Challenges and Opportunities of the Swiss MedTech Industry

Summary

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- This summary does not allow any conclusion to any specific company.
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[Image 543x295 to 567x376]
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 lead 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.

Source: Helbling Analysis
## Market structure and segments show differences between medtech, pharma and biotech

### Boundaries of medtech

<table>
<thead>
<tr>
<th><strong>Medtech</strong></th>
<th><strong>Pharma</strong></th>
<th><strong>Biotech</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Few big companies per segment, numerous small and tiny companies</td>
<td>Few big companies, many SMEs as niche players (specialty pharma)</td>
<td>Few big companies, many SMEs</td>
</tr>
<tr>
<td>Consolidation process for established uses</td>
<td>Process of focusing and consolidation under way</td>
<td>Consolidation process with pharma companies under way</td>
</tr>
<tr>
<td>Heterogeneous products</td>
<td>Relatively homogenous products and segments</td>
<td>Products with new mechanisms of action</td>
</tr>
<tr>
<td>High growth</td>
<td>Gaps in product development</td>
<td>High growth</td>
</tr>
</tbody>
</table>

### Segments

<table>
<thead>
<tr>
<th><strong>Orthopaedics</strong></th>
<th><strong>Pharma</strong></th>
<th><strong>Biotech</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Osteosynthesis</td>
<td>On prescription</td>
<td>Diagnostics and analysis</td>
</tr>
<tr>
<td>Traumatology</td>
<td>Cardiovascular</td>
<td>Pharmaceuticals and chemicals</td>
</tr>
<tr>
<td>Maxillofacial</td>
<td>Central nervous system (CNS)</td>
<td>Bioinformatics and bioelectronics</td>
</tr>
<tr>
<td>Spine</td>
<td>Infection</td>
<td>Genomics and proteomics</td>
</tr>
<tr>
<td><strong>Dental</strong></td>
<td>Inflammation and autoimmune diseases</td>
<td></td>
</tr>
<tr>
<td><strong>Cardiovascular</strong></td>
<td>Metabolism</td>
<td></td>
</tr>
<tr>
<td><strong>Hearing aids</strong></td>
<td>Oncology</td>
<td></td>
</tr>
<tr>
<td><strong>Instruments and equipment</strong></td>
<td>Respiratory system</td>
<td></td>
</tr>
<tr>
<td>Electronic</td>
<td>Transplantation</td>
<td></td>
</tr>
<tr>
<td>Medical</td>
<td>Virology</td>
<td></td>
</tr>
<tr>
<td>Surgical</td>
<td>Non-prescription</td>
<td></td>
</tr>
<tr>
<td><strong>Biomaterials</strong></td>
<td><strong>Generic medicaments</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Diagnostics</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Market volume [CHF in bn]</th>
<th>Economic importance to Switzerland</th>
<th>Development of turnover of top-companies 2004/07 [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Turnover 7.0, Exports -4.5</td>
<td>GDP [bn CHF] 445 Employees [mio] 3.6</td>
<td>Nobel Biocare +90 Ypsomed +83</td>
</tr>
<tr>
<td>+1.5, Imports 4.0</td>
<td>Exports [bn CHF] 206</td>
<td>Straumann +66</td>
</tr>
<tr>
<td>Domestic market</td>
<td></td>
<td>Synthes +56</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Phonak +51</td>
</tr>
</tbody>
</table>

Fragmented SME structure characterizes the Swiss medtech market

Structural data medtech Switzerland 2005

**Main focus on business activity [%]**

- Electro medical devices: 26%
- Surgical instruments: 15%
- Implants: 12%
- Dental products: 11%
- Orthopedic products: 10%
- Diagnostic devices: 6%
- Medical consumables: 6%
- Help for disabled individuals: 7%
- Ophthalmology: 1%
- Others: 1%

**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

<table>
<thead>
<tr>
<th>Focus</th>
<th>Synthes</th>
<th>Phonak</th>
<th>Straumann</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Development and manufacturing of implants, instruments, and devices for traumatology, spine, oral, and maxillofacial surgery</td>
<td>Development, manufacturing and distribution of hearing aids</td>
<td>Development and manufacturing of dental implants and products for gingival regeneration</td>
</tr>
<tr>
<td>Global position</td>
<td># 4 for orthopedics</td>
<td># 3 for hearing aids</td>
<td># 2 for dental implants</td>
</tr>
<tr>
<td>Market cap. [Mio. CHF]</td>
<td>17'400</td>
<td>5'200</td>
<td>4'500</td>
</tr>
<tr>
<td>Sales volume [Mio. CHF]</td>
<td>2'793</td>
<td>679</td>
<td>510</td>
</tr>
<tr>
<td>Employees</td>
<td>7'169</td>
<td>2'719</td>
<td>1'342</td>
</tr>
<tr>
<td>Regions [%]</td>
<td>Europe: 21</td>
<td>Europe: 49</td>
<td>Europe: 62</td>
</tr>
<tr>
<td></td>
<td>Northern America: 64</td>
<td>Northern America: 41</td>
<td>Northern America: 26</td>
</tr>
<tr>
<td></td>
<td>Asia/Pacific: 10</td>
<td>Asia/Pacific: 8</td>
<td>Asia/Pacific: 10</td>
</tr>
<tr>
<td></td>
<td>Rest of world: 5</td>
<td>Rest of world: 2</td>
<td>Rest of world: 2</td>
</tr>
</tbody>
</table>

Source: Companies annual reports 2005/06, Helbling research
Cluster potentials of medtech companies in four regions

Location of medtech companies in Switzerland

Different path dependencies

- Northern region
  - Machine industry
  - Electronic industry
- Basel region
  - Pharma
  - Biotech
- Berne-Jura region
  - Watch industry
  - Electronic industry
- Geneva-Lausanne region
  - Watch industry
  - Electronic industry

Legend
- Manufacturing medtech companies (n=335)
- Trade and/or services medtech companies (n=167)
- Manufacturing companies with only little amount of medtech products (n=84)

Source: PhD thesis Dümmler 2006
Medtech beats pharma and biotech – what drives these growth prospects?


- 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

Impulses for supply
- New technologies
  - Micro-/nanotechnology
  - Mechatronics/robotics
  - Biotechnology and genetics
- Merger with pharma and biotech

Impulses for demand
- Basic social conditions
  - Health expenditures
  - Demographic trends
  - Unhealthy way of living
- Economic wealth of emerging countries
  - Patients’ needs
- Regulation of market access and refund

Source: Helbling Analysis
Growing importance of miniaturization, computerization, and molecular science

Key technologies

Micro electromechanical systems
Minimal invasive surgery
Robotic Surgery
Tissue-Engineering
Nano chips
Micro endoscopy
Proteomics
Molecular visualization
Micro implants
Computer tomography (visualization)
Virtual / augmented reality
Microscopic diagnostics
Laser devices
Telemedicine
Computer assisted surgery
Navigation
Gene therapy
Stem cells
Micro sensors
Robotic Surgery
Computer assisted surgery
Micro sensors
Micro sensors
Miniaturization
Computerization
Molecular science

Source: BMBF 2005
New market opportunities through the merger of medtech with pharma and biotech

Mergers

- New knowledge
- New companies
- New products and application fields
- New markets and customers
- Developments of Synthes
  - Coated implants
  - Bio absorbable materials
- Acquisitions Straumann
  - Kuros Therapeutics
  - Biora AB

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

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 [%]**

- Eastern Europe: 6% in 2000, 7% in 2004
- East Asia & Pacific: 7% in 2000, 8% in 2004
- South Asia: 4% in 2000, 7% in 2004
- OECD: 4% in 2000, 3% in 2004

**Income per capita [USD]**

- Eastern Europe: 2'030 in 2000, 3'290 in 2004
- East Asia & Pacific: 850 in 2000, 1'280 in 2004
- South Asia: 440 in 2000, 590 in 2004
- OECD: 27'530 in 2000, 33'470 in 2004

Source: Worldbank 2006
Regulative requirements affect all phases of the value chain

Value chain phases of medtech products

- **Product Design**
  - Basic regulative guidelines
  - Harmonized standards
  - Risk analysis and clinical valuation
  - Official interpretations and rules

- **Clinical tests**
  - Compliance with product design requirements
  - List of standards
  - Determination of testing organizations
  - Ethic commissions
  - Information to regulatory authorities

- **Information to regulatory authorities**
- Conformity assessment and marking
- Classification I – III
- Dispensing restrictions
- Duty to product observation (vigilance)
- Restrictions in advertising

- **Accounting between care provider and distributor**
- Refunds
  - Patient with health insurance company
  - Care provider with health insurance company

Source: Swissmedic 2006, Helbling research
### Medtech regulation of the European Union as a basis – also for Switzerland

#### Product classes and product approval – European Union

<table>
<thead>
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<th>Product classes</th>
<th>Product approval</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low risk</td>
<td>Declaration of conformity</td>
<td>Stethoscope, Scalpel</td>
</tr>
<tr>
<td>Medium risk</td>
<td>Declaration of conformity, Reduced certification of the production phase, Product verification, Certification of quality assurance</td>
<td>Electrocardiographs, Hearing aids</td>
</tr>
<tr>
<td>Medium risk</td>
<td>Reduced certification of the production phase, Product verification, Certification of quality assurance, Extensive certification</td>
<td>X-ray apparatus</td>
</tr>
<tr>
<td>High risk</td>
<td>Reduced certification of the production process, Product verification, Extensive certification, Physical product verification (random inspection), Inspection of product dosage</td>
<td>Joint replacements/implants, Pacemaker, Catheter</td>
</tr>
</tbody>
</table>

Source: Swissmedic 2006, Helbling research
## Detailed regulation catalogue in the US – only 3% classified as high risk

### Product classes and product approval – USA

<table>
<thead>
<tr>
<th>Product classes</th>
<th>Share of products</th>
<th>Product approval</th>
<th>Examples</th>
</tr>
</thead>
</table>
| **I** Low risk  | 50 %              | - Premarket Notification  
- General controls  
  - Registration of manufacturers  
  - Good-Manufacturing-Practice  
  - Information of FDA | - Medical gloves  
- Elastic bandages |
| **II** Medium risk | 47 % | - Premarket Notification  
- General controls  
- Special controls  
  - Design standards  
  - Market surveillance  
  - Patients’ register | - X-ray apparatus  
- Infusion pumps |
| **III** High risk | 3 %  | - Premarket Notification  
- General controls  
- Special controls  
- Premarket approval | - 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

- **Hearing aids**: 80%
  - Siemens
  - William Demant
  - Phonak
  - GN Store Nord
  - Starkey
- **Dental products**: 90%
  - Nobel Biocare
  - Straumann
  - Biomet
  - Zimmer
  - Dentsply
- **Orthopedics**: 90%
  - Johnson & Johnson
  - Stryker
  - Zimmer
  - Synthes
  - Smith & Nephew

- **Orthopedics**: M&A for diversification (economies of scope)
- **Dental products**: M&A for diversification (economies of scope)
- **Hearing aids**: M&A as a consolidation within the market segment (economies of scale)

**Challenges and opportunities**

- No integrated medtech company
- Consolidation within the market segment for economies of scale
- Little diversification because of low economies of scale
- Challenge through new technologies, start-ups and spin-offs

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.”

Source: PhD thesis Dümmler 2006

<table>
<thead>
<tr>
<th>Distance</th>
<th>Interaction</th>
<th>Externalities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification into region, rest of Switzerland, neighboring countries, rest of the world</td>
<td>Input: Suppliers from rest of Switzerland and the neighboring countries are the most important ones</td>
<td>Highest for the rest of Switzerland and the neighboring countries</td>
</tr>
<tr>
<td>Analysis: five potential clusters in Switzerland</td>
<td>Output: Customers in the region are the least important ones</td>
<td>No connection between regional cooperation and the number of innovations</td>
</tr>
<tr>
<td></td>
<td>Cooperation: Partners from the rest of Switzerland and the neighboring countries are the most important ones</td>
<td></td>
</tr>
</tbody>
</table>
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

Source: PhD thesis Dümmler 2006
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