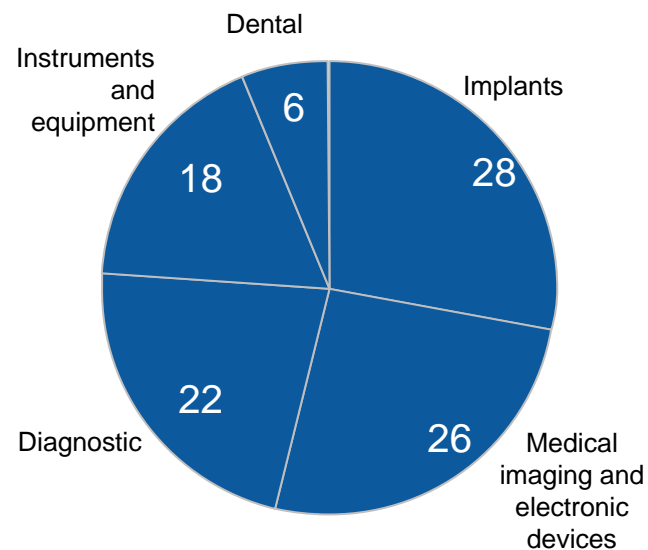
Source: Helbling Analysis

Medtech is a strongly fragmented market with a global volume of CHF 285 billion

Market overview 2005 / 2006

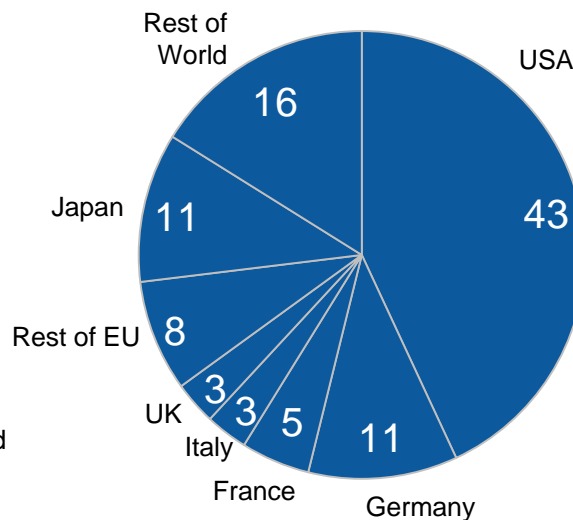
Segments [%]

- Sales volume CHF 285 billion
- Annual growth 8%
- Heterogeneous industry consisting of numerous different products and competencies



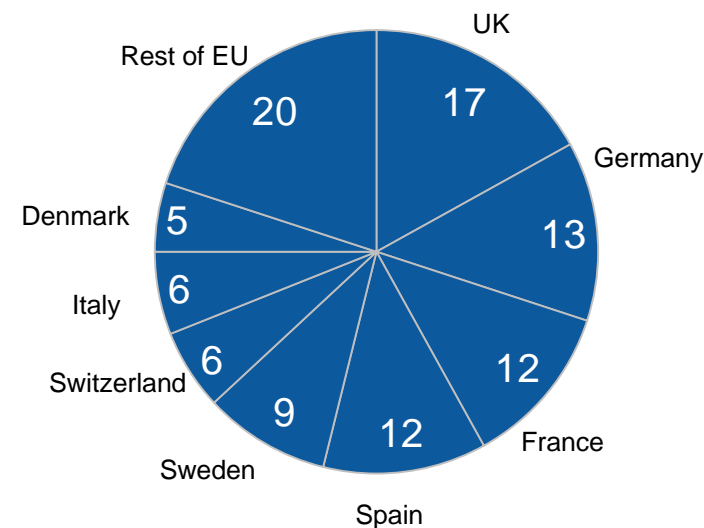
Regional allocation [%]

- Industrialized countries are leading
- USA und EU with a global market share of 73%



Business structure Europe [%]

- Over 80% small and medium-sized enterprises (SME)
- Fragmented SMEs in European countries (Basis approximately 10'000 enterprises)

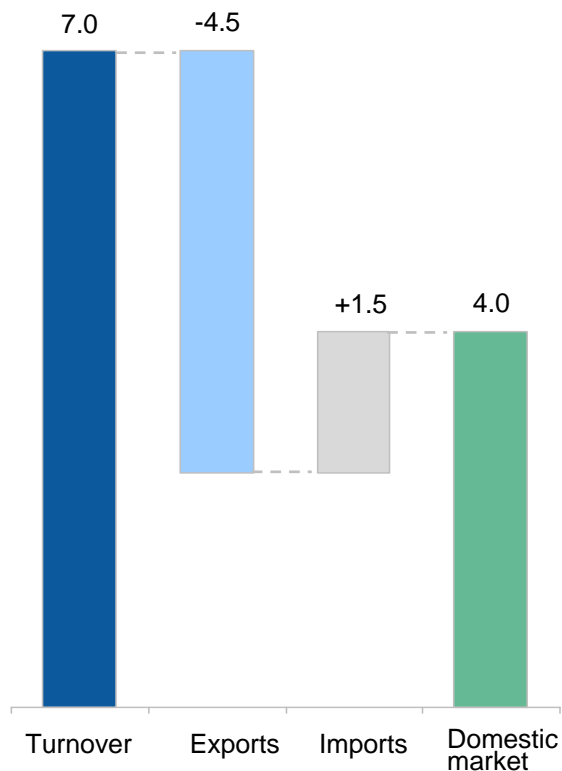


Source: Merrill Lynch, Eucomed 2006, Helbling Research

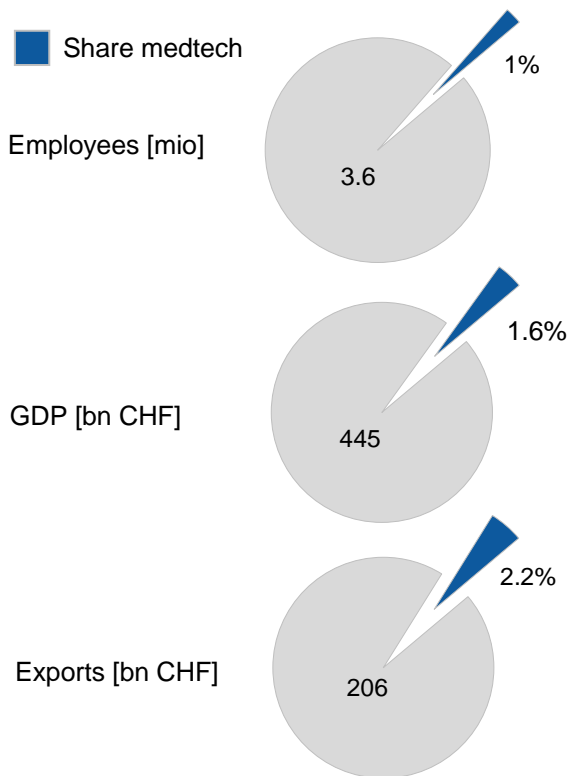
Sales volume of CHF 7 bn and exports of CHF 4.5 bn - Strongly growing Swiss top-companies

Medtech market Switzerland 2005

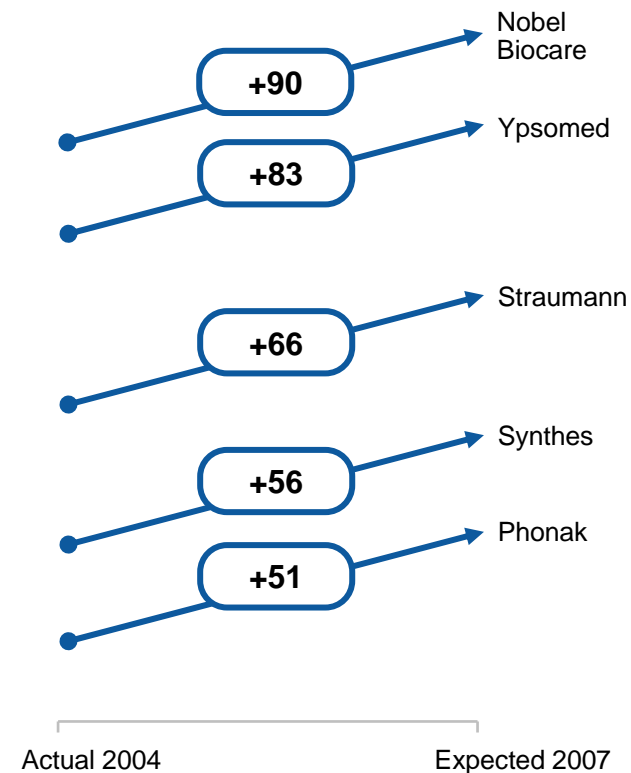
Market volume [CHF in bn]



Economic importance to Switzerland



Development of turnover of top-companies 2004/07 [%]

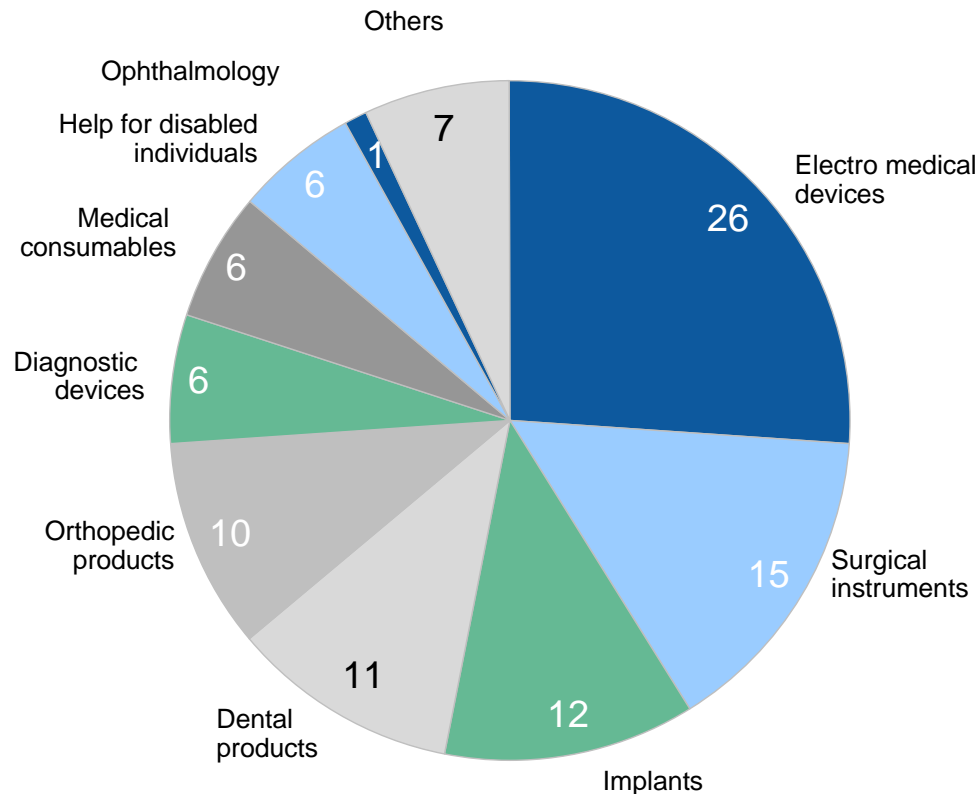


Source: PhD thesis Dümmler 2006, BFS 2006, Helbling Estimates

Fragmented SME structure characterizes the Swiss medtech market

Structural data medtech Switzerland 2005

Main focus on business activity [%]



Main figures

- About 35'000 employees in 586 medtech companies
 - 335 manufacturing companies
 - 167 trading and service companies
 - 84 companies with low medtech share
- SME-structure
 - 76% of medtech companies have less than 50 employees
 - 93% have less than 250 employees
- 57% of medtech companies have a sales volume of less than CHF 5 mio
- R&D-spending is in average of 14% of turnover
- 70% of the products are exported

Comments: Not based on turnover data, but the percentage of companies having business activities in the respective segment; n= 229 medtech companies

Source: PhD thesis Dümmler 2006

Synthes, Phonak and Straumann are three globally leading Swiss medtech companies

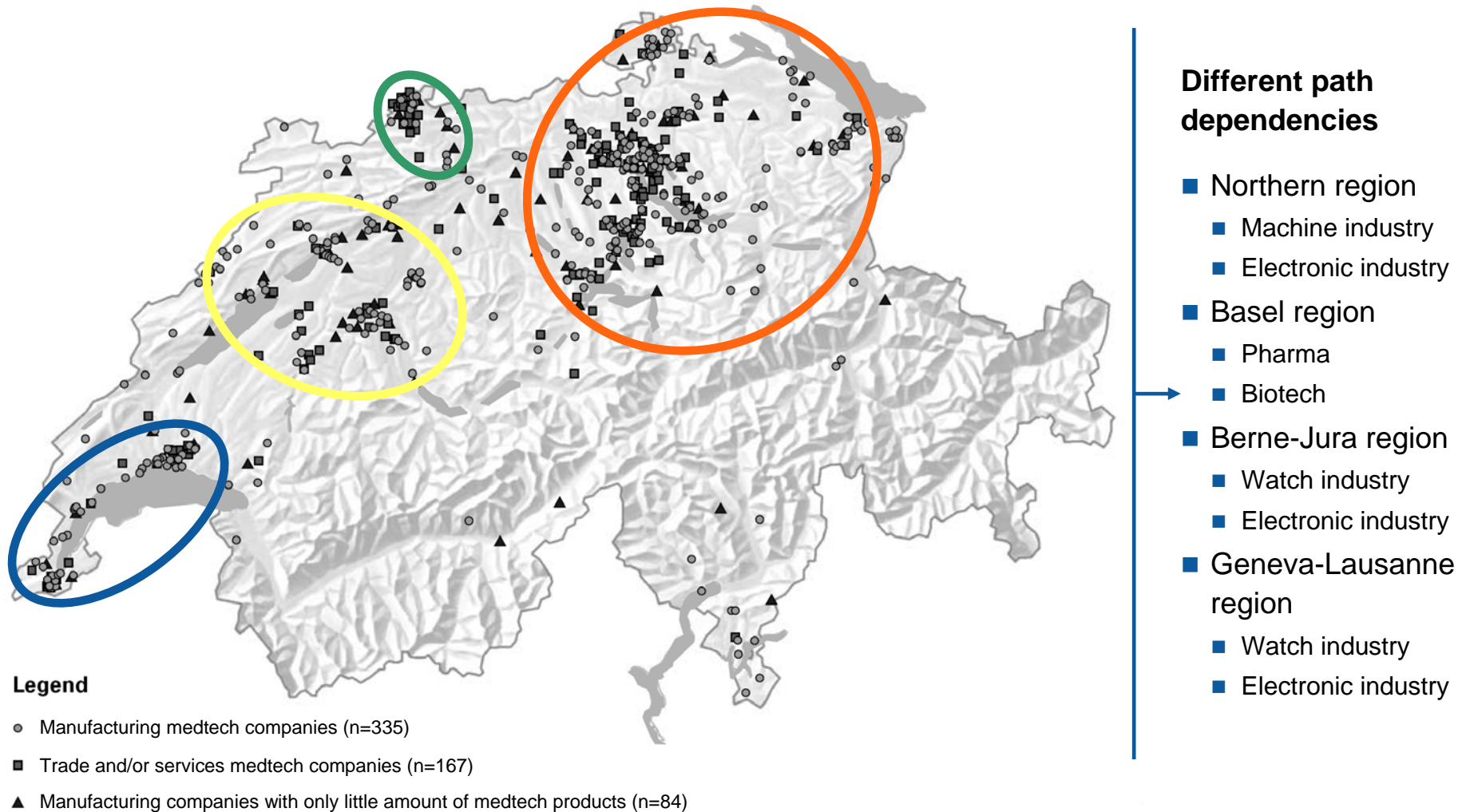
Examples Swiss market participators, 2005

	Synthes	Phonak	Straumann
Focus	<ul style="list-style-type: none"> Development and manufacturing of implants, instruments, and devices for traumatology, spine, oral, and maxillofacial surgery 	<ul style="list-style-type: none"> Development, manufacturing and distribution of hearing aids 	<ul style="list-style-type: none"> Development and manufacturing of dental implants and products for gingival regeneration
Global position	<ul style="list-style-type: none"> # 4 for orthopedics 	<ul style="list-style-type: none"> # 3 for hearing aids 	<ul style="list-style-type: none"> # 2 for dental implants
Market cap. [Mio. CHF]	<ul style="list-style-type: none"> 17'400 	<ul style="list-style-type: none"> 5'200 	<ul style="list-style-type: none"> 4'500
Sales volume [Mio. CHF]	<ul style="list-style-type: none"> 2'793 	<ul style="list-style-type: none"> 679 	<ul style="list-style-type: none"> 510
Employees	<ul style="list-style-type: none"> 7'169 	<ul style="list-style-type: none"> 2'719 	<ul style="list-style-type: none"> 1'342
Regions [%]	<ul style="list-style-type: none"> Europe: 21 Northern America: 64 Asia/Pacific: 10 Rest of world: 5 	<ul style="list-style-type: none"> Europe: 49 Northern America: 41 Asia/Pacific: 8 Rest of world: 2 	<ul style="list-style-type: none"> Europe: 62 Northern America: 26 Asia/Pacific: 10 Rest of world: 2

Source: Companies annual reports 2005/06, Helbling research

Cluster potentials of medtech companies in four regions

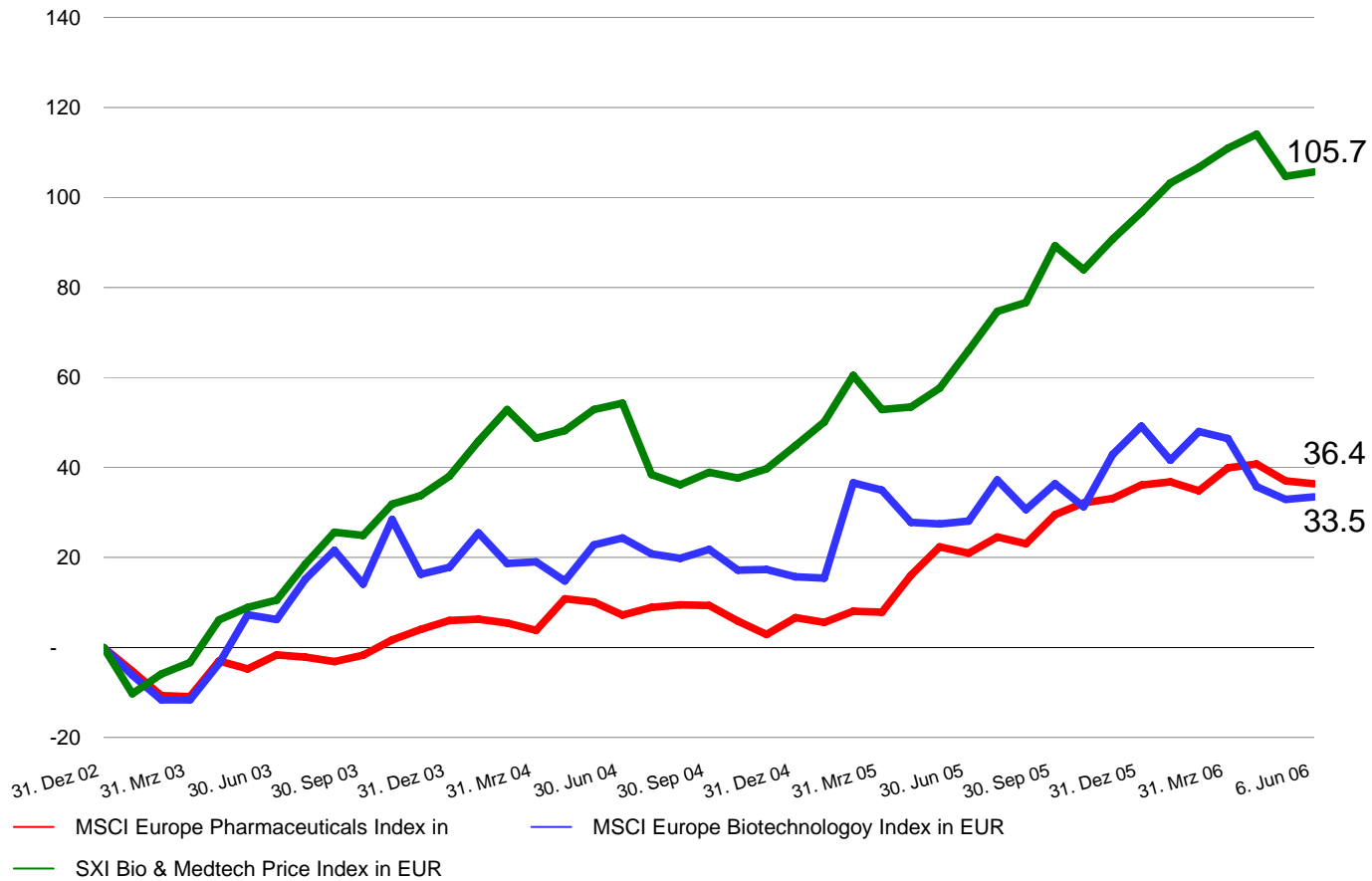
Location of medtech companies in Switzerland



Source: PhD thesis Dümmler 2006

Medtech beats pharma and biotech – what drives these growth prospects?

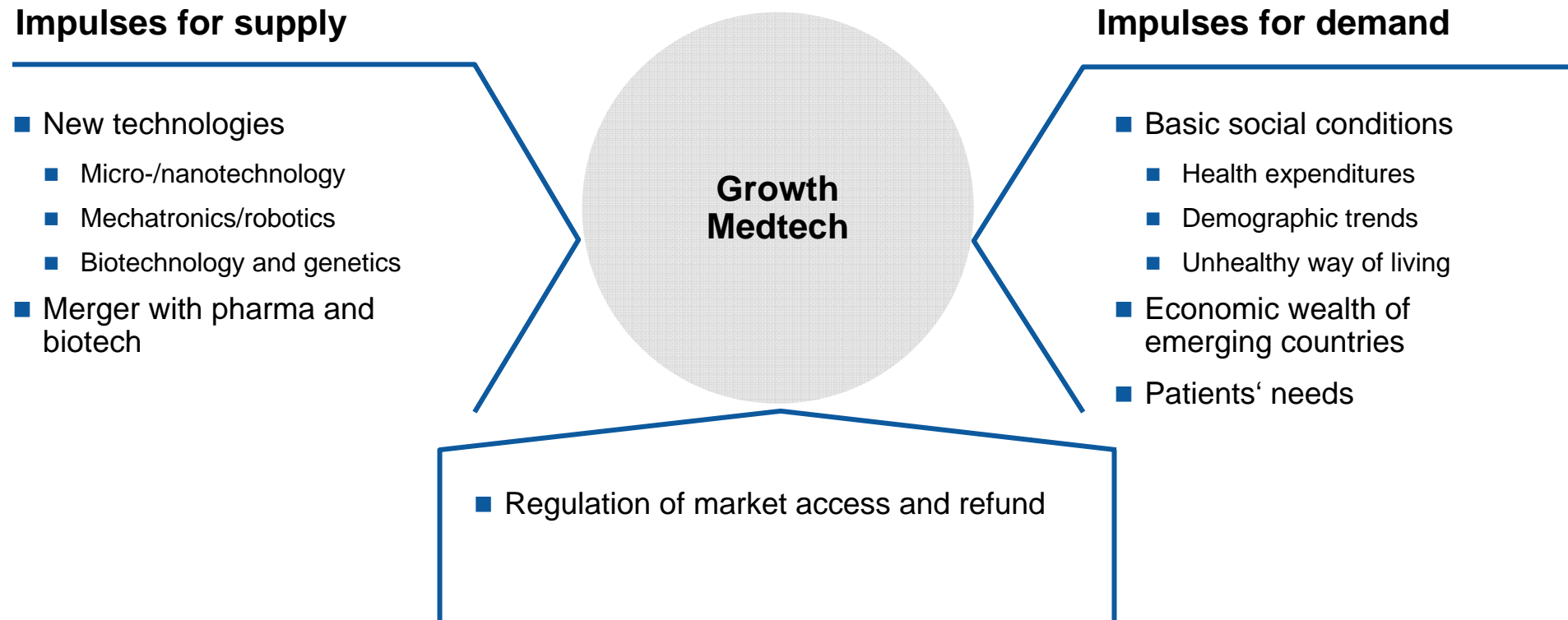
Relative performance January 2003 – June 2006



- Sharper rise of Swiss Medtech/biotech titles in comparison with European pharma and biotech titles
- Reflects the high expectations towards the future potential of the medtech industry
- ROCE
- Margin
- Growth in sales volume

Source: Bloomberg, Helbling Analysis

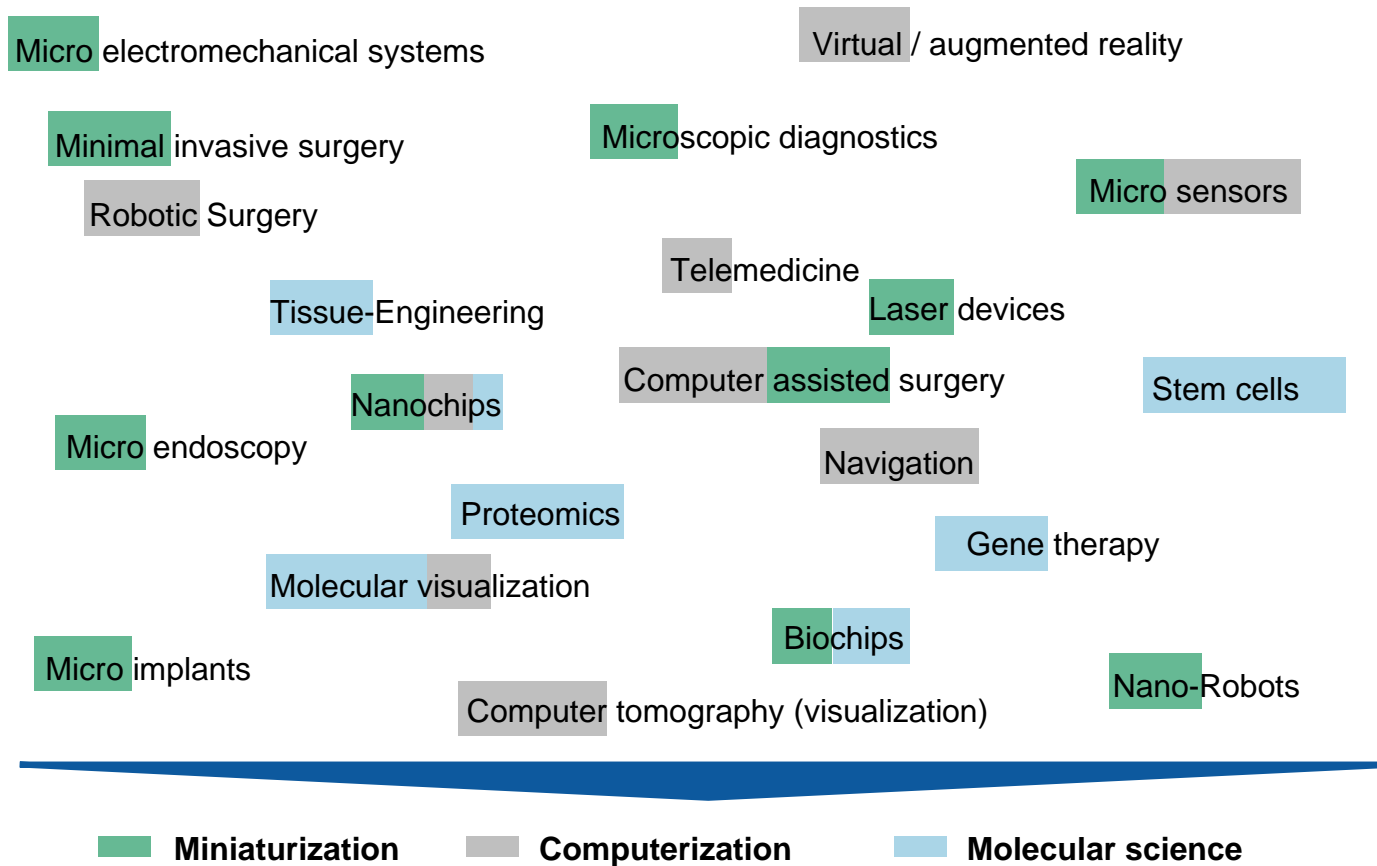
The growth in the medtech market is driven by supply and demand – Additional impact through regulations



Source: Helbling Analysis

Growing importance of miniaturization, computerization, and molecular science

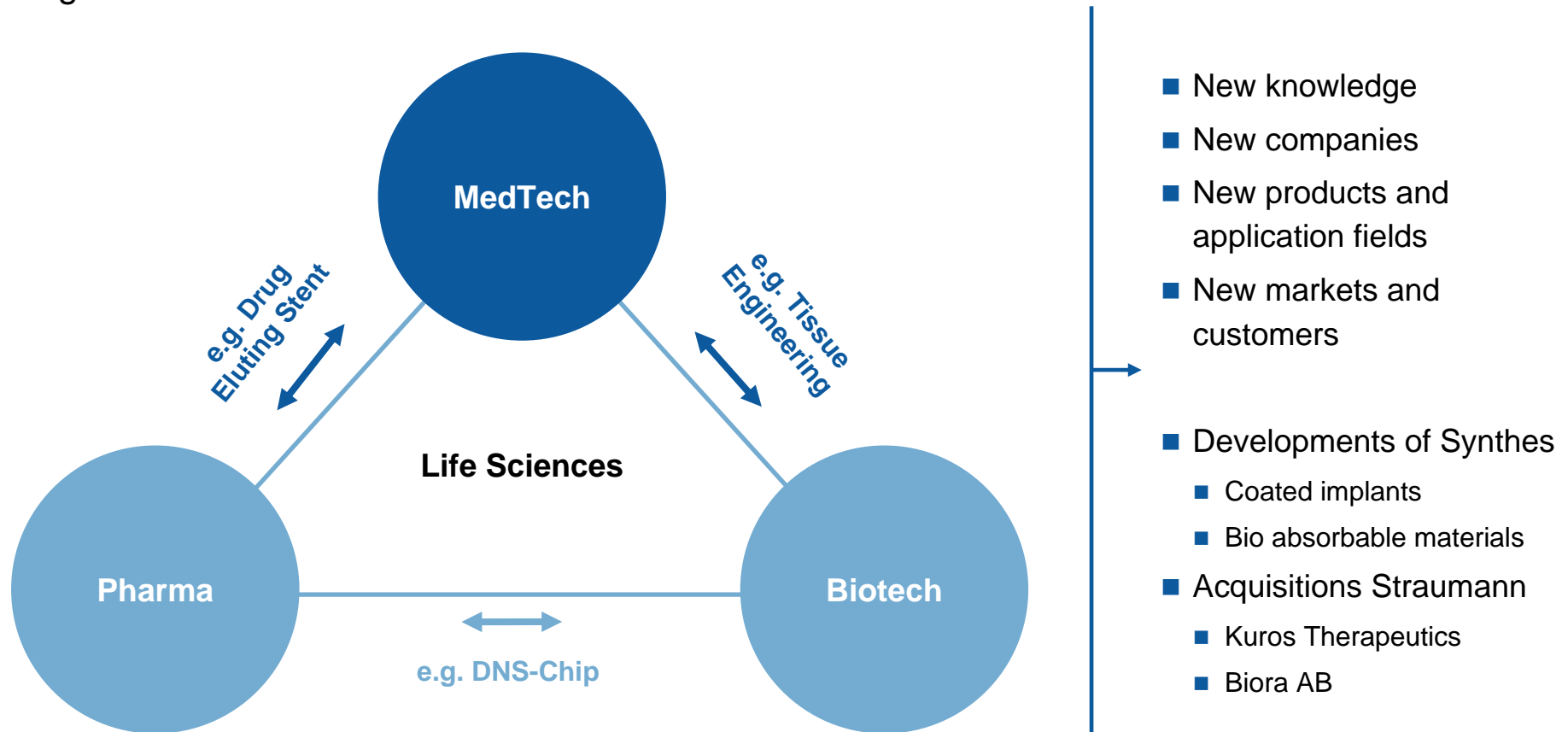
Key technologies



Source: BMBF 2005

New market opportunities through the merger of medtech with pharma and biotech

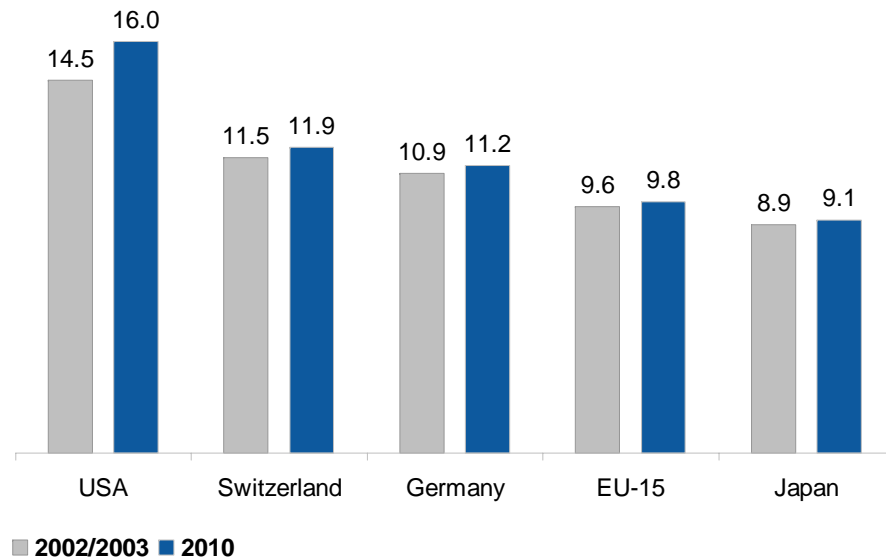
Mergers



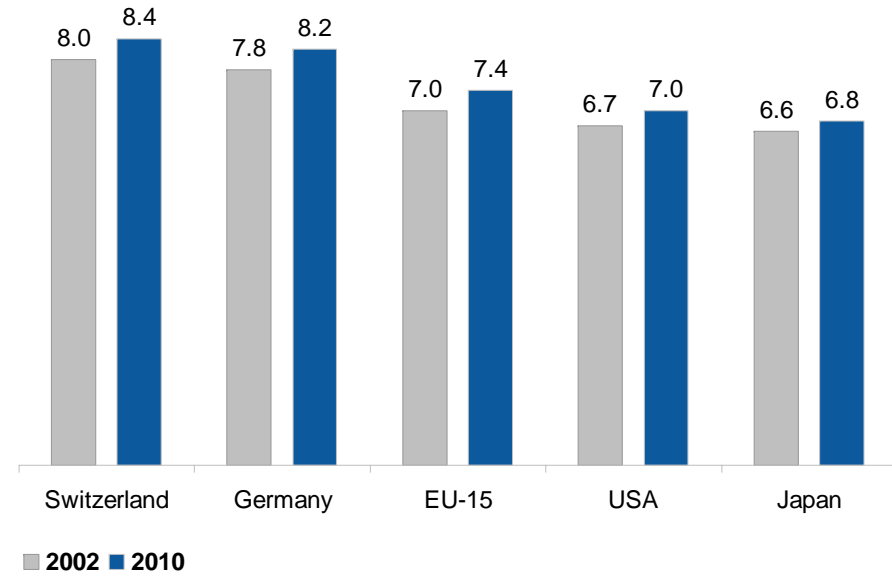
Source: Helbling analysis

Forecast until 2010 assumes growing expenditures for health and medtech

GNP health expenditure [%]



Medtech share of health expenditure [%]



- Rise of world population by 23% up to 8 bn until 2030
- Rise of people over 65 years by 45% up to 650 bn worldwide until 2030
- Increase in demand for health care services will continue

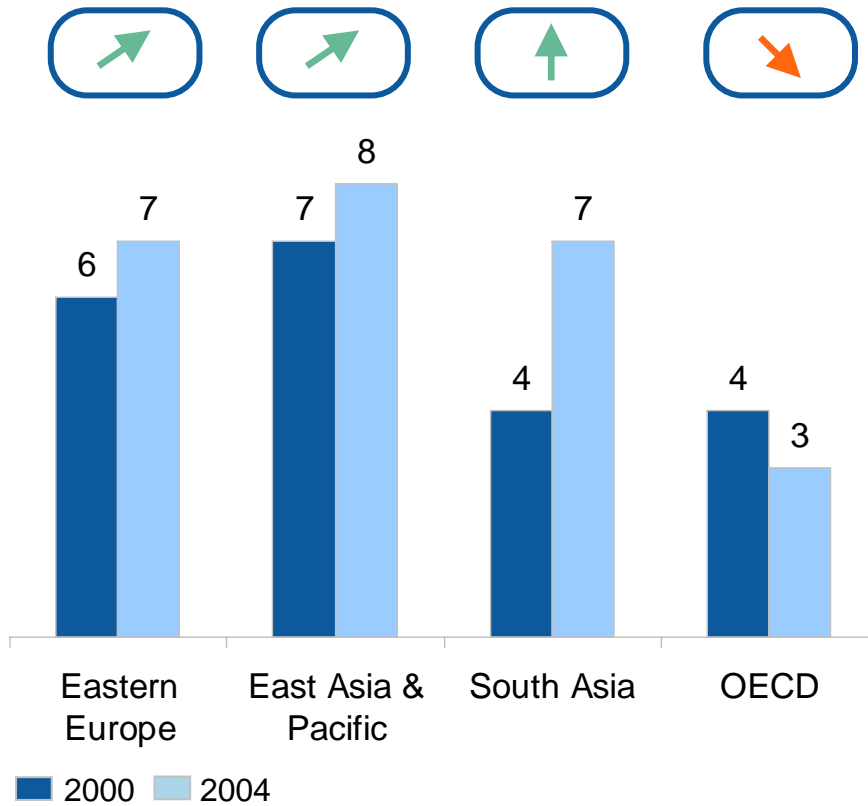
- Medtech products account for an increasing share of health care expenditures

Source: BMBF 2005, BFS 2005, Helbling estimate

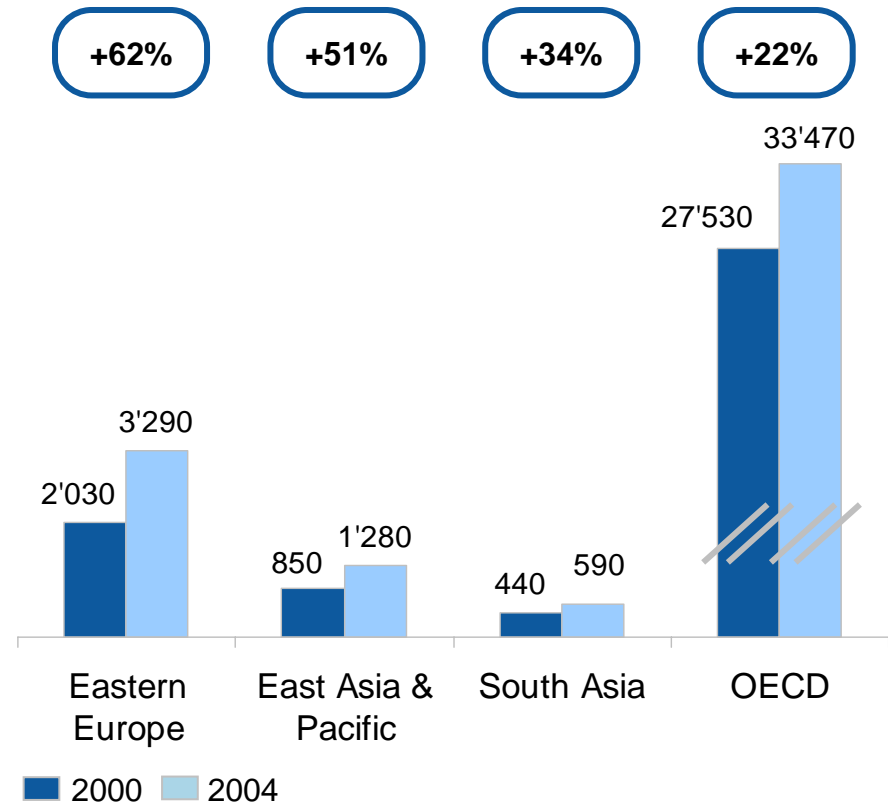
The growth of new markets, particularly in emerging countries, leads to a higher demand

Emerging regions versus OECD

GNP growth [%]



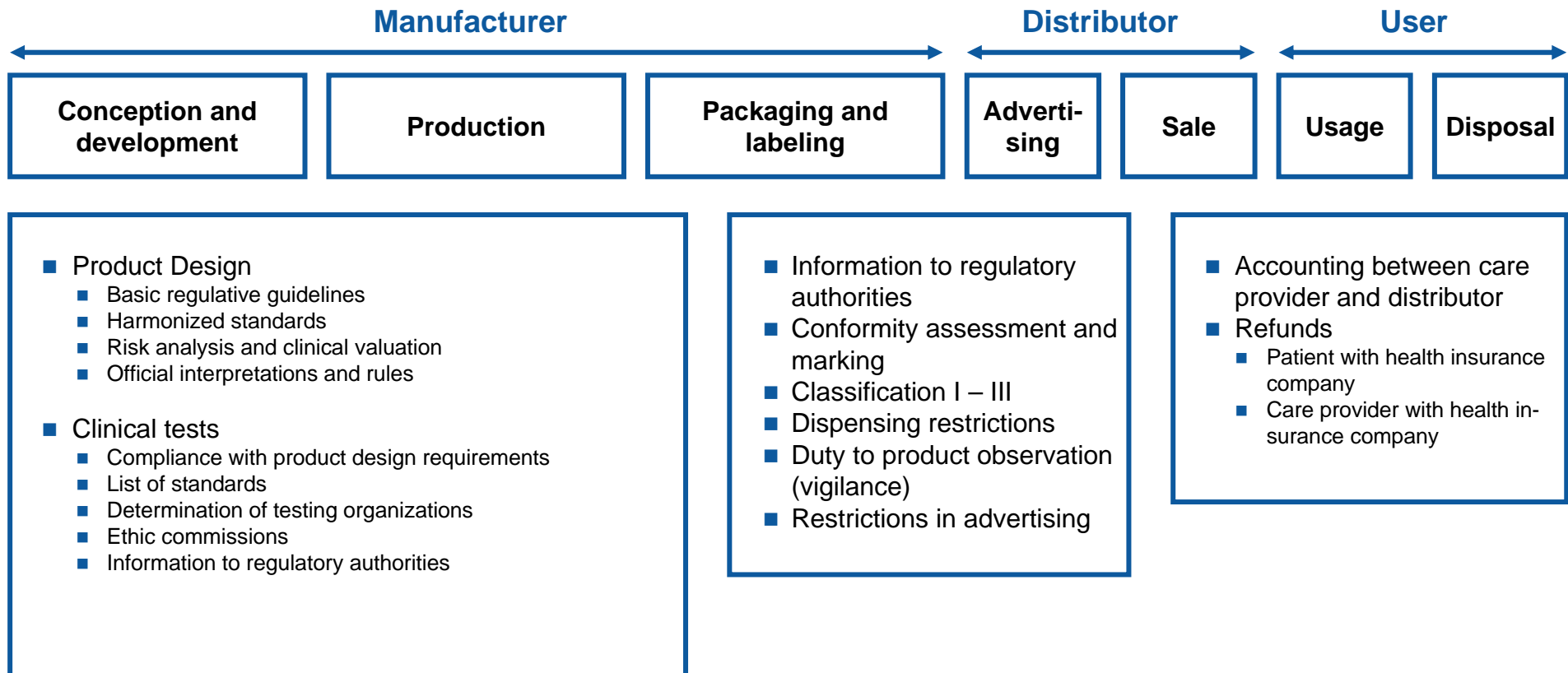
Income per capita [USD]



Source: Worldbank 2006

Regulative requirements affect all phases of the value chain

Value chain phases of medtech products



Source: Swissmedic 2006, Helbling research

Medtech regulation of the European Union as a basis – also for Switzerland

Product classes and product approval – European Union

Product classes	Product approval	Examples
I Low risk <ul style="list-style-type: none"> ■ Non invasive products ■ Reusable surgical instruments 	<ul style="list-style-type: none"> ■ Declaration of conformity 	<ul style="list-style-type: none"> ■ Stethoscope ■ Scalpel
IIa Medium risk <ul style="list-style-type: none"> ■ Active and inactive products ■ Invasive and non-invasive products for short term use 	<ul style="list-style-type: none"> ■ Declaration of conformity ■ Reduced certification of the production phase ■ Product verification ■ Certification of quality assurance Alternatively: <ul style="list-style-type: none"> ■ Extensive certification 	<ul style="list-style-type: none"> ■ Electrocardiographs ■ Hearing aids
IIb Medium risk <ul style="list-style-type: none"> ■ Active products emitting substances or energy with a potential risk ■ Products for long term use 	<ul style="list-style-type: none"> ■ Reduced certification of the production phase ■ Product verification ■ Certification of quality assurance ■ Extensive certification ■ Physical product verification (random inspection) 	<ul style="list-style-type: none"> ■ X-ray apparatus
III High risk <ul style="list-style-type: none"> ■ Products in contact with the central nervous system 	<ul style="list-style-type: none"> ■ Reduced certification of the production process ■ Product verification ■ Extensive certification ■ Physical product verification (random inspection) ■ Inspection of product dosage 	<ul style="list-style-type: none"> ■ Joint replacements/implants ■ Pacemaker ■ Catheter

Source: Swissmedic 2006, Helbling research

Detailed regulation catalogue in the US – only 3% classified as high risk

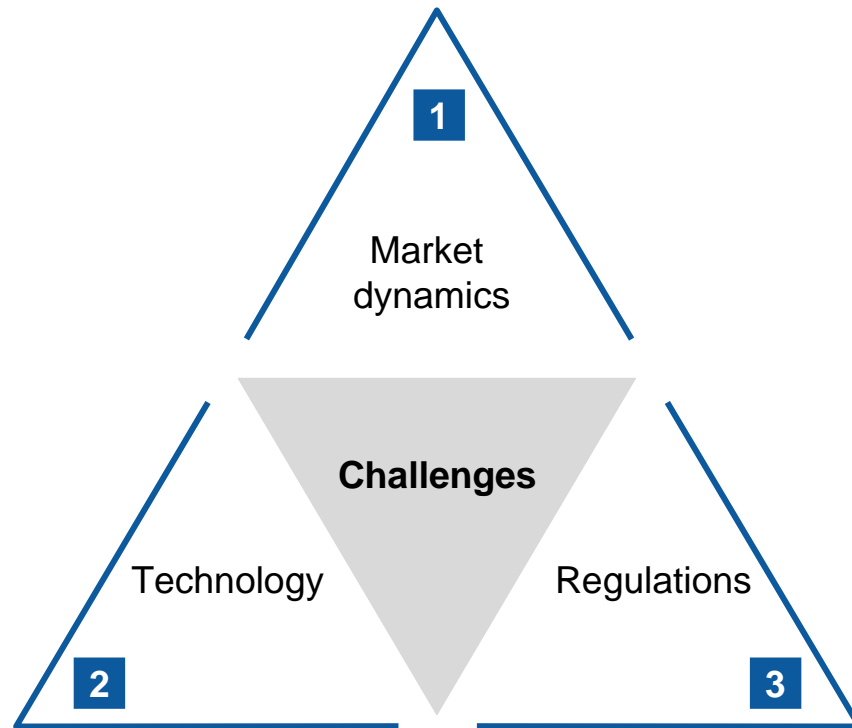
Product classes and product approval – USA

Product classes	Share of products	Product approval	Examples
I Low risk <ul style="list-style-type: none"> ■ Products without the purpose of maintaining or supporting human life 	<ul style="list-style-type: none"> ■ 50 % 	<ul style="list-style-type: none"> ■ Premarket Notification ■ General controls <ul style="list-style-type: none"> ■ Registration of manufacturers ■ Good-Manufacturing-Practice ■ Information of FDA 	<ul style="list-style-type: none"> ■ Medical gloves ■ Elastic bandages
II Medium risk <ul style="list-style-type: none"> ■ Products like category I, but with a higher potential risk 	<ul style="list-style-type: none"> ■ 47 % 	<ul style="list-style-type: none"> ■ Premarket Notification ■ General controls ■ Special controls <ul style="list-style-type: none"> ■ Design standards ■ Market surveillance ■ Patients' register 	<ul style="list-style-type: none"> ■ X-ray apparatus ■ Infusion pumps
III High risk <ul style="list-style-type: none"> ■ Products with the purpose of maintaining or supporting human life 	<ul style="list-style-type: none"> ■ 3 % 	<ul style="list-style-type: none"> ■ Premarket Notification ■ General controls ■ Special controls ■ Premarket approval 	<ul style="list-style-type: none"> ■ Pacemakers

Source: Swissmedic 2006, Helbling research

Market dynamics, technology and regulations are the decisive challenges for medtech companies

Overview

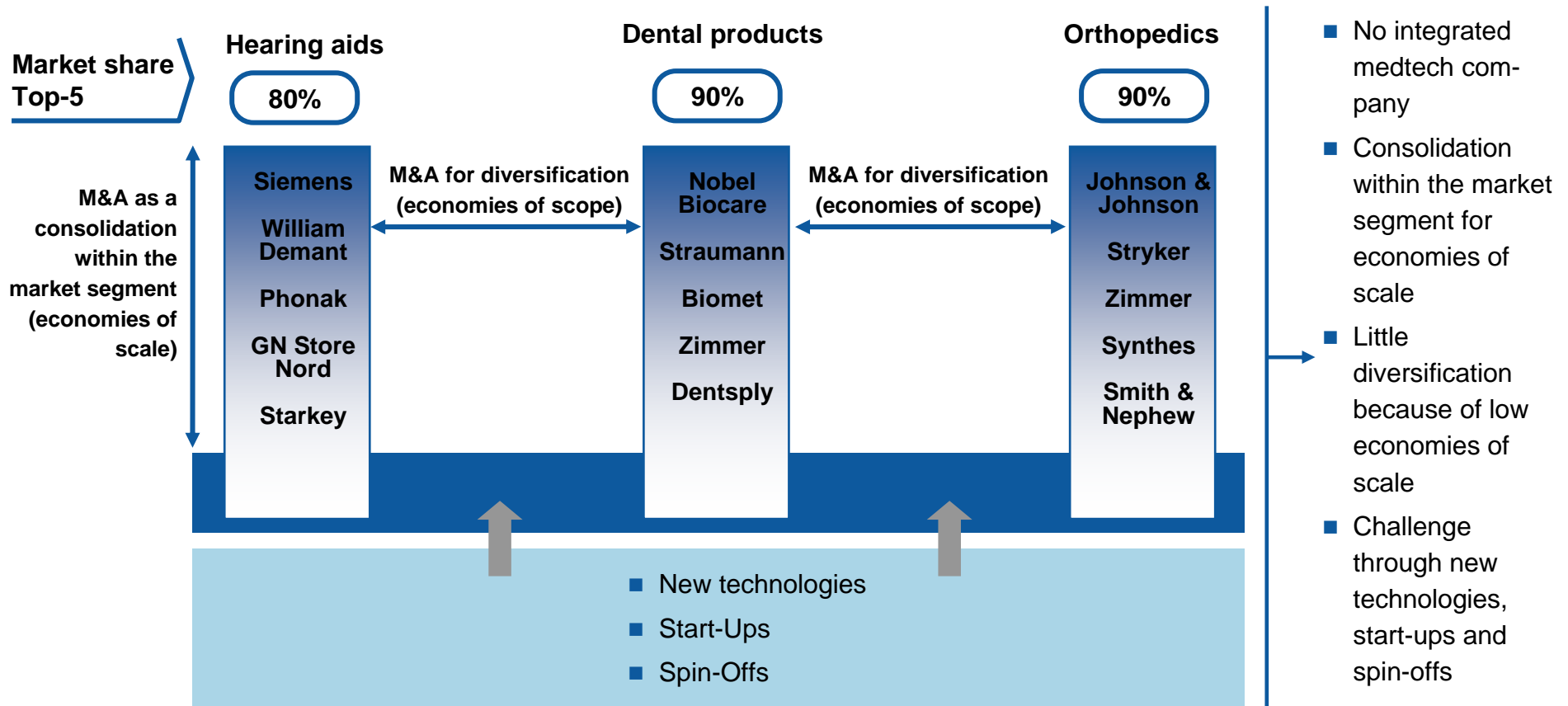


- 1** Market dynamics
 - Increasing number of competitors
 - Clones/copies produced in emerging countries
 - Competition with pharma and biotech companies
 - Economies of scale, weak economies of scope
- 2** Technology
 - New key technologies require new competencies
 - New competitors from other fields of technology
 - Combination of technologies
 - Higher investments in R&D and increasing risks
- 3** Regulations
 - Increasing regulation requirements for product approval
 - Change in refund policy due to cost pressure in health care systems

Source: Helbling analysis

High market share of the top 5 companies in the relevant market segment, but no integrated medtech company in several market segments

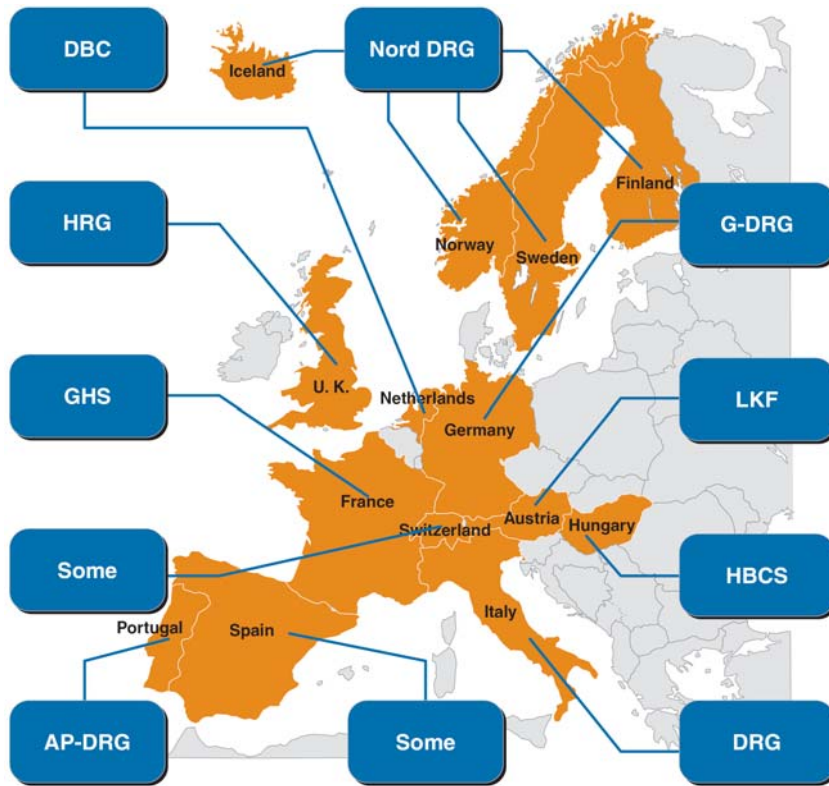
Market segment M&A and consolidation



Source: Helbling analysis

Pressure on the medtech business through new refund policies – increasing complexity in market development

Refund policies in Europe



Germany (gradually since 2005)

- Case based lump sum
- Increasing budget pressure on health care
- Formation of buying syndicates
- Medical doctors lose decision power
- Germany has lowest prices for medical devices in the EU

France (gradually since 2004)

- Daily flat-rate at hospitals
- Case based lump sum
- Compensation of real costs (regarding expensive products); but maximum in-house prices
- Slowly increasing pressure on medtech prices

UK (gradually since 2003)

- Payments by results / case based lump sums
- Slowly increasing pressure on medtech prices

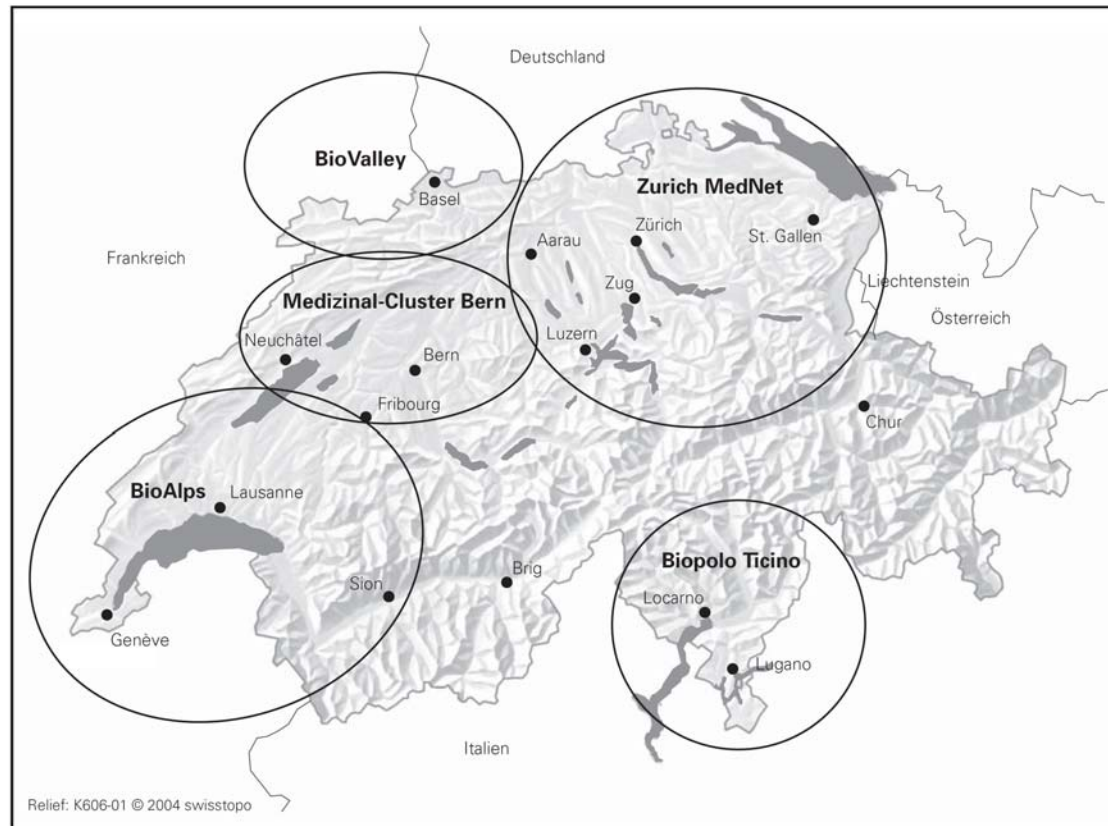
Remarks: DRG: Diagnosis Related Groups
 G-DRG: German Diagnosis Related Groups (Pauschalierendes Entgeltsystem)
 HRG: Healthcare Resource Group
 GHS: Groupes Homogènes de Séjours (Case-Mix Based Payment)

DBC: Diagnosis Treatment Combinations
 LKF: Leistungsorientierte Krankenanstalten-Finanzierung
 HBCS: Homogén Betegség Csoportok (Hungarian DRG)

Source: Broker reports, Helbling research

Five large regional organizations develop and market medtech, pharma, biotech and chemical industry

Five large „cluster“-organizations



Total 71 organizations (excerpt)

- **Zürich MedNet**
 - Founded 1999 as a part of the GZA (Greater Zurich Area)
 - Encompasses about 400 companies
 - Main aim is cluster promotion
 - Partners of GZA support companies
- **Medizinal-Cluster Bern**
 - Founded 1997 as an association
 - Encompasses about 200 companies
 - Aim: Promotion of regional companies
- **BioValley**
 - Founded 1996 as an umbrella organization
 - About 340 companies
 - Aim: Support of networks
 - Mainly focused on pharma and biotech
- **Bioalps**
 - Founded by the cantons in 2003
 - About 200 companies
 - Aim: support of the company-university network
 - Mainly focused on pharma and biotech
- **Biopolo Ticino**
 - Founded as a public-private partnership in 2002
 - Aim: One-Stop-Shop
 - Mainly focused on pharma and chemistry

Source: PhD thesis Dümmler 2006, Helbling analysis

Identification of a cluster through distance, interaction and externalities

Results of a medtech industry survey in Switzerland

“**Clusters** are **spatially concentrated accumulations** of actors in the service industries and industrial companies as well as in institutions that work in the same industry, another industry or in the same value chain like the analyzed actor. The actors are connected with each other through the **formal or informal exchange** of know-how, goods or services and take advantage of **spatially limited externalities** that have a positive effect on the innovation potential and the economic growth of a region.“

Distance

- Classification into region, rest of Switzerland, neighboring countries, rest of the world
- Analysis: five potential clusters in Switzerland

Interaction

- Input: Suppliers from rest of Switzerland and the neighboring countries are the most important ones
- Output: Customers in the region are the least important ones
- Cooperation: Partners from the rest of Switzerland and the neighboring countries are the most important ones

Externalities

- Highest for the rest of Switzerland and the neighboring countries
- No connection between regional cooperation and the number of innovations

The functional range of the medtech industry comprises the whole of Switzerland

Conclusions of medtech cluster analysis

- No regional medtech clusters in Switzerland
- The structure of the 71 economic and regional promoting organizations should be reconsidered
 - Regional orientation is too strong, the organizations' functional range does not correspond with the functional range of the medtech companies
 - One organization alone often has not enough weight (finance, staff) despite partially high unsalaried efforts



To check:
**Strengthening of
the medtech
industry on a
national level**

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