[So What's Happening In Europe With MedTech?]

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Almost all European countries are adopting measures to contain healthcare spending. These actions are negatively impacting orthopedic industry revenues moving Orthopedic companies to shift investments and reallocate resources to emerging markets and more stable countries.

The downward slide in the European economy may be accelerating — with both strong and weak economies being impacted by the debt crisis. Following several months of worsening —in the midst of a grinding fiscal crisis resulting in at least four of the currency union's member states requesting financial aid — there have been predictions that Europe's economy will return to a full-blown recession, which would be its second in four years. There are also growing fears that a deepening downturn in Southern Europe will hamper efforts to resolve the region's debt crisis.

Euro-zone officials have spent the past two years pushing countries to pursue sharp budget cuts — healthcare costs included — in an attempt to reduce deficits. Almost all European countries are adopting measures to contain healthcare spending, allocate available resources adequately and manage expenditure on health and hospital care effectively and efficiently. These include:

- Rationalization of healthcare budgets, staff and services
- Increase in cost sharing for patients
- Reduction in medtech prices (including mandatory changes of pricing in existing and future contracts) and coverage
- Policies for managing device expenditures (including price referencing)

These issues/actions have started to negatively impact orthopedic industry revenues — and may result in continued headwinds through 2013 and beyond.

Impact On The European Orthopedic Market

Estimated global hip and knee growth of ~2% constant currency (CC) in Q2/12 was unchanged versus Quarter 1. However, there was a clear distinction between performance of the large orthopedic companies in the US and OUS. US growth of ~3% cc was slightly better than Q1 — primarily driven by improving procedure growth — while OUS growth of ~1% cc was slower than Quarter 1 — primarily due to issues related to the European market.

The large orthopedic companies will likely shift investment and reallocate resources to emerging markets and to financially stronger and politically more stable countries within or outside the euro-zone as they attempt to compensate for anticipated revenue headwinds in Europe.

A Macroeconomic Look At Europe Today

A) Record Unemployment – A Deep Divide Within The Euro Bloc

The number of unemployed in the 17 nations that share the euro rose to a record of 18.2 million in August. It was the highest total since records were first compiled in January of 1995. The overall unemployment rate was 11.4% — up from 10.1% in the summer of 2011. The figures also illustrate the gulf between stronger and weaker euro-zone nations, one of the underlying causes of the debt crisis. The jobless rate in Austria and Germany was 4.25% and 5.5% respectively, while in Spain it was 25.1%.

More than 55% of Greeks below 25 years old and 53% of young Spaniards remain unemployed versus just over 8% in Germany. This has raised fears of a lost generation of workers who will be unable to establish themselves in the workforce. An economist at Capital Economics proposed that "European joblessness probably hasn't reached its peak and will continue to suppress economic activity".

B) Gap Widening Between Euro-Zone's Two Largest Economies

There are troubling signs that weakness is intruding on the euro-zone's "core" countries that have bankrolled much of the rescue effort during the crisis — most notably Germany. Although some economists believe that Germany is best equipped to withstand the economic strains from inside the euro-zone as well as the slowing global economy, others have suggested that "Germany may be heading for negative GDP growth in the third quarter".

However, German business activity largely stabilized in September, providing some relief that any turndown may be brief. Germany's economy has also expanded by 3% or more in each of the past two years — and is expected to grow about 1% in 2012.

By contrast, French business activity contracted dramatically in September. A Markit economist said of France's slide — "There wasn't a single factor. Rather, it seems to be a real lack of demand, a lack of confidence".

The outlook for Southern European countries — including Italy and Spain — is even bleaker. Given the Euro bloc's deepening economic contraction, it will be harder for Italy and Spain to reduce government debt levels in the midst of increasing strains on social spending.

C) GDP/Inflation And Business/Consumer Confidence

IHS Global Insight contends that "the euro-zone gross domestic product (GDP) will contract around 1.5% at an annualized rate — double the second quarter's decline. The euro-zone hasn't posted any growth since the third quarter of 2011".

Further, the annual rate of inflation in the euro-zone was in the 2.4% to 2.6% range during the summer — above the European Central Bank's target rate of below 2% — and a factor that may impede economic growth.

Finally, confidence has fallen among businesses and households — confidence in August was at its lowest level in three years. Consumer confidence fell to a 40-month low in September.

The European Central Bank's (ECB) Response

The ECB hoped to bolster the euro-zone economy by injecting more than $1.3 trillion of cheap money into the banking system and reducing the main central bank rate to a record low. However, as business activity shrinks and unemployment rises, the ECB's efforts have not yet been successful in reversing the downturn.

A Look At The Existing (Or Proposed) Austerity Plans Impacting MedTech In Europe

Many governments have announced their healthcare budgets for 2013. Most countries are either freezing or cutting spending:

In Spain:

The Spanish government announced cuts to healthcare (and education) spending of $13 billion per year. It also approved a Royal Decree-Law which outlines a series of measures to contain expenditures, such as increasing co-payments and establishing a new central purchasing system for medtech and pharma technology assessment systems.

In Italy:

As examples of austerity measures that may be enacted shortly, the Italian Government is looking to enforce the renegotiation of medtech supply contracts with the objective of bringing them in line with price cuts — which are rather significant.

Currently, there is a proposed legal obligation on the part of regional authorities to enforce renegotiations where supply costs are more than 20% above a new scale of "reference prices". If the terms of contracts are not renegotiated to reflect the new reference prices, the supply agreement would be cancelled. The obligation is consistent with the government's earlier "request" of medtech providers to be prepared "to redraw supply contracts to accommodate annual cuts in medtech supply spending of 5% throughout the second half of 2012, as well as cuts of 4.9% in 2013 and 4.8% in 2014".

Failure to reach an agreement within 30 days of the region's renegotiation proposals "can result in the immediate cancellation of the contract on the part of the buyer". Of course, the regions can overrule this requirement in cases "where the price differential can be justified by technical or logistical considerations".

The medtech association Assobiomedica has been critical of the austerity measures because it is "at odds with EU contract law", which provides specific protections against contract renegotiations. Although the association agrees with the government that the austerity measures "merely seek to ensure that less efficient purchasing policies are brought into line with those of the most efficient regions", Assobiomedica does feel that the measures "put the national health system at grave risk, by reducing both the quality and safety of healthcare products and services. The planned sheer cut in medical technology investment will, in a nutshell, have the following dual impact. On one hand, a progressive slide in the quality of care; on the other, a similar progressive undermining of the economic health of the national health system itself".

What Select European-Based Orthopedic Industry Executives Are Saying

Experienced executives from Germany, France and Italy offered the following regarding the state-of-the-orthopedic business in their countries:

In Germany:

- "Recon and trauma markets still growing but seeing price erosion"
- "Procurement groups are becoming more powerful"
- "Consolidation of group clinics taking some purchasing decisions away from surgeons and forcing price reductions"
- "No negative impact re: reimbursement"
- "People moving toward private insurance"
- "Politicians driving data collection, particularly in recon"

In France:

- "Volume increase offset by price – recon market flat"
- "Tender business becoming even more important"
- "Reimbursement declining for surgeons"
- "Private clinics being acquired (by private companies) and uniform pricing being imposed"
- "DSO terms increasing"
- "In some cases, patients waiting 8 to 10 months before hip or knee surgery"
- "Patients going private pay"

In Italy:

- "Procedures being delayed"
- "Pricing being pushed down and reimbursement to be reduced"
- "Reference pricing is resulting in cuts of up to 25% for some products"
- "Clinical evidence being asked for more and more"
- "Seeing more patients being sent to high-volume centers"
- "Government beauracracy at an all-time high"

In Spain, France and Italy:

- To slow down healthcare spending and limit the entrance of innovations which are not going to significantly reduce cost versus existing alternatives, robust data and clinical evidence — of up to two years — are being requested of new products to be eligible for reimbursement"

Scenarios The Large Orthopedic Companies Are Wishing For In H2/12 and 2013

In an effort to compensate for revenue headwinds in Europe, orthopedic companies will be wishing for some (or all) of the following scenarios to take place the remainder of this year and next:

- The “return of the patient” — acceleration of procedural volume growth in the US for the 3 biggest elective-surgery segments — knees, hips and spine.
- Price discounting no worse than current (vs. accelerated) levels in the US.
- Continued above-average revenue growth in the emerging markets, especially China.
- Some positive signs of a return to growth in the euro-zone.
- Continued accelerated revenue growth in sports medicine and extremities.
- Continued “steady market-growth” in trauma and orthobiologics.

Challenges Accelerating For Large Ortho Companies

Orthopedic companies have started shifting investment and reallocating resources to emerging markets and to financially stronger and politically more stable countries within and outside the euro-zone as they seek to deliver on revenue and earnings projections for the balance of 2012 and in 2013.

Some experts have expressed views that the euro-zone economic issues will deepen in the latter part of 2012 and that “it could take many years for Southern Europe to shake off the crippling economic effects of the debt crisis”. While many short-term measures exist to contain costs, experienced in-country orthopedic executives see no signs yet that providers, payers or policy-makers have identified alternative healthcare models that will be financially sustainable in the long run. As a result, they are expecting the challenges to persist.

The large orthopedic companies will need to again retrench to weather the euro-zone storm — and continue to force themselves to adapt to an ever-changing global healthcare market. And although “big ortho” may be hoping otherwise, the pressures that are surfacing today in Europe are likely to be a common feature of most health systems in the future.

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