

State of the Swiss Medical Technology Industry 2011 *Stormy times ahead?*

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Swiss Medical Technology Industry 2011 – Stormy times ahead?

The Swiss Medical Technology Industry (SMTI) Report 2010 was widely and well received and proved to be a vital instrument to the industry leaders. For our 2011 update, we wanted to respond to the current economic environment influencing the SMTI and provide management with new insights. Today's economy exposes any marginal innovation, compliance and quality gaps faster globally, thus influencing performance of companies.

In late 2010 general sentiment had put the crisis in the past, signalled through many M&A activities. However, as of Spring 2011, the **financial and economic crisis re-emerged more severely and now affects MedTech companies** on a global level. **New challenges** have significant impact on the modus operandi of SMTI. These put management in **a reactive and rather operational mode**. Yet our industry has learned from the past and done its homework early. Our sample of companies remain competitive and grow at a **“black zero”**.

This is the third time since 2009 that the industry **does not achieve double digit growth**. Managing today's complexity, **mastering rising regulatory requirements** and overcoming the crisis, become a necessity to be successful in a globalized market environment. What was helpful in the past turns out to be a strength of the industry for tomorrow, that is: **innovation, quality and proximity to the Swiss MedTech ecosystem**. The competition is global, but the strengths of the industry are still local.

We recall a key statement of the SMTI Survey from 2010 raising the urgency of necessary changes ahead:

*“Paired with increased pressure by payers and governments in major markets towards cost effectiveness and treatment outcome, the Life Sciences industry is now faced with a **paradigm shift** in its **future business model**. Today, the “crisis resistance” due to cash-rich reimbursement systems may be history as healthcare markets are changing rapidly.”*

The SMTI 2011 report provides additional indicative models and descriptive approaches to management in order to trigger internal discussions addressing the relevant issues and challenges in these **stormy times ahead**.

We wish to sincerely thank the participating industry leaders for offering their time for constructive discussions and in-depth insights.

Beatus Hofrichter and Dr. Patrick Dümmler
Authors of the *SMTI 2011 Report*

Today's SMTI & Expert sentiments

"Future expected growth will be attributable to the following three drivers: 40% to China, India & Brazil, 40% to the launch of new radical innovation, and 20% to the organic growth of existing products." – Investor, international service provider

"The MedTech business of non-reimbursed products has started to reach a plateau in traditional markets. The business is now cyclical and growth is not endless." – CEO, SMTI company

"Suppliers need to become more proactive and revisit their business models." – Divisional head, major international manufacturer

"Today, our internal visibility on price differences is created through customer pressure, which puts us in a very weak position." – Managing Director, global manufacturer

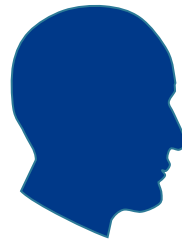
"The MedTech pioneer era is over, the industry is now mature and competition is global." – CEO, SMTI company

"Suppliers need to be flexible and innovative – covering engineering to producing capabilities as a "one stop shop" offering to us." – Head of Production, Global Life Science conglomerate

"The FOREX issue has caused severe disadvantages for Swiss subsidiaries in the internal project competition." – VP Operations, global manufacturer

"The Swiss MTI may lose its leading position within the global competition by focusing too strongly on operations and less on strategic issues." – Divisional Head, major service provider

"Uncertainty about the future outlook for the global economy remains exceptionally high [...]. The deterioration in the outlook for growth and fiscal problems in the advanced economies are both adversely impacting confidence in financial markets worldwide." – SNB, "Monetary Assessment", p. 1, Berne, September 15, 2011



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8. Impact on SMTI
9. Outlook / Conclusion

Appendix

- I SMTI 2011 - Knowledge Base
- II Outlook Activities 2012

Executive Summary

Executive Summary

External forces

Economic conditions and globalization: harsh market environment

- Harsher conditions due to currency effects (CFOs turned pessimistic)
- Average growth expectation for Swiss Medical Technology Industry is between -1% and 5% for 2011, (vs. 12% forecasted)
- A change in public health care spending behavior in major markets has significant negative implications for the MTI overall
- Swiss companies can build continuously on their prime competitive advantages: closeness of cluster network, innovation, quality and reliable supply chain management

Regulatory challenges: highly significant business impact

- Companies experience an increase in regulation on a global level, especially in emerging markets, which leads to higher hurdles of market access
- Increase in sound quality management system and outcome data requirements will drive companies to invest more in documentation and cost-benefit data generation
- Availability of experienced resources and higher costs for processes and quality are greater challenges for SME companies

Internal responses

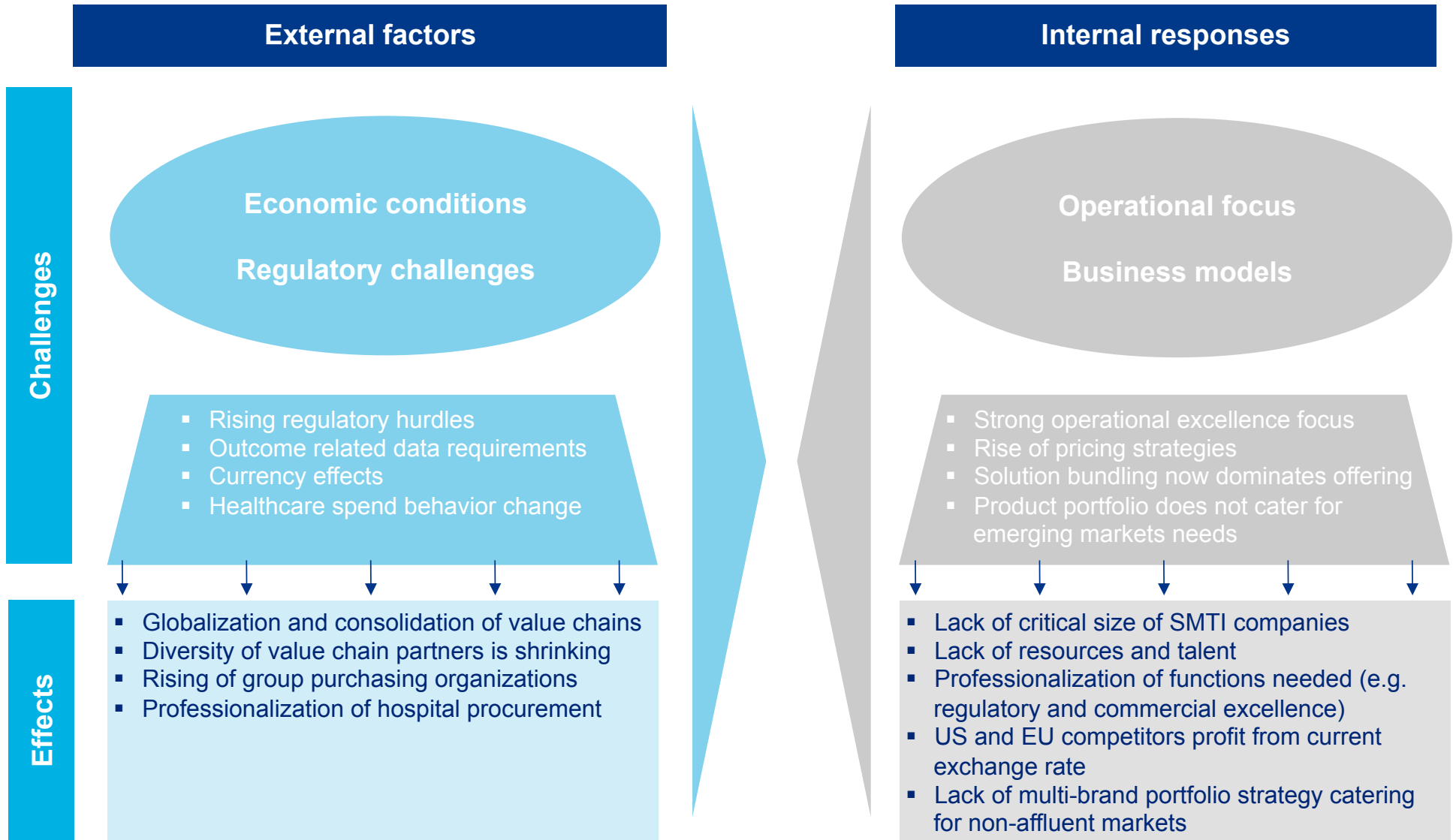
Strategic vs. operational focus: adjust focus to return to a growth path

- Overall the SMTI is faced with many external challenges resulting in a strong focus on operational issues
- Despite current market conditions, innovative niche players are still able to achieve double digit growth
- Suppliers absorb a large part of the cost pressure of the value chain
- For manufacturers, outcome-related, data-based pricing strategy arises as the essential discipline
- Today, more manufacturers are pursuing a solution bundling approach to ensure market share
- Multinational players evaluate larger potentially Swiss-based projects with tighter economical measures

Business models (BM): new approaches needed

- The current operational issues hinder the necessity to focus stronger on strategic orientation and business models
- Manufacturers focus on horizontal integration and stronger in-source production capabilities
- Innovative suppliers tend towards building up own brands and therefore leave traditional models, e.g. contract manufacturing
- Forward looking BM range from “secondary brands” to “Swiss excellence at low cost production” to “industrialization” to “open networked innovator” to “big MedTech to market”

Situational View of MedTech Industry in 2011



State of the SMTI 2011

The “House of Swiss MedTech” is becoming more complex (2010 study revisited)

Swiss MedTech Sector

Product portfolio

Innovation

- Above-average growth expectations due to an innovative, young product portfolio or best in class products
- Higher cost pressure leads to a shift from radical innovation towards incremental innovation in established / mature segments
- Companies that focus on network innovation can expect above-average growth

Collaboration & Bundling

- Price pressure leads companies to push bundled offerings in order to maintain their turnover level and market share
- Companies that focus on bundling tend to reduce their R&D expenditures
- A bundling strategy favors collaboration within the same value chain for incremental innovation
- Demand from buyers will drive “solutions”, forcing companies to change their business models

Market access

Internationalization

- Growth in international markets correlates with bundling and/or secondary brand strategies
- Success in export markets is correlated to understanding the local needs and reimbursement regimes
- Sound positioning for investments into healthcare systems propel export levels of suppliers and manufacturers

Positioning

- Smaller companies lack export strength due to a shortage of know-how and commercial co-operations
- Improved market orientation becomes a priority due to increased competitiveness amongst providers and pressures from payers
- Early stage development requires a market pull perspective as well as strategic marketing and regulatory affairs management

Medical & Regulatory Affairs Management

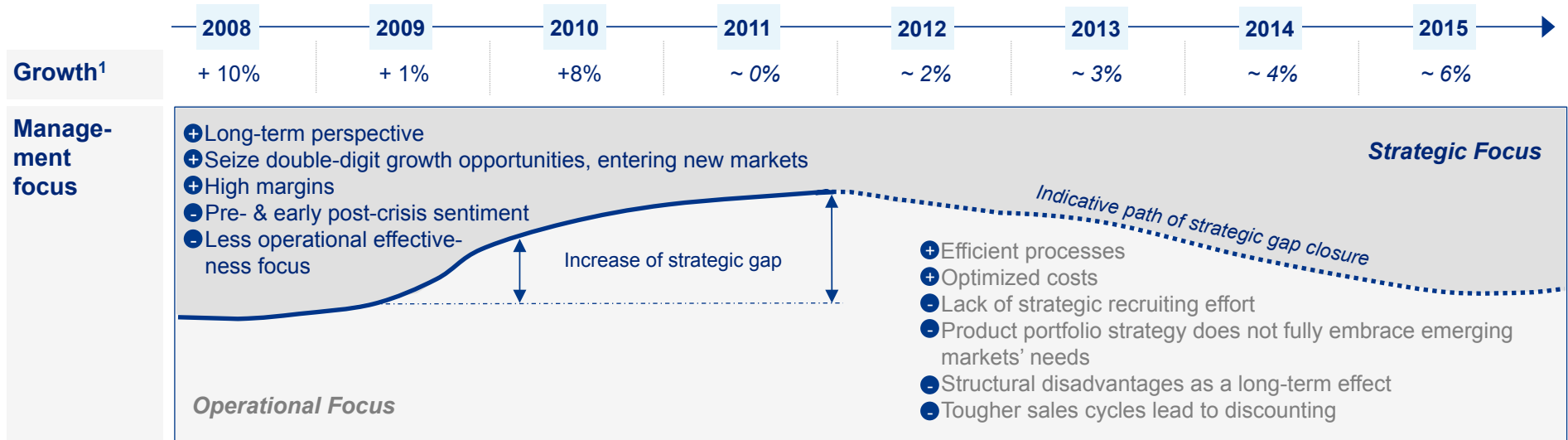
- Managing and demonstrating improved / heightened cost-benefits will promote success in tomorrow’s market access and reimbursement schemes
- Critical back-office service and clinical trials talent becomes more vital in the globalized competition
- Regardless of size, a sound quality management system is a prerequisite
- Radical innovation medical product requires early on DRG-case registration supporting a significant positioning

Source: Based on SMTI 2010

□ Unchanged value dimensions

■ New or amended value dimensions

Since 2009, strong operational focus to overcome the crisis. With a single digit growth path ahead, margins are under further scrutiny



General: Tight access to resources (originally scarcity of engineering resources, nowadays scarcity of talent (i.e. regulatory, strategic marketing, as well as after-sales services))

Comments

- Summer 2009 was a turning point for many MTI companies. Management attention shifted towards a more tactical focus:
 - Suppliers responded to new challenges in the aftermath of the 2009 events
 - The “triple challenges”² arose across the SMTI
 - We indicated then, that SMTI companies seem to approach business conservatively before returning to a “growth mode”³
- Today, this sentiment still continues. Given a further slow down, managers tend to shift strongly to operational efficiency. Recent additional challenges include managing currency exposure, increasing regulatory complexity, tighter market access, and economic uncertainties in existing markets
- The effect is:
 - Lesser marketing investments and know-how build-up may provoke...
 - ... a loss of competitive advantage, which could cause...
 - ... a slower growth rate

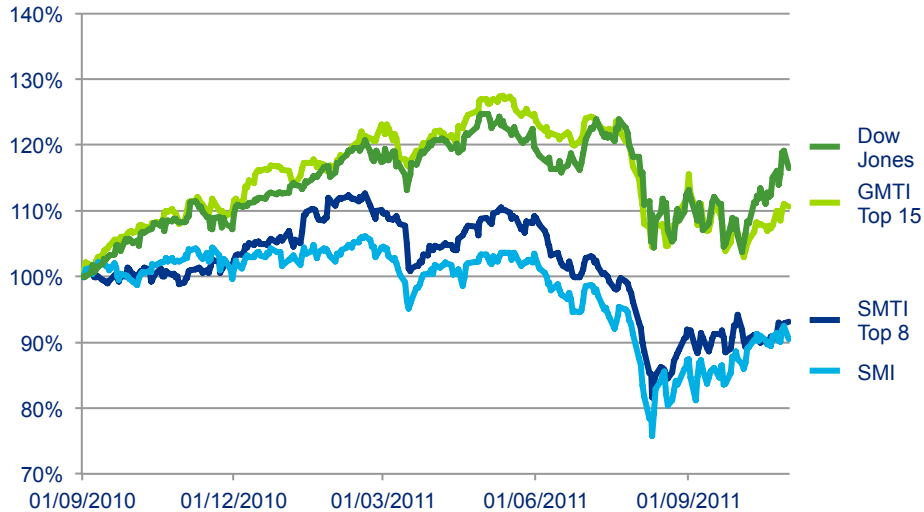
1) Estimated growth – Global Data; Medtech Switzerland research

2) Triple challenges “Cost pressure, price pressure and intensifying competition” concerned >82% of all participants in SMTI 2011 survey

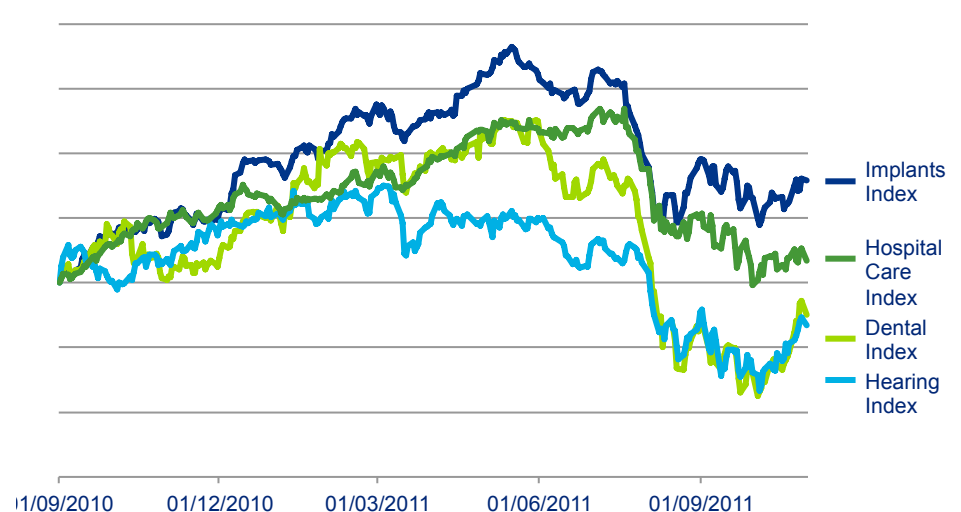
3) SMTI 2010 survey, Chapter C – Strategic Actions, page 30

Since Sept 2010, stocks of global MTI and Implant-focused firms out-perform leading indices

Global view



Sub-sector view

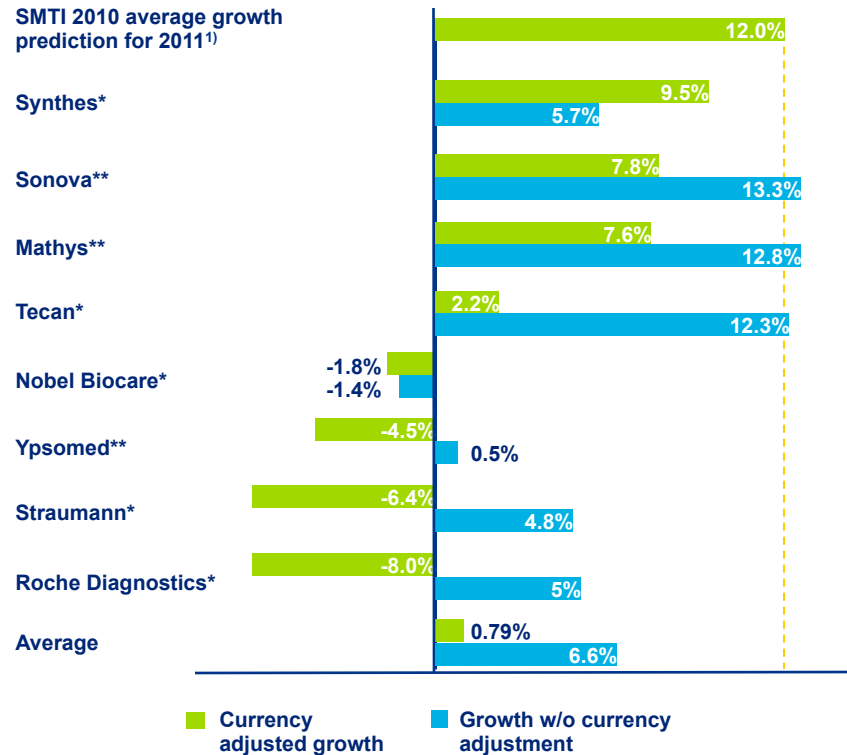


Comments

- Gap of an average of 14% in performance between GMTI and SMTI relates to
 - FOREX exposure (strong Swiss Franc)
 - Strong single sub-sector focus (e.g. hearing, dental, diagnostics)
 - Management issues and regulatory set backs
 - General difference between the market environments (SMI vs. Dow Jones)
- Gap of an average of 16% annual in performance between implant (e.g. orthopedic, cardiovascular) and dental relates to
 - Companies' evaluation is triggered by a) cost benefit and b) the likelihood of reimbursement of new products
 - Implants and hospital care are related to reimbursement which is catered by internationally operating manufacturers and consumable product providers
 - Hearing and dental have an underlying investment sentiment of internationally non-reimbursement

Due to FOREX issues, leading Swiss firms realized ~ 1% adjusted growth rate in 1st half 2011

Selected Swiss MedTech Firms - Revenue Growth in 1st Half of 2011



* Company reports half-year ** Company reports annual

Comments

- Currently, we observe a moderate to negative growth amongst SMTI companies
- This heavily contrasts to the growth expectations of 12% for 2011 given by the companies in Spring 2010¹
- Major listed SMTI firms have registered an average dip in reported revenues of more than 10% in the last 12 months, mainly due to adverse currency impacts. The average adjusted growth rate of eight companies for the selected companies was below 1% for the first half of 2011
- Today's management sentiment for 2011 is mixed; most manufacturers will continue to single digit growth, while some suppliers may face losses in a contracting market

1) SMTI 2010 (n= 188, p. 31)

Source: Deloitte Research, Company reports; September 2011

Challenges & Trends

Strong collaboration within the SMTI ecosystem is a major strength

Top trends within the MTI

- Evolution of manufacturer MTI business models, i.e. from standard medical device supplier towards full solution provider (i.e. logistics, hospital process consulting, IT, training, etc.)
- Evolution of supplier MTI business models from part provider towards “One-stop-supplier” (engineering and component assembly)
- Big MedTech firms shifting innovation risk exposure further towards network partners, and entering the innovation process at a later stage
- Integration, eConnectivity of multiple proprietary technologies/devices by different manufacturers (i.e. voice controlled systems, Bluetooth interfaces, etc)
- Rising long-term consolidation pressure driven by multinational corporate MedTech firms influencing the SMTI eco system. Rational for consolidation:
 - Access to technologies and skills
 - Build-up of complementary product portfolios
 - Build-up of shared services
- Investors are very short-term opportunity driven resulting in cyclical M&A peaks (we noticed about three mini M&A cycles within Q3 2010 – Q4 2011)

Top strengths of the SMTI

Top strengths of **Swiss MedTech Cluster**:

- Internationally very high density of ~740 suppliers and manufacturers embedded in a well established Swiss MedTech eco system
- Strong collaboration approach amongst all MedTech stakeholders (e.g. academia, suppliers, engineering partners, manufacturers, medical specialists, finance experts, key opinion leaders and institutions) based on geographical proximity, social and cultural closeness

Top strengths of **manufacturers** in the SMTI:

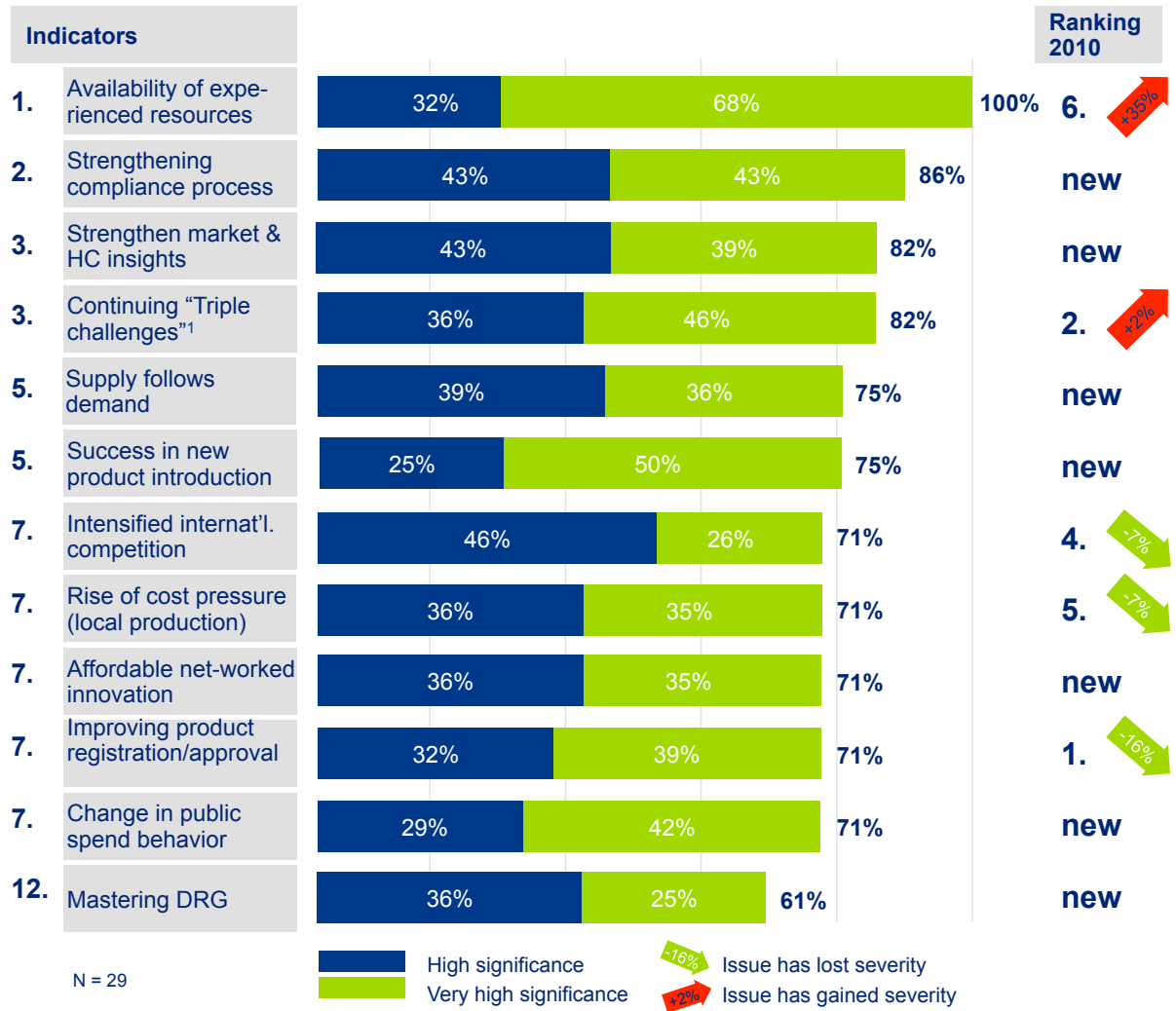
- High level of know-how, skills, innovation and quality approach
- Integration in well-functioning networks with suppliers, purchasers (hospital, physicians) and research institutions (universities, public and private research institutes, etc.)

Top strengths of **suppliers** in the SMTI:

- High level of know-how, skills, quality and flexibility
- Good understanding of the quality standards required in the MTI (versus suppliers from other branches that enter the market)
- New innovative business concepts could become a future strength for local suppliers

Additional and complex challenges strongly affecting SMTI – especially the availability of experienced resources

Top 12 Challenges of the SMTI 2011 Comments

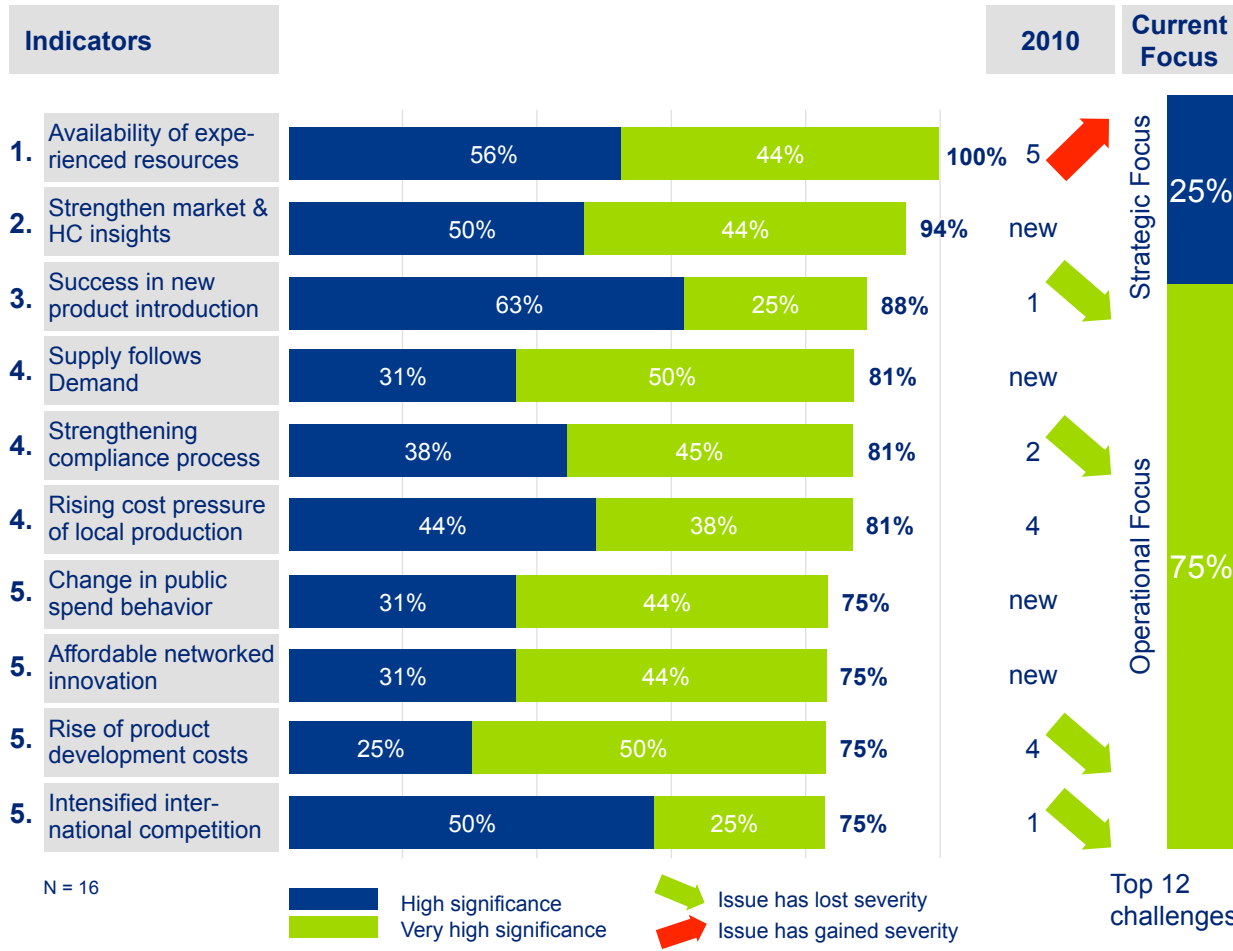


- The environment is becoming highly competitive. Several existing and new challenges mentioned divide into two main groups: regulatory and market based challenges
- The availability of skilled employees in regulatory, quality management, strategic marketing, and after-sales services is a severe issue for all companies – even cross-border recruitment does not ease the situation
- The “triple challenge” is an increasing burden on the industry, and is dramatically influencing current management sentiments
- Mastering the regulatory impact is recognized for its importance in managing future market access
- Today’s management is fully absorbed in operational issues as the crisis is also now reaching the healthcare sector (due to spending cuts and currency issues)

1) Triple challenges “Cost pressure, price pressure and intensifying competition”
 Source: SMTI 2011 – Industry leader Interviews
 Note: Certain indicators were either updated or adjusted to current needs.

Manufacturers are operationally focused and need to strengthen their commercial excellence capabilities

Top 10 Challenges for Manufacturers



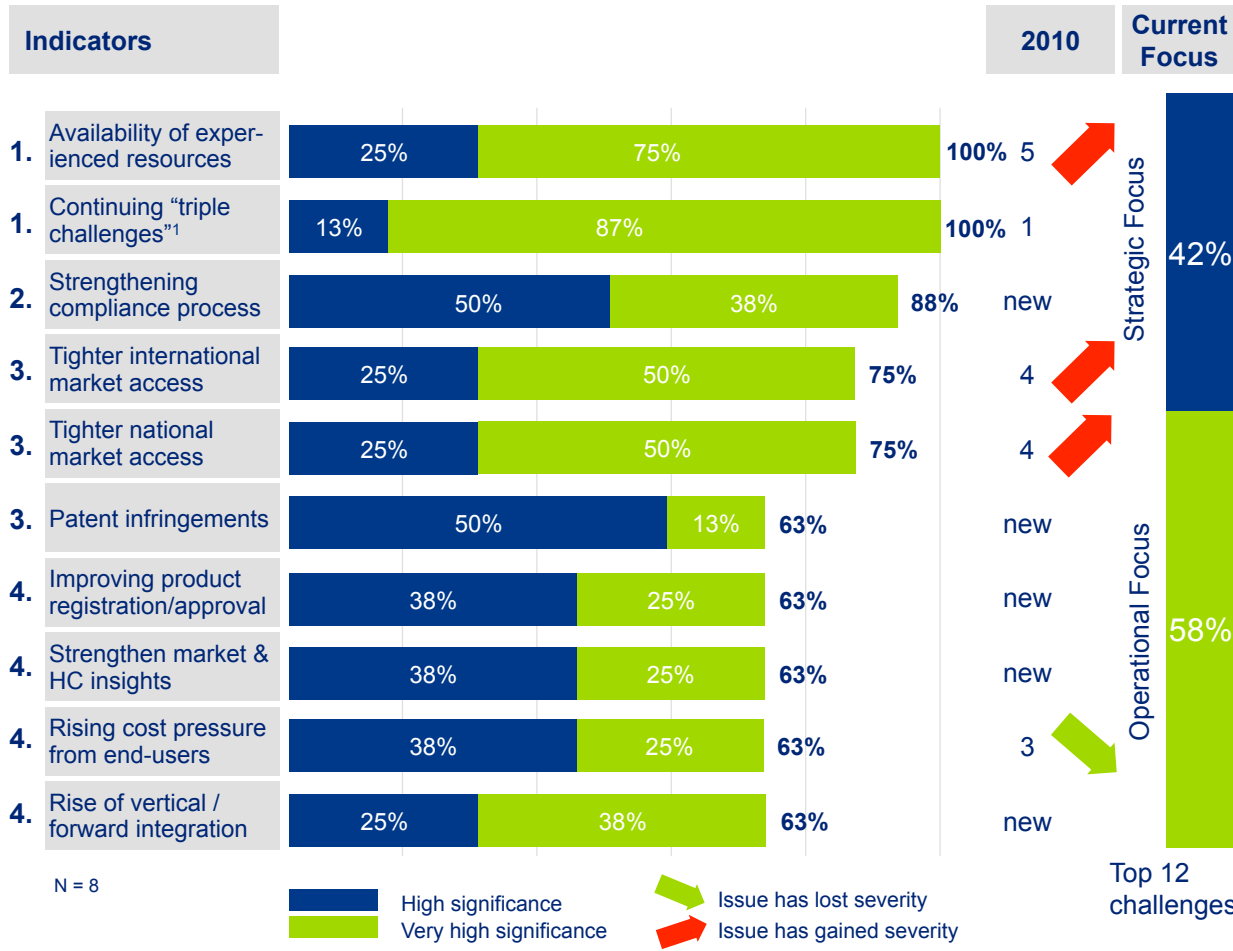
Comments

- Today manufacturers face more challenges than in 2010 (a total of 33 challenges are mentioned above 50%)
- Those challenges predominantly fall within the function of strategic marketing, operations, and regulatory affairs. The top priorities (above 90%) are:
 - Availability of experienced resources (has become a significant issue)
 - Strengthening of market and HC insights
 - Success in new product introduction
- There is a high imbalance between strategic and operational focus amongst manufacturers; in order to emerge from the crisis better positioned than international competitors, management should now embrace new business models

1) Triple challenges "Cost pressure, price pressure and intensifying competition"
 Source: SMTI 2011 – Industry leader Interviews

Suppliers address strategic options proactively to overcome their strong dependencies on MedTech manufacturers

Top 10 Challenges for Suppliers



Comments

- Suppliers face fewer challenges over 50% mentioned affecting their business today. They carry a heavier financial burden as they are the extended innovation and workbench of manufacturers
- Top challenges remain:
 - Availability of experienced resources (has become a significant issue)
 - Continuing "triple challenges" (valid for all suppliers (+22% vs. 2010))
 - Regulatory process management
 - Tighter international and national market access and patent infringements
- It becomes apparent that some suppliers become proactive in their management style.
- Multiple opportunities to increase business are arising from 2012 onwards as manufacturers adapt their business models to the new environment

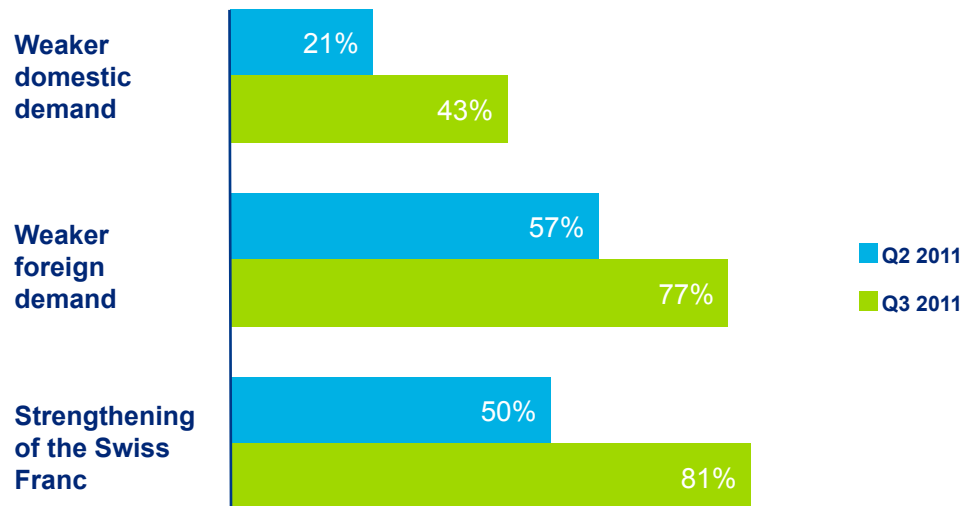
1) Triple challenges "Cost pressure, price pressure and intensifying competition"
 Source: SMTI 2011 – Industry Leader Interviews

External Factors

An Outside-In view: Swiss CFOs' optimism has strongly eroded as of Q3 2011

External risk factors for Swiss based manufacturers

Factors implying a significant risk to business



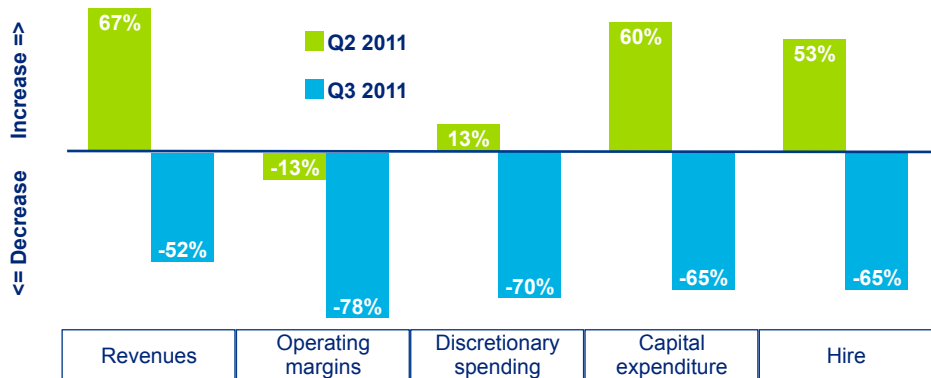
Comments

- CFO optimism has effectively vanished in Q3 2011 with 36% of participating CFOs from manufacturing companies expecting a recession in Switzerland either in 2012 or 2013
- Prominently behind the rising pessimism are external risk factors
- In Q3 77% of CFOs from manufacturing companies regarded the weakening of foreign demand as a significant risk to their company over the next 12 months, up 20 percentage points from Q2
- In contrast 43% regarded weakening domestic demand as a significant risk, also up from Q2
- The biggest overall risk factor was the strengthening of the Swiss Franc, with 81% reporting that as a significant risk
- With both weaker foreign demand and price competitiveness undermined by the strong Swiss Franc, the export growth outlook seems to have markedly deteriorated over the last few quarters for Swiss based manufacturers, and – assuming similar sentiments for MedTech companies – also, for the SMTI

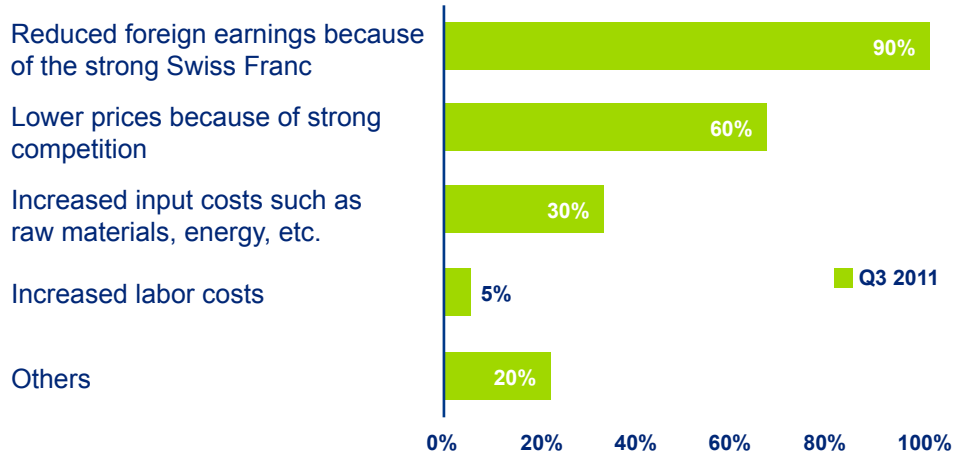
An Outside-In view: Most Swiss CFO's expect revenues to decrease

Strong Swiss Franc hurts margins

Expected change of key metrics for Swiss manufacturers over the next 12 months



Main reasons for reduced margins

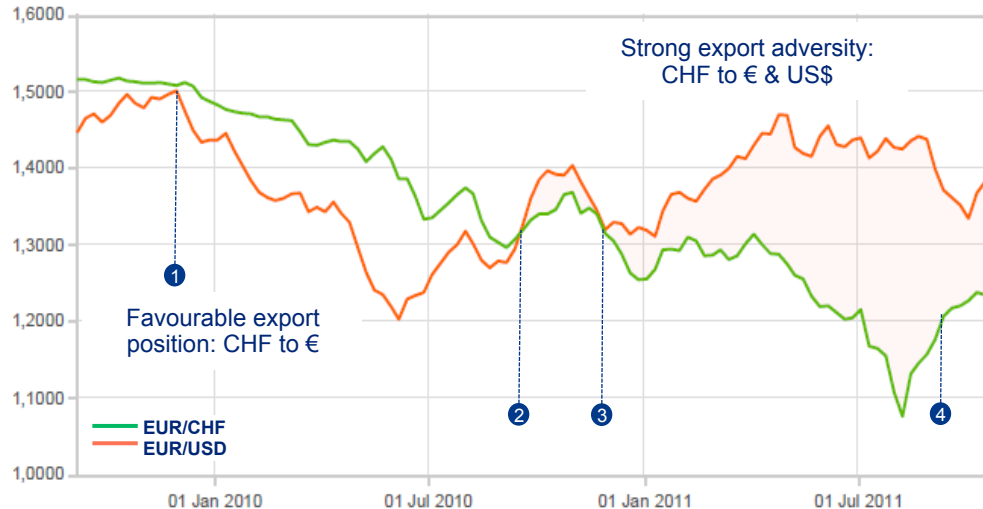


Comments

- In Q3 CFOs of manufacturing companies were markedly more pessimistic about their expectations for revenues and operating margins
- A negative net balance of 52% of CFOs expect revenues to decrease over the next 12 months. This is in sharp contrast to last quarter where 67% of CFOs still expected an increase
- An even larger majority (78%) anticipates that operating margins will decline over the next 12 months
- An overwhelming majority of 90% of CFOs identify the strong Swiss Franc as a major reason for declining margins. Manufacturing companies are even more affected by the strong Swiss Franc than the overall sample of answering CFOs, where 82% see currency effects as a major reason for declining margins
- All participating CFOs from manufacturing companies expect the strength of the Swiss Franc to continue with nobody expecting the EUR/CHF exchange rate to be above 1.30 CHF in twelve months' time

An Outside-In view: Since 2009, budgeting is a nightmare – SMTI’s export strength was clearly undermined by FOREX adversity

Comparison EUR vs. CHF and USD (09/2009 - 10/2011)



Source: www.Qanda.com, October 31, 2011

Note: The rates are shown as an average weekly rate.

Legend:

- ① Q4 2009: Beginning of Euro crisis due to the debt crisis of Greece
- ② September 2010: Dollar is weakening because of slow economic recovery
Q4 2010: Euro is weakening because of fear that Ireland and Portugal need to get financial support from the EU
- ③ 6. September 2011: Intervention of Swiss National Bank; minimum exchange rate fixed at CHF/EUR 1.20.
- ④

Comments

- Companies’ budget cycles were taken by surprise by the recent currency crisis as the Euro and the Dollar depreciated strongly over the last two years
 - Budget 2009/10 was commonly based at ~1.50 CHF/EUR, leading to a negative currency effect of ~15% in 2010
 - Budget 2010/11 was adjusted to an exchange rate ~1.30 CHF/EUR, resulting in a negative currency effect of at least ~8.5% by today
 - Natural hedging is a general SMTI strategy based on product sourcing or production abroad
- With the appreciation of the Swiss currency, exported goods are much more expensive in key markets
- This had two negative effects on the SMTI (**double currency effect** - see as of Point ②)
 - The US-Dollar depreciation against the Euro made exports of European products into the US market cheaper compared to Swiss exports
 - The US-Dollar depreciating against the Swiss Franc made US imports into the EU markets significantly cheaper and attractive. US-multinationals therefore benefited more compared to smaller Swiss companies (see graph: “Strong export adversity”)

Mastering regulatory affairs become a new core competency for global competition

Managing the complexity – improving capabilities

Mastering....		Future requirements	
		Manufacturers	Suppliers
Processes	Certification		
	Complaints		n.a.
	Clinical evidence document'n.		
	Quality Management		
	Registration / Validation		
	Software Validation		
	Vigilance		
Topics	Clinical utility		n.a.
	Comparative effectiveness		n.a.
	Diagnostic related groupings		n.a.
	Health technology assessment		
Technologies	Bio – Technology ¹		
	Combination products		
	Nano – Technology		
	Software / Apps		

No changes
 Moderate Impact
 Significant Impact

Comments

- The regulatory environment for the MedTech industry is slowly growing beyond the CE (Conformity Evaluation) for Class IIb and Class III products. Such producers are required to
 - strengthen the topical scope within their functional teams
 - engage in post market surveillance studies
- Both manufacturers and suppliers, who produce Pharma / MedTech convergence products and/or new technologies must anticipate moderate to significant regulatory requirement increases
- Software in or for medical products (including apps.) is now governed within the regulations and thus requires full validation prior to deployment. Manufacturers and suppliers must meet these requirements
- Also, suppliers to the MedTech industry feel the increased regulatory requirements that are passed down by the manufacturers in the form of higher documentation and certification requirements
- Manufacturers adapt to the new requirements by hiring experts, investing more time and money to comply

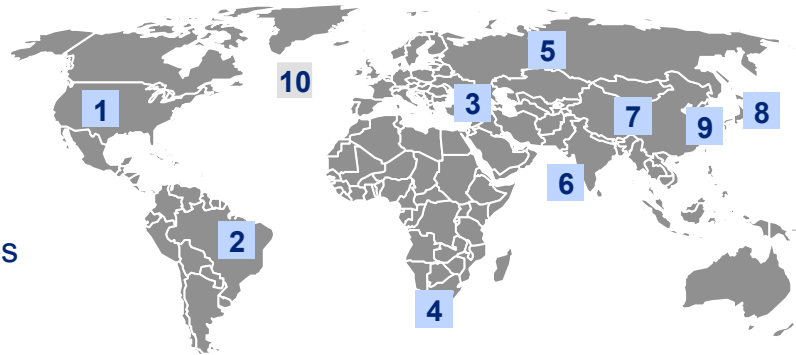
1) Including substance of human tissues, bio-marker, and personal medicine diagnosis methods, etc.
Source: SMTI 2011 Interviews

The regulatory environment is changing in future growth markets

A global increase in regulatory standards can be seen

WORLDWIDE

- Growing regulatory demand on
 - Clinical outcome data
 - Clinical utility
 - Combined products
 - Improved validation of software/apps
 - Quality management
 - Vigilance

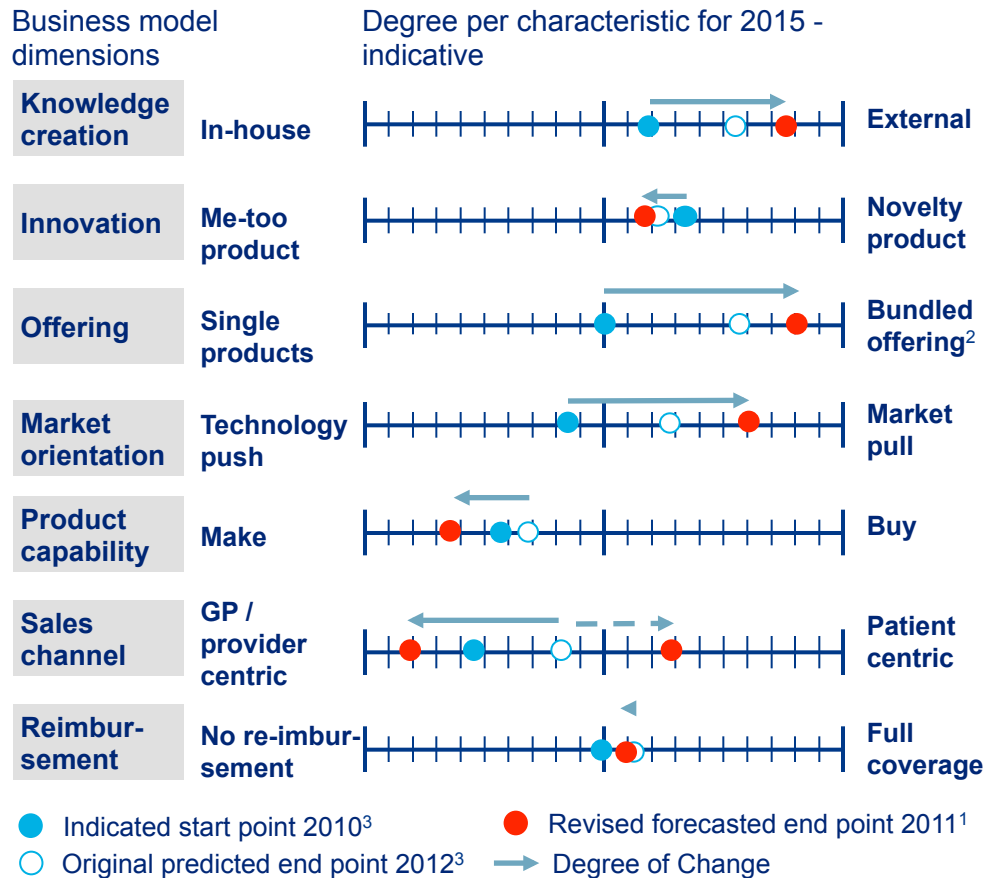


<p>1 USA</p> <ul style="list-style-type: none"> ▪ Tighter vigilance practice ▪ Uncertainty about 510(k) changes ▪ Medical device tax of “+2.3%” tax increase 	<p>4 South Africa</p> <ul style="list-style-type: none"> ▪ Draft of comprehensive regulation system ▪ Products approved by USFDA or those carrying CE mark do not yet face regulatory issues except electromagnetic devices 	<p>7 China</p> <ul style="list-style-type: none"> ▪ Medical device regulations endorsed in 2000 and amended re. “Recalls” & “Vigilance” ▪ All companies must get pre-market approval from SFDA or its affiliates
<p>2 Brazil</p> <ul style="list-style-type: none"> ▪ Authorized Brazilian office or local distributor required (distributor registers the device) ▪ ANVISA inspections and GMP required 	<p>5 Russia</p> <ul style="list-style-type: none"> ▪ Regularly changing requirements/standards ▪ Direct Russian partnership is advantageous 	<p>8 Japan</p> <ul style="list-style-type: none"> ▪ Significant change with implementation of revised PALL in 2005
<p>3 Europe</p> <ul style="list-style-type: none"> ▪ CH – Introducing DRG by 2012 ▪ EU – Introducing ‘Re-Cast’ approach by end of Q1 2012 ▪ France – Introducing French Sunshine Act ▪ Turkey – Agreement with EU excludes SMTI and could lead to trade disadvantages ▪ UK – Introducing clinical utility focus by 2013 	<p>6 India</p> <ul style="list-style-type: none"> ▪ Medical devices are freely imported with some exceptions – to be revisited by 2012 ▪ Some registration needs / evaluation by purchaser in terms of quality ▪ Draft of Asian regulation community as counterpart to European commission can be expected 	<p>9 Republic of Korea</p> <ul style="list-style-type: none"> ▪ Foreign manufacturers without local office cannot submit device registration application ▪ Application for the registration through importer or hired independent third party Korean organization possible ▪ Pre-market approval in country-of-manufacture is a requirement
<p>10 Global</p> <ul style="list-style-type: none"> • Rise of parallel imports due to cost pressures and growing strength of GPO’s • Healthcare spend cuts in major markets • Greater clinical evidence and post launch surveillance data documentation • Implementation of Unique Device Identifiers (UDI) 		

Growth Factors

SMTI Business Model Mixer “revisited” – Broader changes and a higher strategic focus are necessary to achieve tomorrow’s growth

Continuing significant impact on changing business models¹



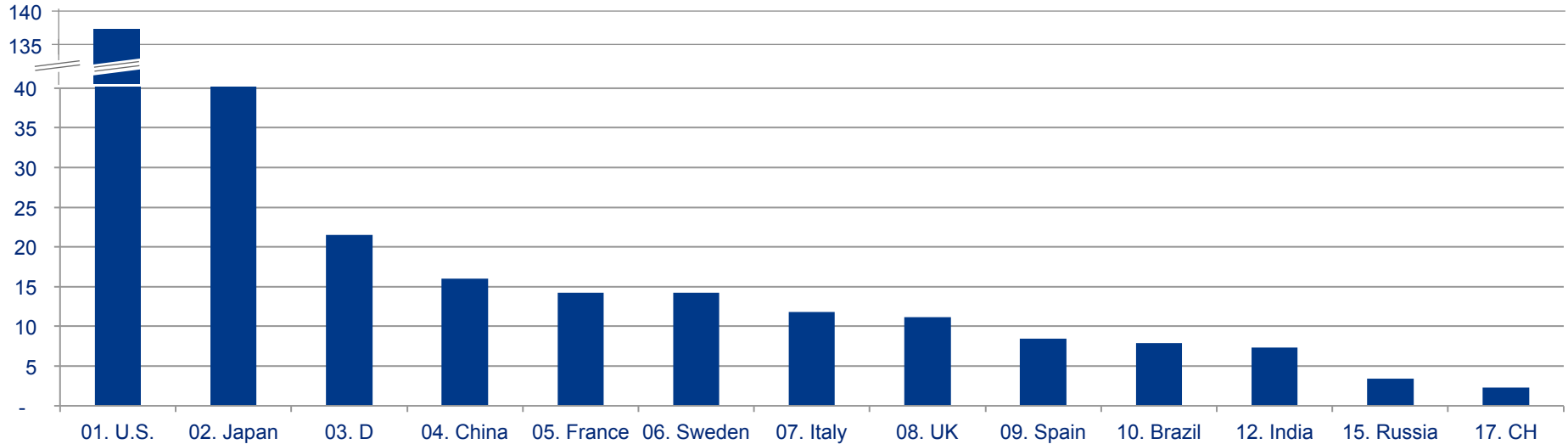
1) Tendencies based on SMTI 2011 interviews
 2) Combined offering such as a) "own device / technology, software, consumables materials, local maintenance / service, and / or training", or b) "combined products" (pharma / biotech and medical devices incl. third party product), c) enhancements through value added "solutions", or d) package tenders
 3) Tendencies based on SMTI 2010 interviews

Comments

- Since September 2010, the attitude of management has been influenced by the economic conditions and globalization (further growth in APAC regions), forcing the industry towards change
- Further shifts in business models can be seen along the value chains towards:
 - Externalization of knowledge sourcing
 - Additional technology (consolidation of portfolio offerings) to secure market share (bundled offerings)
 - Stronger market pull orientation
 - Increased GP / provider centric channel management
- Furthermore, companies tend to:
 - Stronger in-sourcing of production capabilities
 - forward integration
- Notions regarding long-term strategic orientation are now broader, including:
 - “From Box-Mover” to “Solution Providers”
 - “Best in class” vs. “One-Stop-Shop”
 - “In-licensor” vs. “Open Networked Innovator”

Midterm growth in major markets is positive, but single digit on average

The U.S. remains the largest medical equipment markets by far (2011, constant USD bn, global rank)



Comments

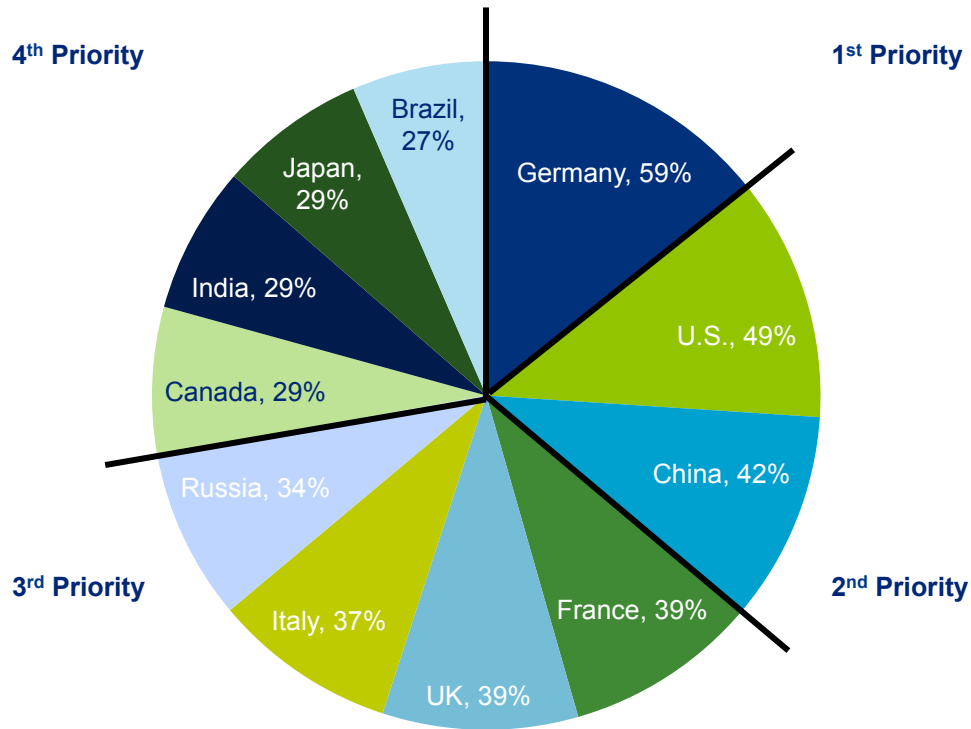
- The U.S. remains by far the biggest MedTech market in the world, more than 3 times as big as second ranked Japan
- With China among the leading users of medical technology, the other BRIC states are in the top 15
- Switzerland, being by far the smallest country in population among the top 20 markets ranks 17. This is mainly due to the good and modern healthcare infrastructure (other countries are Canada (11th), Australia (13th), Korea (14th), Netherlands (16th), Turkey (18th), South Africa (19th), and Saudi Arabia (20th))

Estimated avg. healthcare and life sciences growth in the major export regions²:

	2011	2010 – 2017
USA	0% to +2%	+6%
Japan	-2% to +2%	+5%
Germany	+1% to +6%	+5%
Switzerland	-1% to +5%	+4%
Euro (€) Zone	-3% to +3%	+4%
China	+9% to +12%	+10%
Brazil	+4% to +7%	+7%
India	+8% to +15%	+9%
Russia	+6% to +8%	+5%

SMTI firms are focusing on Germany, USA and China as major export markets

Focus markets and desired management insights for growth in export



Multiple responses possible, n=41

Source: Medtech Switzerland survey

Comments

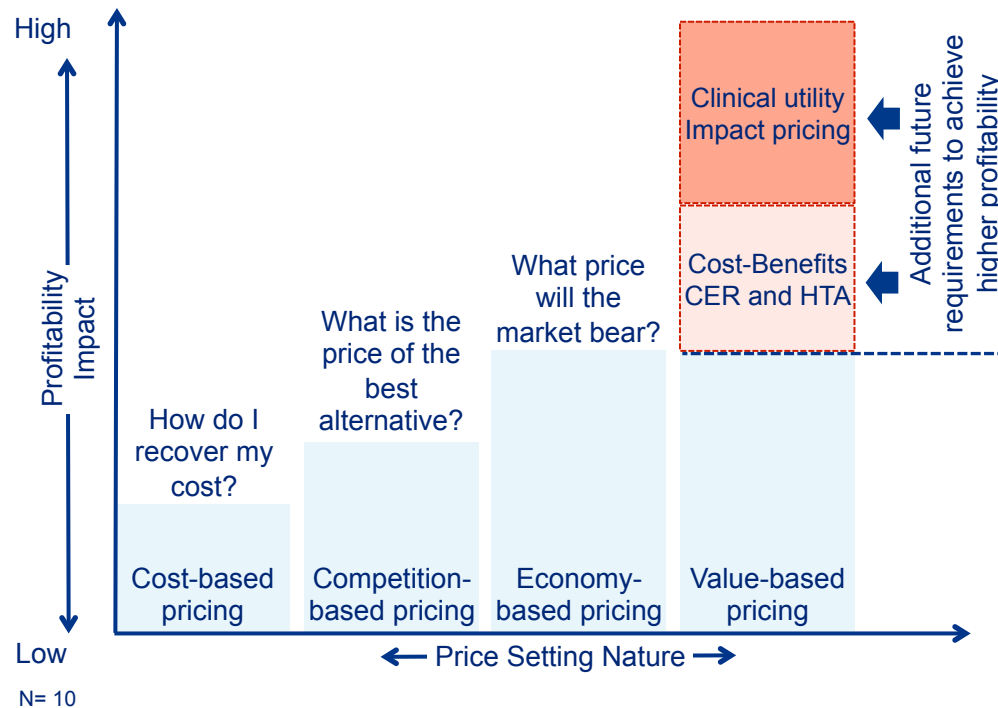
- For most of the Swiss MedTech companies, the established countries remain the most important export markets
- According to the sample used, most MedTech companies show the strongest interest in the German market. This is also usually the first step for many Swiss companies in their export activities
- Geographical closeness, a similar business understanding and – at least for the majority of the Swiss – the same language, facilitates ease of access market entry
- The U.S. is the largest MedTech market in the world, almost half of all companies show an interest in that market. After having entered one to several EU countries, the U.S. is usually the next big step in exporting for Swiss companies
- The sheer size and impressive growth rates makes China third on the list, almost equal to two other big European markets, France and the UK
- Today, companies increasingly turn their heads south and east. As in many other economic figures, the healthcare markets of the BRIC states are growing rapidly. Investments in healthcare infrastructure is a top priority of many emerging markets governments

Impact on SMTI

The strategy of pricing: demonstrating value & healthcare system benefits

Current threats to MTI Pricing

Regulatory changes will have an impact on pricing in Life Science

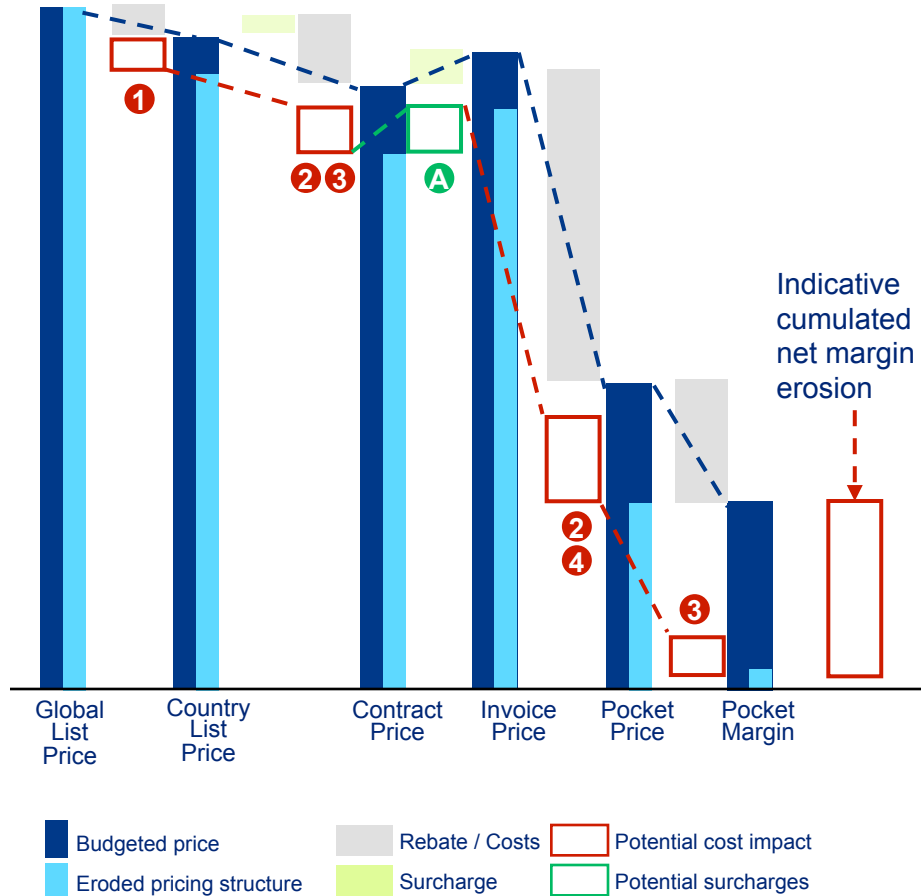


Comments

- Today, most MTI firms do not use pricing as a strategic element, but rather as a tactical tool for short-term and local profit optimization
- With an increase in outcome data availability, pricing transparency and the demonstration of the “value” benefit for the client (see graph) gain greater significance. However, within the next few years, HTA, CER and Clinical utility requirements demand more resources for an optimal positioning
- MTI firms often lack¹
 - Market insights regarding customer needs
 - Pricing simulations which can respond proactively to external impacts
 - Strong business relationships
- A common notion within MTI Management is that market share can be gained by initially applying discounts when launching new products and / or entering new markets
- In the future MTI companies should focus their sales arguments on the outcome proven benefits of a new product and not on the price
- Cost-Benefit-pricing is already essential for the successful positioning of products for Pharma companies

Addressing “pricing strategy” is a future must due to further margin erosion that might undermine single digit growth

Current threats to the MTI Pricing Model (Indicative)



Source: Deloitte, International Pricing Survey 2011

Comments

- Due to increased competition, paired with the increase in regulatory requirements and the resultant pressure on public funding, multiple issues are having a global impact on the MTI globally
- Current manufacturer margins are being squeezed (see red dotted line), who retrospectively pass on a great deal to their suppliers. This poses severe problems to them, resulting in management searching for alternative options, e.g. transferring capacities abroad)

We observe two types of effect on the pricing model:

Unbudgeted impact

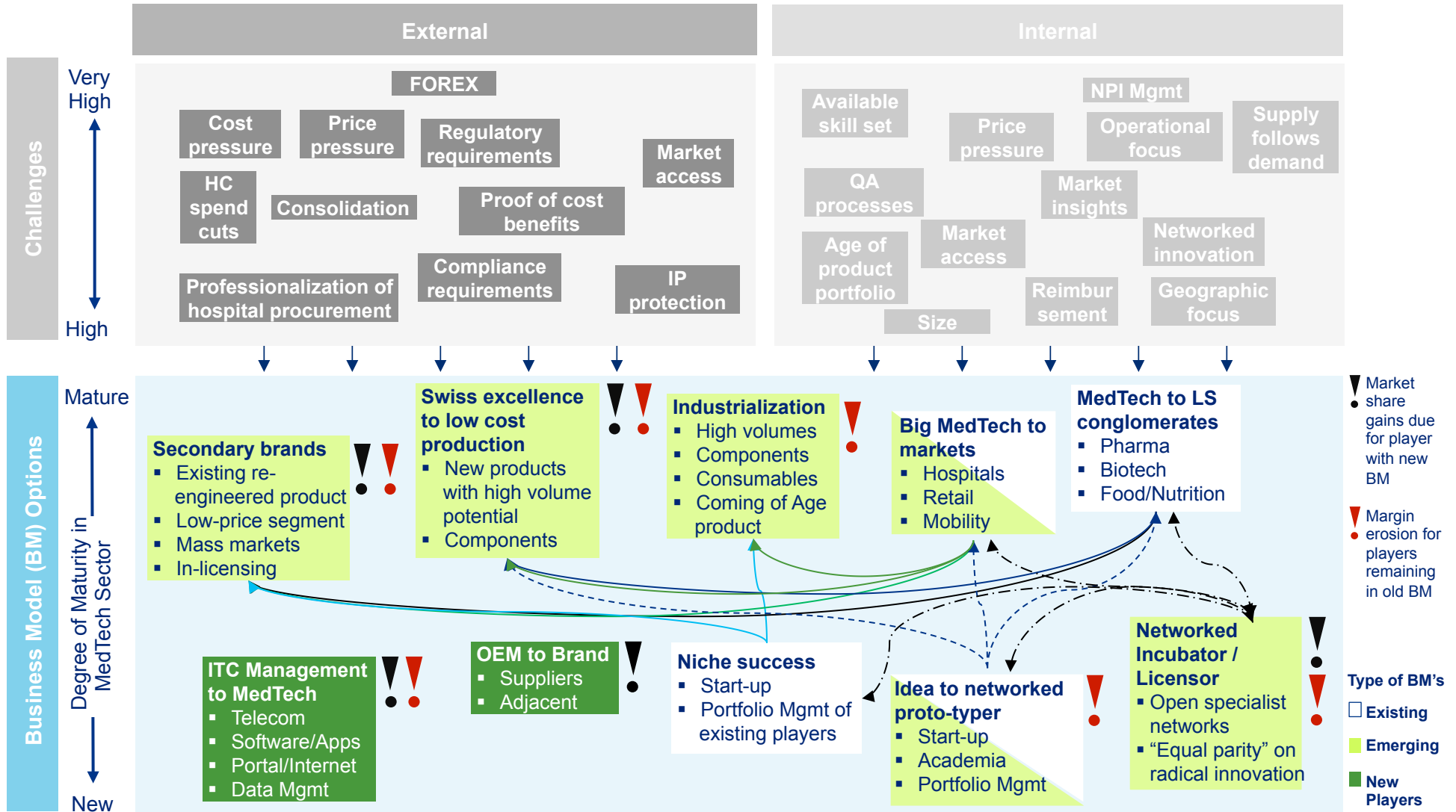
- FOREX effects
- Increased regulation (i.e. Vigilance, QMS, HTA, DRG, Software validation, etc.)
- Improvement of Marketing & Sales (i.e. due to increase of tenders, rise of GPOs, after sales-services, older portfolio, etc.)
- Increased clinical requirements (i.e. Comparative effectiveness studies, Clinical utility, etc)

Upscale impact

- New business model, improved portfolio management, or improved pricing strategy & outcome data management

Outlook & Conclusion

How could SMTI firms adapt to challenges – Examples of emerging Business Models



The SMTI: entering the next years with a strong crisis mindset and single-digit growth ...

Key Findings

- The SMTI has a **vital base** and is not yet fully exposed to the down-turn
- The average expected growth for the SMTI is between -1% and 5% for 2011 and 4% in the long-term perspective, this signals the end of the double digit growth period and of single products (except niche products). Single market entries limit product launch success in a globalized and data richer world
- The current status of the SMTI is worse than 12 months ago; an operational hectic and crisis mindset reigns. However, in contrast to many other export industries several MedTech companies plan to increase their headcounts. There is **limited headcount reduction anticipated**, as well as strategic project stops foreseen
- The survey highlighted that SMTI management aims to **achieve further efficiency gains** in order to improve performance in the magnitude of +5% to +10%, despite ongoing lean and continuous improvement programs
- The previous years shaped the current mood of the industry and this **crisis mindset** is partly responsible for diminishing returns and shrinking revenues
- The SMTI has significant competitive advantages based on the Swiss MedTech ecosystem like **closeness of cluster networks, networked innovation and reliability of supply chain management**
- **Value chain partner diversity might shrink** if the down-turn continues (i.e. selection of suppliers abroad due to price pressure)

... future competitive advantages reside in optimizing today's business models

Conclusion

Given the current vast challenges impacting SMTI, it is apparent that changes are required to master the stormy sea. Even though the SMTI companies seem to be in good shape, it would be advisable to depart from crisis mode and attain future competitive advantages by **strategically optimizing business models** in order to meet globalizing competition. As for now, there are multiple in-roads to change:

- New business model approaches
- Strengthening of innovation
- Strengthening of regulatory & quality management
- Strengthening skill sets
- Broadening the offerings

These set the strategic direction and influence tomorrow's modus operandi. Additionally, there is a **strong pressure to consolidate** that will drive change despite own actions. However, the main challenge is the **lack of skilled and experienced resources**, which may hinder immediate actions and the execution of forward strategies.

Upon reflection of the SMTI survey 2011, management should take the following steps to overcome their crisis mentality:

- Engage in a proactive recruiting strategy
- Strengthen market insights for potential strategy revision, including commercial excellence and regulatory excellence
- Strengthen networked innovation or engage in other business model options
- Outsource non-core competencies or functions to established global service providers

Appendix

I. SMTI 2011 Knowledge Base – Methodology

Objective

- The SMTI 2011 Report
 - Aims to embrace a selective industry sample comprising primarily manufacturers, suppliers, and other industry stakeholders
 - Reflects on the trends, challenges and priorities along the SMTI value chain
 - Highlights and interprets changes in the industry compared with the situation reported in the "SMTI 2010 Report"

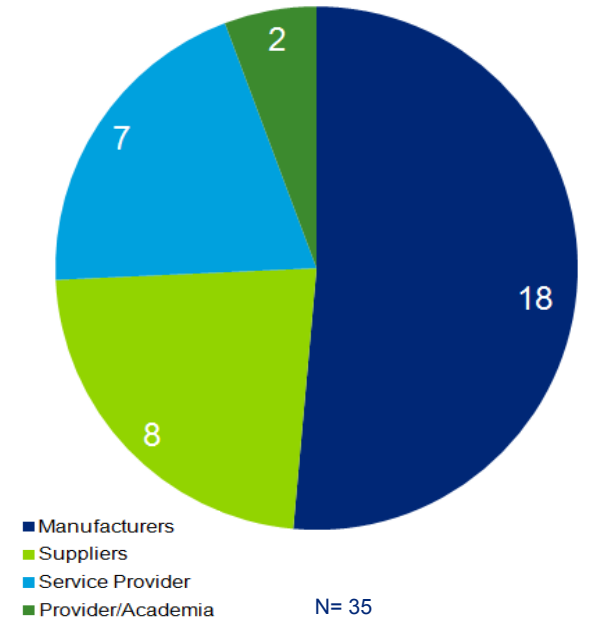
Approach

- Deloitte, in association with Medtech Switzerland, jointly carried out a validation of the 2010 industry survey findings
- The intention is to update the report annually, allowing tracking of MedTech Industry trends and issues
- Interviews were conducted mainly between August and November 2011

Methodology

- A tailored stakeholder interview approach addressing the
 - Challenges along the MedTech value chain
 - Management response in these uncertain economic times
- Testing 5 focal areas
 - Innovation & Engineering excellence
 - Regulatory excellence
 - Market Access
 - Consolidation
 - Changes or New Life Science / Healthcare players
- Direct market insight and current management thinking was accessed through these interviews
- Validation of the report was conducted by the main local industry bodies







Sample distribution



We would like to thank all the participating companies and institutions and their representatives for taking part in the interviews and providing valuable information. Based on this input it was possible to obtain a broadly-founded picture of the current state of the SMTI.

I. SMTI 2011 Knowledge Base

This is the sixth report on the SMTI

REPORT						
DESCRIPTION	Wissensbasierte Cluster in der Schweiz: Realität oder Fiktion? – Das Beispiel der Medizinal-technikbranche	Herausforderungen und Chancen der Schweizer MedTech Branche	SMTI 2008	Schweiz – weiterhin führend in Medizintechnik Quick-Check on SMTI 2008	SMTI 2010	SMTI 2011 Stormy times ahead? Quick-Check on SMTI 2010
FOCUS	<ul style="list-style-type: none"> • MedTech Industry • Innovation • Knowledge based actors • Structure and cluster of the SMTI 	<ul style="list-style-type: none"> • MedTech Industry • Challenges and opportunities 	<ul style="list-style-type: none"> • MedTech Industry • Challenges and strategic actions • R&D 	<ul style="list-style-type: none"> • MedTech Industry • Growth expectations • Challenges and strategic actions 	<ul style="list-style-type: none"> • MedTech Industry • Challenges and strategic actions • Development of healthcare market • R&D 	<ul style="list-style-type: none"> • Growth expectations • Challenges and strategic actions • Export • Regulations
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II. Outlook of Activities in 2012

World MedTech Forum



- Date: September 25th-27th, 2012
- Location: Lucerne, Switzerland
- Global conference with focus on international MedTech trends & challenges, particular in the USA, the EU, China/India and Asian MedTech markets
- Trade fair focusing on suppliers
- Partnering tool and corporate events

Global MTI Survey 2012



- Deloitte's 1st Global MedTech Industry (GMTI) 2012 Report
 - Focus markets are USA, CH, D, F, SE, UK, I, JP, India, China, Brazil
- GMTI 2012 results to be presented on September 25th 2012 during the 1st World MedTech Forum Lucerne

SMTI Survey 2012



- 4th SMTI survey, questionnaire will be based on +30 expert and industry leader interviews
- Results to be presented at the CTI/KTI MedTech Event Sept. 24th, 2012 in Lucerne
- Workshops on insights in special sessions

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This report was written in the autumn of 2011 involving companies in the field of medical technology in Switzerland. It makes use of expert interviews and desk research. The statistical data presented reflects the opinion of the participating companies at the time of the data gathering (September to November 2011) and may therefore not reflect the current market environment at the time of reading.

The parties involved in the study confirm that the collection, analysis and interpretation of all data was carried out carefully and anonymously. This publication contains information in summary form and is therefore intended for general guidance only. The authors and their respective company/association cannot accept any responsibility for loss occasioned to any person acting or refraining from action as a result of any material in this publication.

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