

European Medtech: The Grass Is Not Greener

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Amidst a currently effervescent biotech scene, medtech is suffering. Sector newsflow is dominated by layoffs, regulatory escalation and a harsh fiscal environment. In this context, it is appealing for medtech companies domiciled outside Europe to look across the Atlantic and see brighter prospects. After all, Europe represents the second largest medtech market worldwide and the regulatory process to market authorization (CE Mark) is orders of magnitude simpler and faster than a PMA or even a 510(k) application. Indeed, we are regularly approached by US and Israeli medtech companies that have run into FDA complications seeking the easier route to market in Europe. Indeed, a 2012 survey of 1,866 medtech firms revealed that 39% of US firms would choose to commercialise a new device first in Europe in view of the US regulatory challenges¹. But, of course, nothing is ever as simple as it first appears, and the 'greener grass' in Europe turns out to be just as full of challenge as that in the USA, albeit with a different set of underlying issues.

Europe Can Be Hard To Navigate...



Issue 1: Europe Is Not A Single Market
The Single Market provisions of the EU which mandates free movement of goods and services does not, in practice, result in a homogeneous market for medtech

products across all 27 states and 504 million people. Whilst it does allow a single regulatory process for the entire region, it does not remove the distinct national and loco-regional characteristics of the marketplace. Medical systems are organised and funded very differently throughout EU27 and in most cases it is necessary to establish no fewer than 27 legal entities to gain pan-EU marketing coverage. The shortcut of working with distributors rarely works well and is another of those 'easy', 'painless' routes to market that generally disappoint.

insufficient to enable active market uptake. Firstly, EU physicians tend, on average, to be conservative and considerable KOL programmes are often required based on data packages that in practice do not differ materially from those seen in a PMA. And the evidence base needed for payers is another issue altogether.

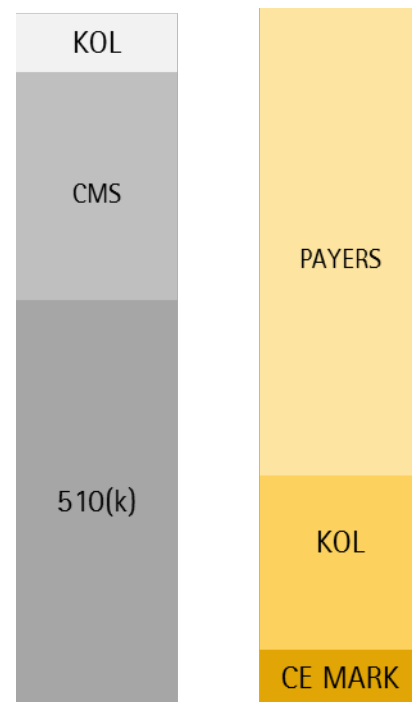
Issue 2: Hurdles To Market Acceptance Are Just As High

Compared to securing FDA approval, gaining CE Mark status can be almost trivially easy. It is true that standards and procedures are going to be tightened up, but no-one expects stringency to approach US levels. The issues are that:

- Time-to-market (i.e. including pricing, reimbursement and market access processes) is operationally what counts, not the time-to-CE Mark. End-to-end, European time to market is comparable, or longer, than the US equivalent².
- The risk profiles are different, but the overall hurdle height is comparable. In the US, key risks focus on FDA. In Europe, the dominant risk focusses on payers (see illustration right).

Achieving the 'regulatory approval' of a CE Mark allows a medtech product to be put on the market but is totally

Different risk profiles, same hurdle height...



² N Engl J Med 2012; 367:485-488



Issue 3: Payers

As might be expected, payers in different EU countries can take radically different views. This has been seen most vividly in the Rx field where, in one example, following regulatory approval with a broad label:

- In France, the payers assessed the entire labelled indication but concluded that the level of clinical benefit was 'minor';
- In Germany, payers segmented the label population into three sub groups. In one, they assess the product as having no benefit, in the second no quantifiable benefit and only in the third group was the benefit deemed substantial versus the comparator. Needless to say, the third group was numerically by far the smallest.

Similar is occurring in the medtech field. In the UK, the pricing/market access agency NICE recently approved the use of Oncotype DX as a test in early breast cancer to guide chemotherapy decisions. Compared to the US label for the test, the NICE authorisation was narrower in terms of population, restricted use to situations where the case for chemotherapy was unclear and was conditional on the manufacturer providing it to NHS organisations at the price offered through the confidential arrangement agreed with NICE. In other words, a narrower population, a more restricted set of circumstances and a lower price. Significantly, the MammaPrint, IHC4 and

Mammostrat tests which were evaluated at the same time, were simply not recommended for use on the grounds of lack of evidence of clinical and cost effectiveness³. This is certainly not an example of 'greener grass'.

How To Succeed in Europe

Despite these complications, Europe is too big a market opportunity to be ignored. It is possible to achieve commercial success, but only if the appropriate market and payer work is undertaken upfront. This is a material investment of time and resource, but it is an absolutely essential step.

Europe is significantly ahead of the US in the transition away from "the best available care for the individual patient" to "the best value acceptable quality care across a population within a limited resource base". As a result, payer relevance now extends significantly before the pre-launch phase (the traditional time for consideration of these issues), and we recommend integrating a payer perspective into product development. Specifically:

- Payer value elements (clinical and economic) should be an explicit part of a target product profile;
- Clinical assessments should be designed to address payer needs, not just regulator and KOL requirements. It is significantly cheaper and more efficient to do this prospectively as retro-collection of data is often impractical;

³ NICE diagnostics guidance 10

- Additional payer evidence generation should be considered in parallel where it is more efficient.

Designing 'strategic market access' parameters into a development programme is driven by appropriate payer research, either one-to-one interviews or through payer advisory boards. We find it always pays off to work with real payers who have current roles that involve actual decisions on healthcare product pricing and reimbursement – they provide significantly more useful input than academic health economists who are often consulted in these contexts. For payer research, real world practitioners are more relevant than economic opinion leaders. Through numerous assignments, we have uncovered payer factors that differ significantly from issues of interest to clinicians, underlining the need for proactive payer research. If you get it right, you can win (reasonably) big in Europe.

Importantly, such payer considerations are not restricted to Europe, as CMS and insurance companies gradually adopt similar or analogous approaches to focussing on outcomes-driven reimbursement decisions.

The Grass Is Not Greener But...

Despite the complications of commercialising in Europe (remember, bureaucracy is a word invented in Europe), it is too large a market to be ignored. Whilst it is not a panacea to regulatory frustration in the USA, success is possible even if it's not as easy as it seemed from a distance.

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