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Buoyant MedTech Outlook But Tempered by Looming EU Regulatory Changes Ahead

MedTech business leaders sentiment about growth is at a new high of 8.3pts according to the 11th LIMEDex Index Report, compiled by ConCepus since 2015. All three LIMEDex indices hit new highs. (Fig. 1)

WEGGIS, LUCERNE — The **LIMEDex Index**, which captures MedTech industry's sentiment on key business indicators on a quarterly basis since January 2015, is **at a new high of 8.3pts** (up by +1.7pts and up +4.3pts Y-T-Y), according to the 11th LIMEDex Index Report compiled by ConCepus since 2015. All three LIMEDex indices were growing positively, driven by **growth in access in export markets and new order entries**.

Managers' confidence in Operations is at a new high of +12.3pts (up +2.4pts Q-T-Q). The outlook on Market Access is steadily improving but still negative. The Financial outlook for the next 12 months is now at 2.6pts, up by +0.7pts, reflecting a high level of commercial activity but the view is tempered by industry-specific perceived risks and anticipation of the EU regulatory challenges ahead. The projected **average revenue growth rate** weakened to **+3.6%** and risk-adjusted revenue growth is **+1.1%** for the coming 12 months. (Fig. 2)

The majority of managers surveyed (94%) indicate **a high risk exposure to forthcoming EU regulatory requirements** (Fig. 3). "We undertook extraordinary primary and secondary research to determine the impact in terms of cost, time and human resources. Our analysis shows that the EU MedTech eco-system is faced with an **estimated operational cost of USD+18bn** (SMEs alone face USD +16bn) over the coming 3 years. The European MedTech market was worth USD +110bn in 2015 with an estimated R&D share of 6.5%. Given the estimated cost of compliance of ~ USD 6.3bn p.a. it will may consume huge portion or all of companies R&D budget.

"The **EBIT impact** is estimated to be **-4.0% for the next 24 months**," commented Mr. Beatus Hofrichter, ConCepus founder and author of the LIMEDex Index Reports.

The sheer amount of qualified talent required EU-wide is significant. Based on our analysis we estimate an **incremental Governmental Affairs resource** need of **+31,000 FTE**.

"Managers are not without options. They can address the challenges in a timely manner and for the more difficult ones, out of the box thinking could work. We compiled 12 tactical options for dealing with skills shortages, for example, in the report. However, it's unlikely that the cost of compliance can be avoided entirely," says Mr. Beatus Hofrichter, author of the LIMEDex Index Reports. Also, the new regulatory requirements are starting to affect the outlook on investing. The overall investment mood is positive, but declining moderately.

The majority of MedTech managers are confident in their current skill basis over the coming 24 months, despite the heated competitive environment and scarcity on back-office experts (Fig. 3). As managers are confident about the growth in sales and order fulfillment, they are also certain to weather the storm if they control their cash-flow tightly. As the industry grows steadily at a single-digit growth rate, it is expected to be able to sustain the burdensome transition towards the new "Pharma-like" regulations. The extra effort needed will be hard on many players, but it also provides the chance to strengthen the value based clinical evidence required in the future.

LIMEDex Index is based on quarterly surveys of more than 125 international Medtech leaders working in a range of company sizes (including niche, SME and large multinationals) to determine their outlook on key performance indicators (KPI).

Find out more about **THINKING AHEAD! 11th LIMEDex Index Report**; A Quarterly Economic Outlook for MedTech Leaders, download on www.conceplus.com/en/

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Figure 1: LIMEDex Sub-indices since Q4/ 2014

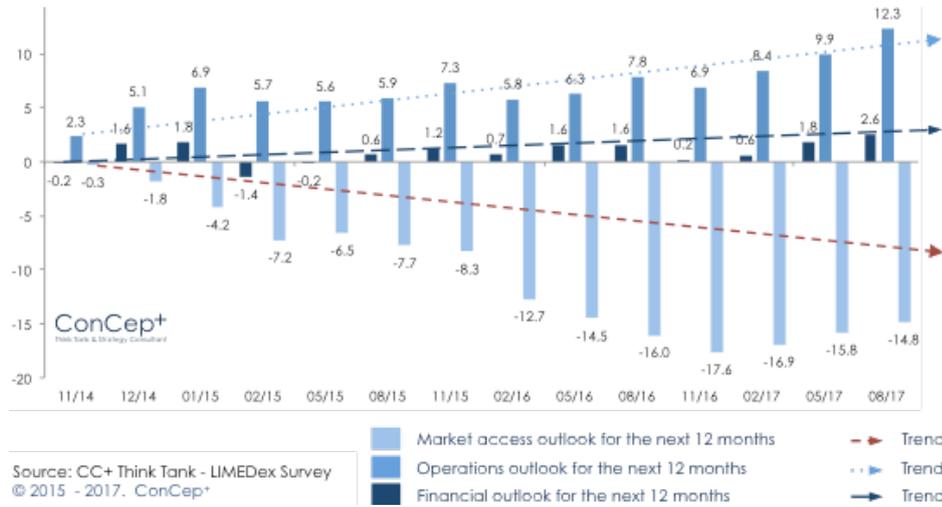


Figure 2: LIMEDex Index – Risk impact on Top line growth expectation since Q4/ 2014

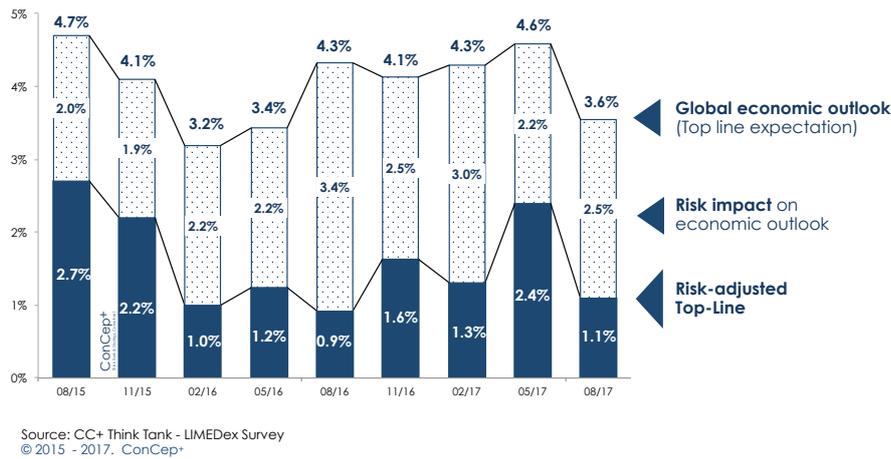
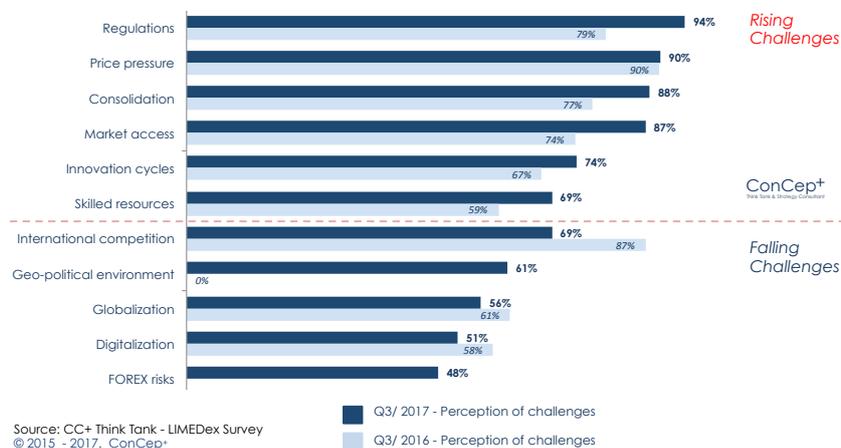


Figure 3: LIMEDex Index – Core challenges to the industry – Y-T-Y Q3/ 2017 vs. Q3/ 2016 in %



About LIMEDex Index

LIMEDex Index – a **Leading Indicator of Medtech Industry Index** is developed and published quarterly by ConCeplus GmbH, Switzerland since 2015. LIMEDex is designed to identify and understand emerging trends and key themes, enabling MedTech leaders prompt insights to understand impacts and potential consequences for their business. It is a qualitative monitor on **Market Access, Operations, and the Financial performance** given the underlying outlook on challenges to MedTech firms for the coming 12 months.

Due to the data sets available to us, we are now in the position to conduct timeline analysis, moving averages, Year-To-Year (Y-T-Y), and Quarter-To-Quarter (Q-T-Q) comparisons and provide trend lines on a single KPI or on a subset of KPIs were appropriate.

Additionally, in this edition we examine the international trade performance and internationalization of the vertical value chains of key Medtech producing nations. We selected **20 major Medtech producing/ trading nations** and their most important international trading partners for the past 5 years (since 2012). This analysis is purely based on desk research and on publicly free available data. It is planned to conduct this research annually, indicating the national, regional and global trends on exports.

Furthermore, upon expressed request of our LIMEDex Index readers and strategic partners, we included a special feature on “Regulatory Impacts in the EU” in this report, focusing on the challenges and overall impacts of the new EU MDR/ IVDR and extended clinical requirements for MedTech companies of all sizes. For this deep-dive analysis, we applied a dual approach, (a) 3 dedicated qualitative questions directed to the LIMEDex survey participants, and (b) selected interviews with functional experts and national industry stakeholders. In this respect, CC+ would like to thank all experts and industry leaders for their dedicated and timely support providing specific contextual insights on this pressing issue to industry leaders and stakeholders.

The LIMEDex Index survey applies a standard set of **20** focused questions on key performance indicators. The results usually show the net perception value of industry leaders, i.e. the delta between “confirming” and “disputing” answers are calculated, while subduing the “neutral” replies. The longitudinal data allows for high-level trend analysis per KPI.

The LIMEDex Index survey was conducted fro August 18th to September 3rd, 2017. Enriching secondary desk research of data publicly accessible to substantiate our findings and highlight industry and macro-economical trends impacting MedTech ended on September 3rd, 2017.

More than **107 international** MedTech leaders/ industry experts participated in these recent surveys.

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