A CEO's Guide to

# Launching a Medical Device into Europe

*Achieve success and avoid the pitfalls*

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# INTRODUCTION

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## Launching a medical device into Europe:

## Avoiding the pitfalls to ensure success

Why are some medical device product launches into Europe of products a massive success where as others can be a huge disappointment? The difference can often be explained by the recognition, or otherwise of the variability of the European market place. If proper consideration is given to this variability then the likelihood of success is considerably enhanced.

The European Single Market might be referred to as a single market, but it is not in any way similar in relative uniformity to, say, the US market.

The truth is most non-European business people understand that Europe is a non-uniform or amorphous market, and quite unlike the other big markets.

The question is, though, do non-European CEOs really understand where those variations are and what they should do about it to ensure success?

This essential, concise e-book/guide has resulted in discussions from numerous medical device business leaders who have real experience in making medical device launches work in Europe, many of whom have had to learn it the "hard way". It does not attempt or claim to cover everything, and as mentioned on a number of occasions through the book, you are strongly advised to get expert local advice on the various aspects that are discussed.

It is also designed to make you aware of the challenges you will face; not to discourage , but to make you aware of the potential complications and costs, so that a properly balanced and fully informed business plan can ensure success.

# THE EUROPEAN HEALTHCARE MARKET;

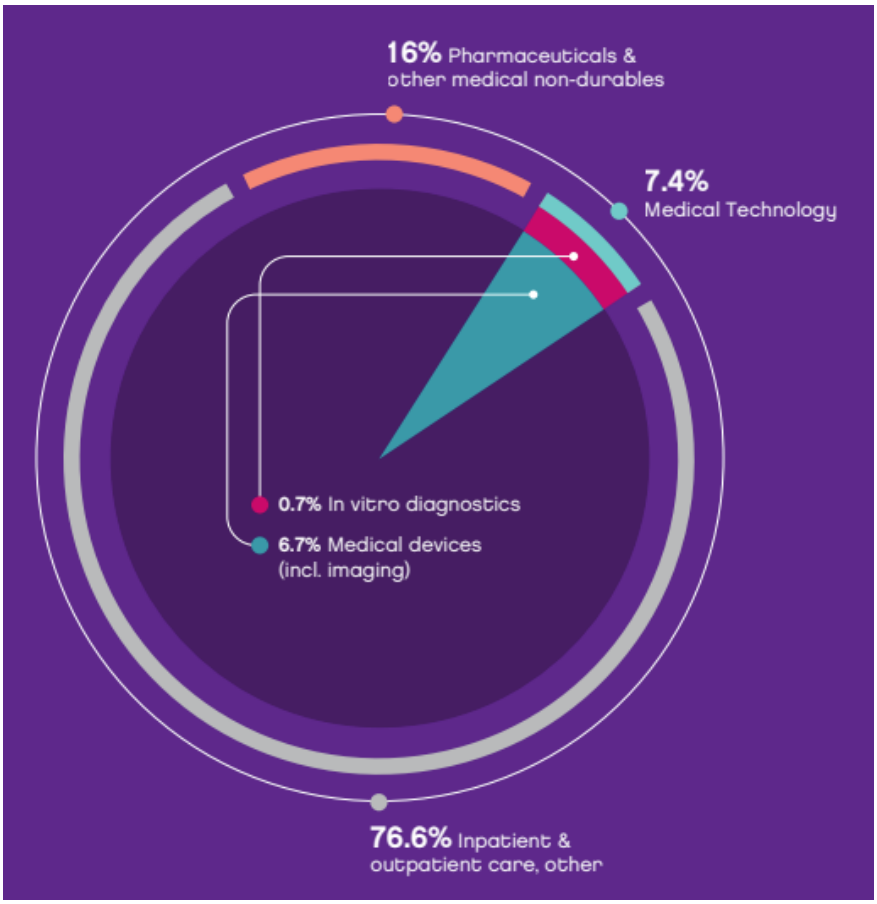
# SIZE & SCOPE

The raw intelligence is compelling. The European Union plus the UK (now no longer a member), has an approximate population of 508 Million . It is a geographical region that is highly advanced, has sophisticated highly qualified healthcare professionals and an aging population. In terms of selling medical products, as the saying goes, “what’s not to like?”!

In more detail, an average of 10% of gross domestic product (GDP) is spent on healthcare in Europe. Of this figure, around 7.4% is attributed to medical technologies.

The spending on medical technology is estimated to vary significantly across European countries, ranging from around 5% to 12% of the total healthcare expenditure. Expenditure on medical technology per capita in Europe is at around €225, contrasting with approx. €380 in the US. Immediately one sees that same recurring theme that needs to be considered when making your decisions: variability.

Breakdown of total healthcare expenditure in Europe
*(from Medtech Europe report: The European Medical Technology industry in Figures 2021)*




Total European Market: The European medical technology market is estimated at roughly €120 billion (2018).

Based upon manufacturer prices the European medical technology market is estimated to make up 31% of the world market. It is the second largest medical technology market after the US (± 40%).

Largest Individual Country Markets by Size: The largest medical technology markets in Europe in order of size are Germany, France, United Kingdom, Italy and Spain. The same countries make up the top 5 IVD markets in Europe.

Market Growth: The European medical technology market has been growing on average by 4% per annum over the past 7 years.

# HEALTHCARE SYSTEMS IN EUROPE

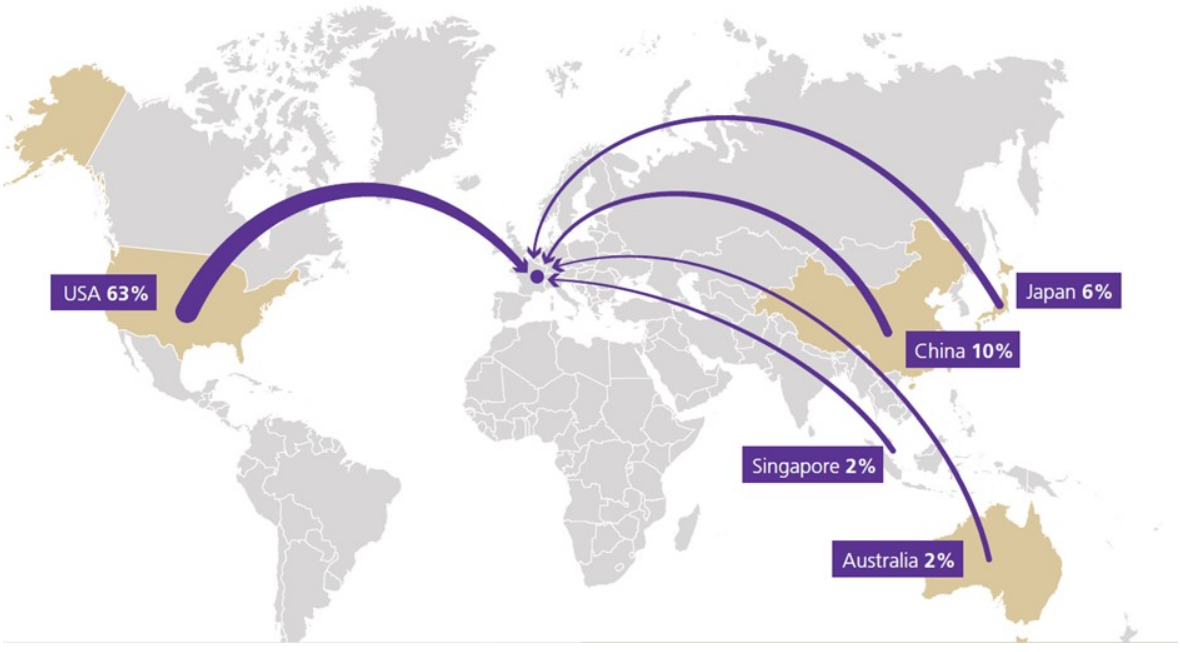
A good overview of the complexity of European healthcare systems is described in Wikipedia:

> *Healthcare in Europe is provided through a wide range of different systems run at the national level. The systems are primarily publicly funded through taxation (universal health care). Private funding may represent personal contributions towards meeting the non-taxpayer refunded portion of costs or may reflect totally private (non-subsidized) healthcare either paid out of pocket or met by some form of personal or employer funded insurance. All EU and many other European countries offer their citizens a European Health Insurance Card which, on a reciprocal basis, provides insurance for emergency medical treatment insurance when visiting other participating European countries.*
>
> *The European Union has no major administrative responsibility in the field of healthcare. The European Commission's Directorate-General for Health and Consumers however seeks to align national laws on the safety of food and other products, on consumers' rights and on the protection of people's health, to form new EU wide laws and thus strengthen its internal markets.*

A summation might be that whilst there are similarities between some countries health systems, it is safer to work on the basis that each is different, some in radically different ways. This in turn means that barriers to entry and selling opportunities can be very different between European countries.

A more in depth analysis from the European Commission can be found here: **http://ec.europa.eu/health/systems_performance_assessment/health_systems_organisation/comparing_organisation_en**

Top suppliers of medical technology products to Europe (imports) *(from Medtech Europe report: The European Medical Technology industry in Figures)*




**Conclusions?** This is a big market! Get your CE mark and go for it! Really? Well there are a few other things to consider…

# BARRIERS TO ENTRY TO THE EUROPEAN MARKET

Putting aside the mind perplexing unknown unknowns, and knowing that there are some known unknowns, what are the actual things we know you will need to address?

***They are definitely these:***

- ***Avoiding Mistakes in the CE Mark Process*** *– You know that failure to have one will mean you cannot commercially sell your product in the EU*
- ***Choice of KOL*** *-You know you need to choose them, and work with them. The wrong choice can be highly damaging*
- ***Navigating Regulatory and Reimbursement*** *-You know you will need to understand and navigate the complexities: Failure to do so will land your launch on the nearest rock*
- ***Not Getting Heard*** *- You know that you need the message to get through to the customers. If you are a small company with a limited budget how can you make yourself heard above the noise created by the large corporations?*

We already know that if we plan to introduce a medical device or product into Europe the first barrier to entry is getting a C.E. mark.

Simple, so the C.E.O. could get his team to procure a CE mark with the very clear direction;

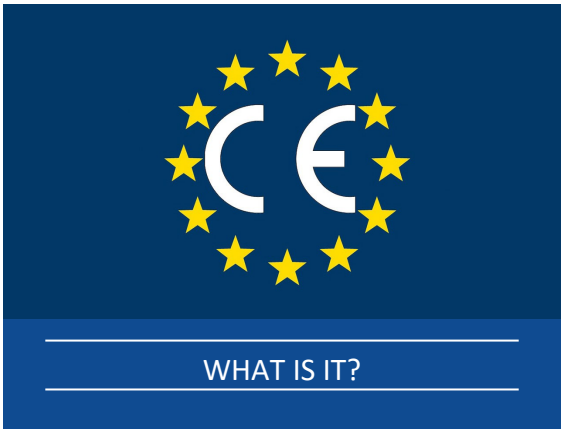
*"What will it take to get one and how quickly can we get it done and what is the most cost effective way of doing it".*

This is a logical and pragmatic direction that any C.E.O. would make, unless of course you consider a few of the known unknowns and then the solution can become a little more complex.

But, *"Surely a CE mark is a CE mark is a CE mark?!"*

As discussed later in this publication, and if we may paraphrase George Orwell here, 'All CE marks are equal but some are more equal than others'

In theory there should be no distinction between a CE mark issued in any part of the E.U. but in practice you might want to consider how much weight they objectively and subjectively carry and the reliability of that CE mark for the future. Does a CE mark issued from one notified body carry as much influence as a CE mark issued from more established notified bodies? Due to a number of previous controversies there still exists a subjective prejudice around 'the who issued what and how was it granted'. The old phrase of "perception is reality" means that you should not wish to be perceived as a company that has gained its CE mark in the cheapest and least rigorous way.




To sell medical devices in the European Union, you must obtain a CE Mark (Conformité Européenne - a symbol shown on products that indicates market approval throughout the EU) for your product. CE Marking indicates the compliance of a technology with EU regulations and enables the commercialization of your products over 30 European countries. As the medical device manufacturer, responsibility lies with you for maintaining regulatory compliance and securing CE marking for your product, regardless of whether you outsource any or all components of your manufacturing operation.

Over many years medical device companies have found that applying for CE mark may sometimes be faster than regulatory approval in the US, which in turn means that products may be available for commercial release in Europe in advance of the US. However, it is essential to emphasize that while Europe's new Medical Device Regulation (MDR) that came into force in May 2020 made the process more similar to the FDA, it is still strongly differentiated.

CE is not a quality mark, but demonstrates compliance with EU Directives, and requires you to meet specific standards of performance, quality, and safety for your product type. Odd as it may seem to some, CE marking does not seem to require any proof of greater efficacy than existing systems but focuses on safety and performance. You should therefore:

- Not design a study to prove you are the gold standard for that particular product group. This may well cause you to miss your statistical end points resulting in failure.
- Ensure you are not under budgeted for your clinical trial. Trials need to be costed appropriately and this cost needs to reflect the scale and scope of the end-points you need to achieve. The overall cost of running a trial is often underestimated, especially in the CE marking phase as the cost of the implant as well as the technology may need to be covered. CE mark certifying bodies also like to see patient inclusions across multiple countries in the EU as this is more likely to provide a representative selection of the general population; again, this has financial implications. If you under budget, you may need to redesign your trial (for example reducing the number of patients). This will potentially cause a significant delay in the CE marking process leading to damaging clinical and commercial consequences. There are a number of examples of medical devices that have effectively "missed the boat" and allowed competitors to take the market advantage due to poorly designed trials.
- Make yourselves familiar with the new requirements of the MDR, in particular the requirement for 1, 2 and 3 year follow-up on some classes of device.
- As mentioned previously, choose your notified body with care. There have been a number of notified bodies that have ceased to exist, and this may increase as competent authorities are now auditing these organizations. If your notified body ceases to exist you will be required to recertify. This recertification would need to ensure that the original processes conform to the rigor of the current requirements, and they may not! In tandem with this there are implications to the country you choose to use to pursue CE mark study in (quantitatively with particular reference to the time required to get alignment on ethics and qualitatively with reference to the institution and investigators you propose using).
- Choose carefully which countries you are going to conduct your trials in. Some countries are more receptive to trials than others and this may have significant time and cost implications for the completion of your CE mark application.

The fundamental principal is to plan carefully & take the best possible advice to ensure you get your CE mark in the most time-efficient & reliable manner.

## Choosing the right KOLs

Who will you choose to engage with to help you on your clinical journey? Normally that involves one or more clinical key opinion leader (KOLs) from your chosen field.

Typically, new market entrants like to engage with the 'Big Names'. That is not a bad strategy per-se but you should be mindful of the fact that probably everybody else in your field will also be engaging with the same KOLs. There is good news and bad news in this strategy. The good news is that the KOL is a known quantity and can advocate on behalf of the technology or product, the bad news is, that given that everyone else is using them too, your KOL may easily get distracted. It goes without saying that you have to ensure that any KOL stays focused on your proposition and does not get too side-tracked with other distractions. This invariably takes good KOL management. We have had many discussions with disgruntled C.E.O.s asking us how can they get their top teaching institution back 'on the programme'.

There are many strategies that can be employed to manage a KOL in this regard, too many to list in this chapter and this is likely a topic for another day. Suffice it to say you will likely need the right talent in place to sufficiently and skilfully influence your chosen KOLs accordingly.

Usually that requires talent with a good contact list, a solid history and a good set of relationships in place who will do a thorough 'discovery' of the landscape, build trust with the key players and provide a solution that works for all parties. The mistake that many C.E.O.s usually make at this point is, that once the local talent gets the ball rolling, they often take back control of the KOL management process, overlooking the fact that the 'discovery' and the 'building of trust' was brokered by the very person that got the ball rolling. Often progress may stall again at this point.

You should also consider how well your KOL is politically connected. How close to the local reimbursement agency is your KOL?

You should know well in advance if they sit on any commissioning committees relevant to your chosen field. Are they a respected or a divisive authority in their field? Do they have good podium presence? Are they well published? Are they ethical? Again, get your due diligence done well in advance. Local advisors can help you with this assessment - such an investment is relatively small; it will save you time and money as well as reducing your overall production of Cortisol in the process!

You should also reflect if your 'Big Name' KOL is likely to become your commercial champion? It's important for you to get your head around this early on, so as to save yourself from any undue late frustration; the Big Name doesn't need to be a commercial champion because they have everybody and their dog coming to their door most of the time ( just like you did!). If you get too pushy on commercial grounds you may lose the argument on clinical grounds (they are the experts here after all!), or worse still they may stall on you. One has to appreciate that one of the reasons they've become a Big Name is that they probably have a reputation and a history of being objective and impartial and that is something they will actively want to protect and not tarnish by being overly commercial.

Perhaps you need to consider cultivating your own commercial champions in tandem with the Big Name KOL's as you proceed. These two tactics can be intimately linked but the skill here is in identifying each strand, and keeping them motivated throughout (and usually keeping them at arms-length from each other until it is too late for either to back out).

Why? Because one usually has a vested interest in your product not commercializing too soon (probably because you continue to provide them with plenty of research opportunities and funding!). Meanwhile the other will likely want to make a name for themselves by commercializing as soon as possible, leveraging any and all evidence generated, including any from the Big Name KOL you engaged at the outset. This sort of potential clash of ego management is not an uncommon dynamic for you to have to manage and requires some delicate handling. Again, you would be well advised to engage local expertise to help you.

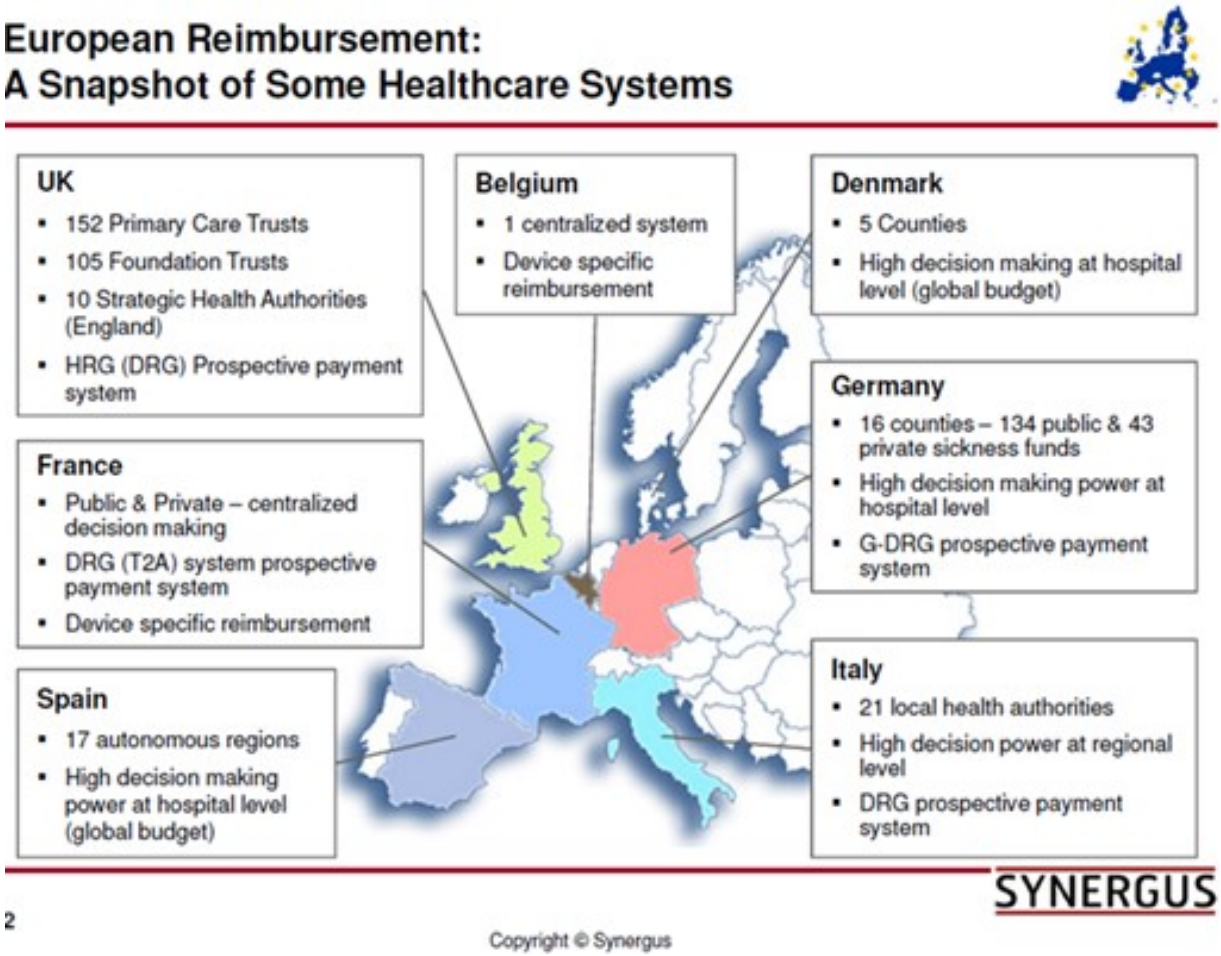
## THE EUROPEAN

### REIMBURSEMENT LANDSCAPE

In theory one would be forgiven for thinking that understanding the reimbursement landscape should be a fairly transactional set of activities to execute. After all, once you have your CE mark technically you are able to commercialize your product, right? However it is never quite as straight forward at that.

Although any Health Care Professional (HCP) could choose to use your product once it has CE mark, the likelihood is that they will not do so unless it has received further endorsement by their local regulatory agency and Ethics organizations. The HCP will need reassurance that there will be no ethical, medical or legal comeback if they use a new technology or product even if they feel it is the greatest product ever! They are very unlikely to risk their registration on a promise…

When it comes to reimbursement, again the watchword is variability. The image below, reproduced by kind permission of Mattias Kyhlstedt, CEO of Synergus, shows the diversity across a number of European countries. It is sensible to think of strategies relating to the relevant markets when considering which countries you wish to launch your company/product in.




Though a CE mark can be granted on the basis of less clinical data than is required for FDA approval (and is therefore normally substantially quicker), European standards for reimbursement are normally the same or higher than those of the FDA. European countries can require additional data on the device's safety and effectiveness, as well as on cost-effectiveness, and each country has to decide individually on matters of reimbursement. There are also varying local regulatory requirements, e.g. labelling.

With the French system, reimbursement decisions are made by centralized body only after assessing the safety and effectiveness of individual devices. Reimbursement decisions in Italy are devolved to the various regions, and in the UK and Germany broader assessments of device types or procedures are conducted, rather than of individual devices.

We will not go into granular detail on all the requisite regulatory idiosyncrasies for every market across Europe so for the sake of time we will reference some of the U.K.'s processes as examples.

Another point of note is that the U.K.'s regulatory processes are fairly rigorous and still well respected across the EU, so in the past if you were to crack the U.K. you will most likely have done most of the hard yards towards cracking other large EU markets too, with some not insignificant modifications. This may of course change with the uncertainties produced by Britain's withdrawal from the EU.

Typically in the U.K. the National Institute of Health and Clinical Excellence (NICE) will usually need to have some endorsement in place before any mainstream HCP will even consider touching your product, particularly if it's is an implantable device.

The added complexity here is that NICE adds is one of cost effectiveness as well as the 'given' of clinical efficacy, but we are getting ahead of ourselves here. We'll come back to cost effectiveness shortly.

To start, you need to understand that any NICE endorsement or 'guidance' is an advisory state and not a mandatory instruction to HCP's, but without their endorsement any new treatment product or technology faces a tortuous route to market. It is not impossible to proceed without NICE but it can be rather complex to make progress without engaging them and should you get some modest traction on adoption in the meantime you will inevitably come face to face with NICE at some point. Invariably, the first thing a UK HCP will ask you will be is "What does NICE say about your product?"

Better for you to choose the time and date of your meeting with NICE rather than the other way around...

Navigating your product or technology through this maze can be complex but it is quite methodical. It's also mandatory for any procedure of an interventional nature. Just when you choose to engage NICE (or NICE chooses to engage you!) could be open to a little latitude, but in any case, it's just like Christmas; you know it's coming so you may as well plan for it.

In engaging the Interventional Procedures (IP) Advisory Committee you will unquestionably need a robust form of clinical programme or evaluation in place before; preferably a randomized controlled trial (RCT) of sufficient power with a follow up most likely in excess of 6 months. This is where your well connected KOL can show their worth in advising on sufficiently pragmatic and robust clinical programme designs that will meet or exceed NICE's current exacting criteria. Their political weight may also help you understand the process and define a reasonable timetable of events for you to plan your activities and investments. around.

### Why will your study need a follow up in 6 months or more?

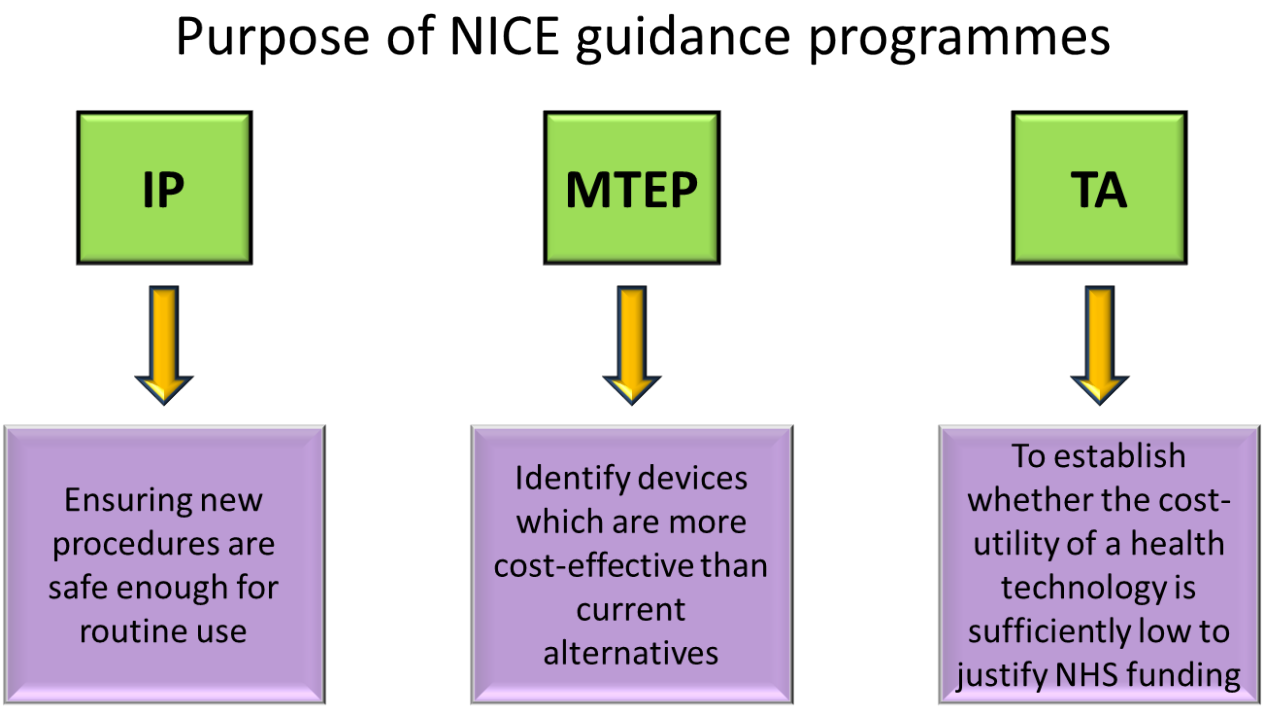
You can choose to have any length of follow up that you like but in our experience, if you engage the Interventional Procedures (IP) Advisory Committee you will need a longer rather than shorter follow up time because IP have the option to award your interventional technology with one of four outcomes.

These will affect quite substantially how quickly you can get to commercialize your product. We will therefore concisely outline these outcomes:

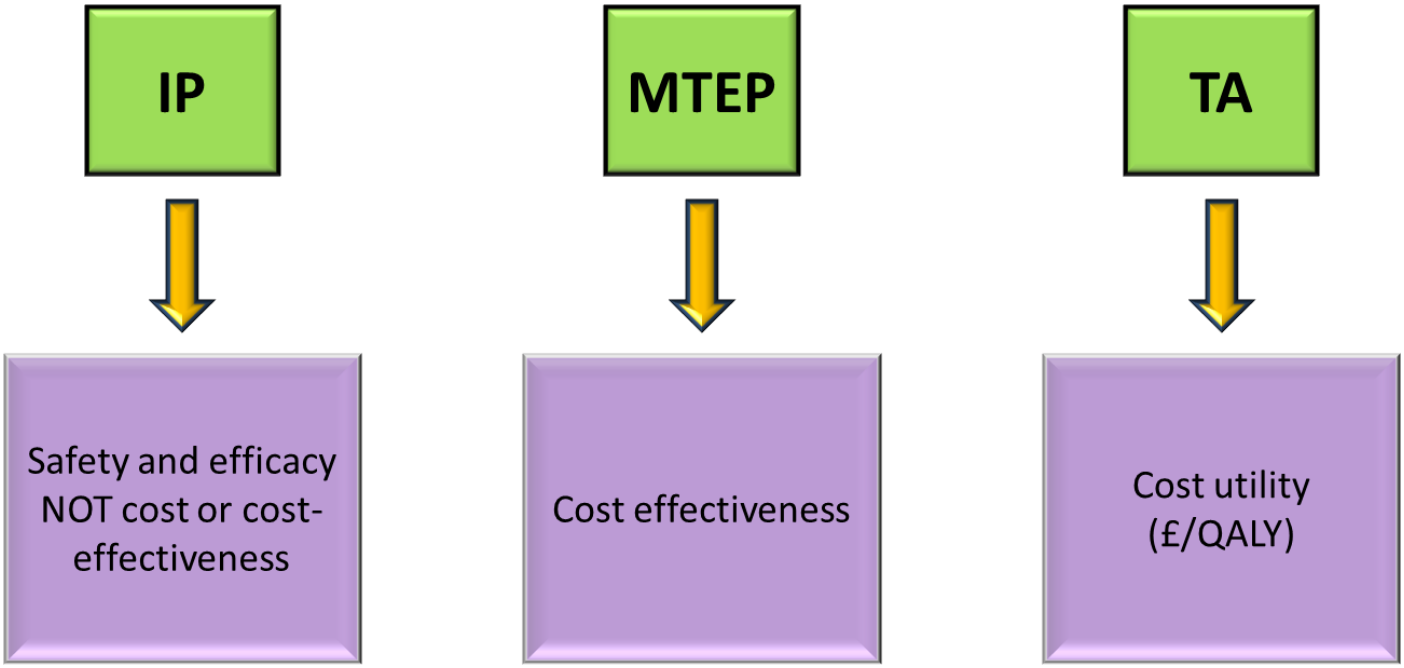
1. Normal Use: As this implies, everyone is open to undertake the product and procedure freely.
    - A Normal Use award is very rare.
2. Special Measures: This means that anyone can undertake the product and procedure but must do so with caution as the data so far is limited.
    - This requires a solid body of clinical evidence , and again this is not a common award. However, you can commercialize under this award.
3. Research Only: This means the procedure can only be undertaken under the auspices of a clinical study
    - A Research Only award is what you will get if your data set is light and you can then only move forward on a non-commercial basis, i.e. as part of a study.
4. Do not use: This means the procedure is patently unsafe
    - This "award" means you're toast!

The graphics below and on the next pages describe a general outline to the relevant processes for new technologies intent on entering the UK market. It's likely that only IP and MTEP will be on the immediate horizon for you. It's also fair to say that, again, this process is worth a chapter of detail in its own right. The acronyms are as follows:

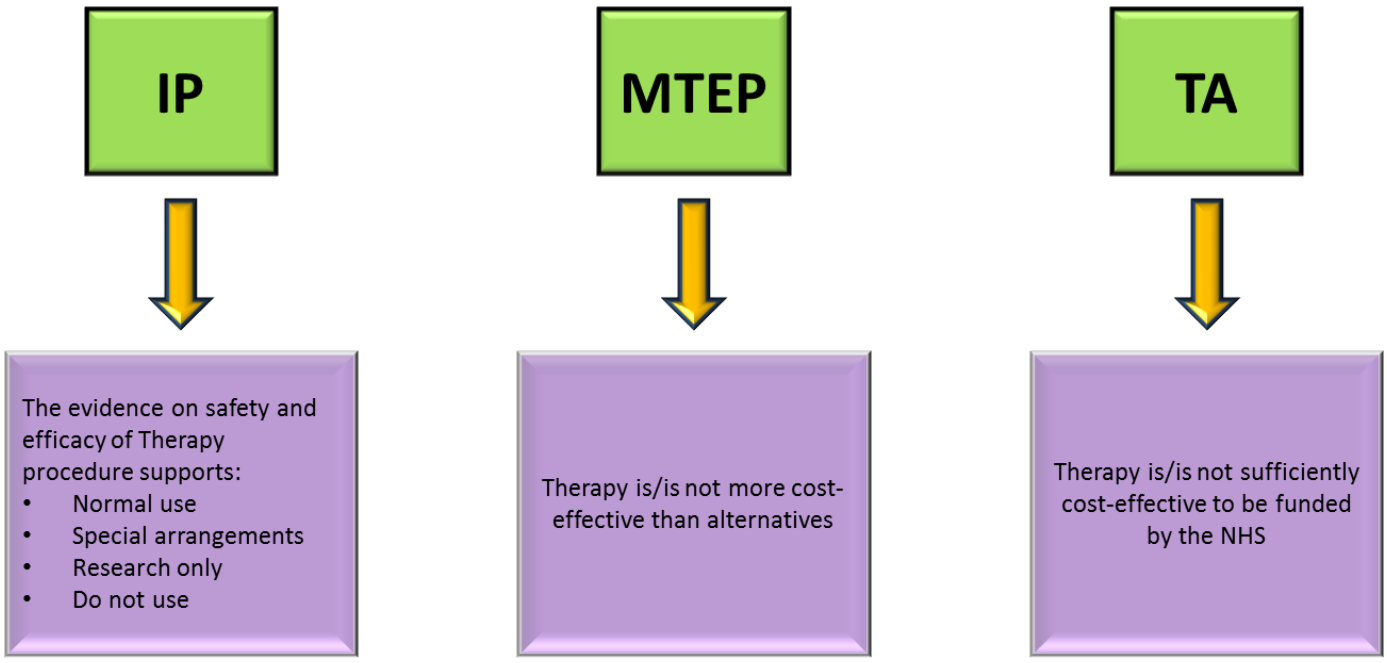
**IP:** Interventional Procedures Advisory Committee, **MTEP:** Medical Technology Evaluation Programme, **TA:** Technology Appraisal.



# What outcomes NICE guidance programmes look at




# Type of guidance produced




**IP: I**nterventional Procedures Advisory Committee, **MTEP:** Medical Technology Evaluation Programme, **TA:** Technology Appraisal.

# NICE guidance programme—implications for reimbursement

**IP**

i. Normal and special arrangements – safe enough to be funded but no statement as to whether procedure should be funded
ii. Research only = no mainstream NHS funding
iii. Do not use = no market

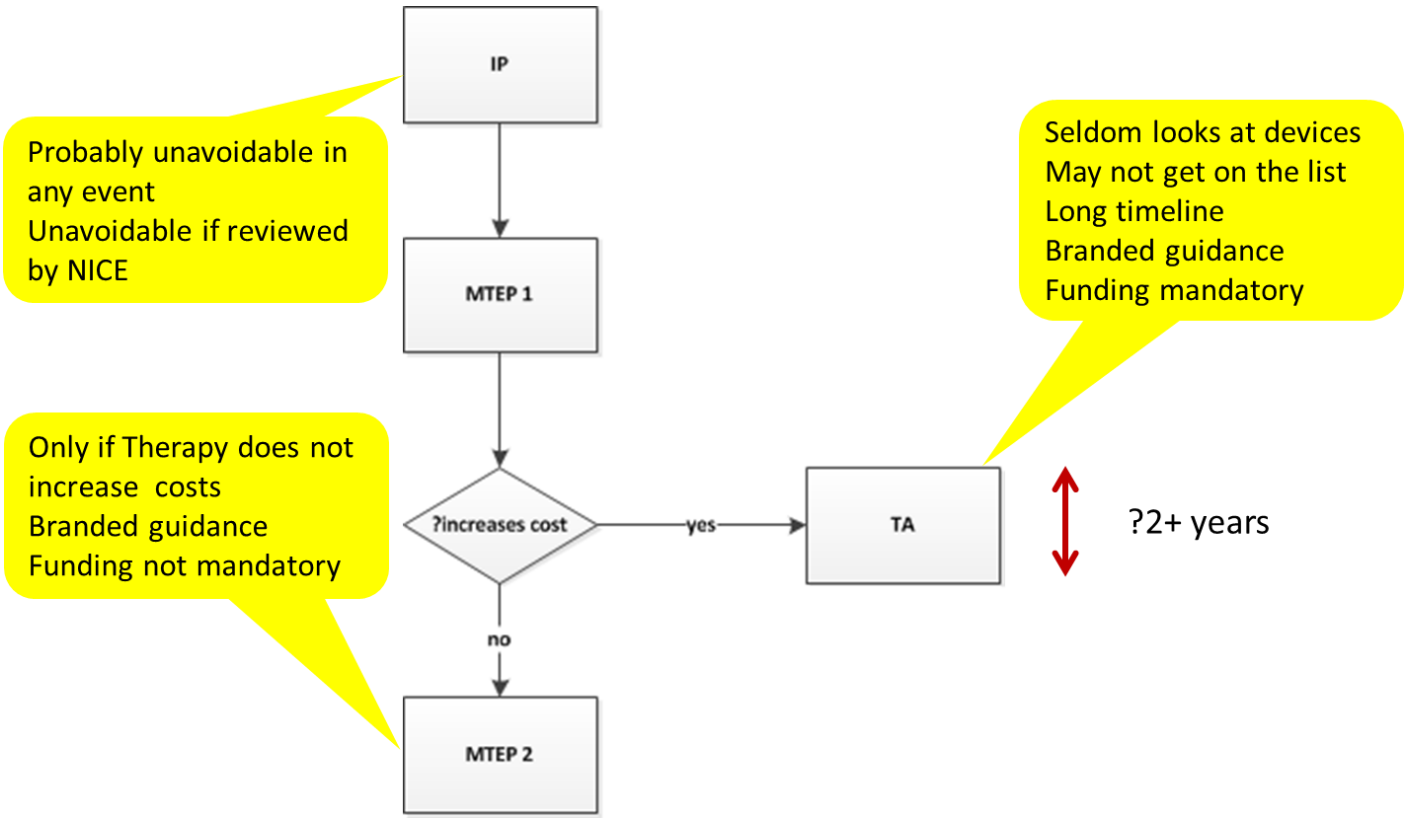
**MTEP**

If more cost-effective than alternatives strong incentive to use but not mandatory
If less cost-effective than alternatives, strong disincentive to fund

**TA**

If cost utility below threshold, funding mandatory
If cost utility above threshold, recommended that health technology is not funded

# Likely pathway for Therapy



# GETTING PAID

How are you going to get paid? Each existing procedure, therapy or treatment needs to be paid for. Someone somewhere holds a budget for this. In the UK the payers are the Clinical Commissioning Groups (CCGs).

The CCG sets up contracts with hospitals in their catchment area to provide a variety of services and treatments for a set price. These therapies are coded with a Hospital Resource Group code (HRGs).

Once the hospital treats a patient they will back charge the CCG with relevant treatment codes and the CCG will reimburse the hospital accordingly.

So how does the new market entrant manage to get a hospital to pay for a treatment that is not coded? In short, not that easily.

In any case, a CCG will not consider funding even the most disruptive, most cost effective and most efficacious therapy or treatment if it hasn't been through the initial NICE processes. Even if the therapy or treatment whizzed through these NICE assessments with flying colours, there is still no obligation for any CCG to pay unless a full Therapy Assessment has been undertaken and positive guidance issued. This is rare and even then you will have to compete with the existing and established gold standard of care. It's also worth remembering that a healthcare commissioners worst nightmare is a new treatment that meets an unmet need and for which there is no budget!

So this brings us back to the relevance of clinical programmes which include a concomitant health economic/ materials cost arm designed into the study.

If your therapy or product shows efficacy and you can demonstrate reasonable cost effectiveness or equivalence versus the established gold standard you may be able to influence some commercial activity locally under the radar, and even in advance of any NICE process, provided that you can show and demonstrate tangibly cost savings immediately or downstream.

If you can show a small series of treatments with positive clinical outcomes, some theoretical cost equivalence or cost effectiveness which your KOL can talk about with confidence, you have a very good springboard for generating a positive proposition with people that hold the purse strings. This is not easy to do but it is doable and takes a particular strategy rather than transactional approach in establishing your clinical proposition.

Just a footnote on designing any study to include a health economic assessment: Although this may add to the cost of any initial clinical assessment it will invariably save time and money in the long run as a consequence of capturing this data from the outset. Once you manage to convince an institution qualitatively that your product or procedure can affect savings you will need to prove it quantitatively. Many evaluations or service provision programmes are increasingly being audited by commissioning management groups. If you can't deliver on your proposition and meet established fiscal KPIs for your evaluation, following audit, you will most likely be shut down.

Getting heard above the noise created by the big corporates may be a challenge. If you are positioning yourself as a niche player this may be easier. If not you may wish to consider whether you wish to occupy some initial niches where you may be heard.

The power of P.R. can help here so local connections with a suitably well connected P.R. professional are worth developing. Good news buzz for your technology bodes well for overcoming the next barrier to entry.

Do check that your PR advisors are up to date on the latest practices and techniques of ethical electronic persuasion; that they really do understand the power of digital marketing and its potential to produce great impact at minimal cost. This is a developing field and while you need to be aware of some of the regulatory challenges of online promotion, e-marketing has great potential for small and medium sized companies.

Patient Groups and Patient Advocacy Groups can also be a valuable ally in softening the local barriers to entry and a strand of any investment should be apportioned towards these 'soft' pressure groups. Patient's problems and solutions are emotive and persuasive.

Many of these strategies are all equally applicable for entry into Germany, Holland, The Nordics, Italy and Spain. Less so for Belgium and France, both which require more formal government engagement for both efficacy and cost effectiveness. Higher political connections are clearly more important in accessing these two markets, so either ensure you have them on hand or be prepared for your entry into these markets to take longer.

## SELLING IN EUROPE: POSSIBLE ROUTES TO MARKET

The choice of channels to market are pretty straightforward:

- Direct sales channel (a fully employed sales force)
- Distributor/agent channel. Either multi-country or by country or by region
- Mixed channel model

So how does one choose?

Distributor model: The most common solution for most non-European companies is to work with distributors. This can give immediate impact, and often smaller companies will benefit not just from the increased sales but also the potential increase in shareholder value driven by the perception of the acceptance of the technology in a new market.

So, what are the pitfalls?

Well, many are common to using distributors anywhere in the world. Firstly, and obviously, are they the right partner? The wrong one can be a very expensive and disappointing mistake! Recruiting a distributor is not that unlike recruiting an employee in the sense that you should look at their capabilities, their attitude and approach and their willingness to invest and adapt their processes to meet (within reason) your needs. Once you have something of a shortlist of distributors, reference like crazy! Ideally speak to customers and other non-competitive companies that have used them previously. Ask them how they would sell and promote the product. Agree a system of targets and non-micro-managed performance monitoring, but remember they are not employees but business partners.

Most of all ensure that from the outset you have a legally enforceable agreement that works for you. Many clients have told us horror stories of attempting to extricate themselves from poorly drafted distributor agreements. The cost of a poorly drafted legal agreement is save now – pay later – big time!

Most clients we have spoken to strongly recommend a directly employed or interim distributor manager on the ground in Europe, NOT back in the US, China or Japan.

## SELLING IN EUROPE: POSSIBLE ROUTES TO MARKET CONT...

The benefits are that they are in (mainly) the same time zone, they will have a better cultural awareness, knowledge of the variabilities in the markets, and often they will be able to drive sales in their home nation (e.g. Germany, UK, France etc.) This is a more specialised hire than one might consider on the face of it. It's not a case of simply finding a good seller. Such a hire usually needs a strong sales mind-set but they need much more.

To mention just a few attributes: tact, diplomacy, cultural awareness, strategic and tactical marketing, coaching, people- management and mentoring. They need the ability to work at a high level on a business to business basis with a distributor, but also lead the technical proposition at the user end. A good distributor manager is invaluable and invariably the good ones are fairly scarce.

Variability: There are great differences from country to country in Europe for distributor models. For many product areas there are many distributors that are only interested in a region of their country, Italy is very common for this. Indeed, in Italy it is very common for companies to employ self-employed agents who may represent a number of companies. Spain, on the other hand tends to have very large distributors with very large sales forces and large portfolios of products. We are told this is mainly as the Spanish state healthcare system has very long payment terms that make it very difficult to thrive for smaller independent distributors that are common in other parts, such as the UK.

**Direct Sales Force Model:** An expensive investment, but if you have the resources to go for it, it may prove a good one. Without wishing to disrespect the professionalism of distributor sales people, many of whom are excellent, it is accepted by most in the industry that on average, direct sales force employees have greater perceived expertise and professionalism than their distributor equivalents in Europe. This is possibly because direct sales people prefer the specialism that one may have when working for a company direct. This is one of the reasons companies may prefer direct sales people. Additionally it may be argued that direct employees are easy to, well, direct! Management and reporting, *should* be more straightforward.

**Mixed Channel Model:** As it infers, partly direct sales people, partly distributors or agents. Some of our client companies have started a direct sales force in one country and had distributors in others. Others may have a network of distributor managers across Europe to help drive the sales.

**European Entity:** If you wish to have employees in Europe you will need to set up a European legal entity, preferably in the country of residence of the employee. Be aware of the variability in tax and labor laws in relation to this decision that are discussed later.

**Logistics:** Check your margins can support which ever sales channel model you follow. If you are US based your costs of transport etc. may be relatively low for your domestic market and you may be competitive with the large players at your current pricing. When you also add in the margin required by a distributor, or have to respond to a local market's demand for consignment stock what then?

**Conclusions?** OK, so we have the CE mark, all we need is the distributors yes? Well, you could, but maybe consider a few more things…..

## VARIABILITY OF LABO(U)R LAWS

**Labor law** (or labour law as we spell it in the UK!) is a particularly thorny issue for any company wishing to start a business or launch a product in Europe.

Many US companies that we have spoken to have made decisions on hiring and the expansion of their business that have been heavily influenced by the labor laws of the individual European country. Such laws are constantly changing and it is highly advisable that proper legal advice is taken in the country of employment from an employment specialist before hiring anyone. We understand that US employment contacts are not admissible in most if not all the jurisdictions of Europe, making any agreement to non-compete and non-solicitation clauses potentially toothless.

### Employment at will? Nope – sorry!

In the US, the principle of "employment at will" is so well accepted that it can come as a shock to a US company that they cannot easily dismiss an underperforming employee. Some countries, such as the UK and Switzerland and to some extent Germany have processes that enable you to dismiss underperforming staff provided that the prescribed process is thoroughly carried out. In France, and the Netherlands, for example, it is very much harder. Additionally it should be noted that laws governing sick leave, parental leave and vacation generally are much more liberal/generous in Europe, and it is necessary to understand this to compete for the best people. Again it is strongly advised that good local advice is followed.

## VARIABILITY OF TAXATION REGIMES

The two main areas of taxation that impact on a business in Europe are corporation/company tax and employee payroll tax. Additionally it is good to consider the impact of other taxes on cost of living and the inflationary effect that high personal/income tax has on wage inflation.

Payroll taxes are justified by European governments as a way of paying for social costs. The variation is vast between countries. Essentially it means the on-cost of employing someone can be massively different between different countries. Payroll taxes in Sweden are the highest in Europe at 48% (France close behind at 47%), and lowest at 9% in Malta! The median in the EU+UK is 31%, but countries such as UK, Ireland and Denmark are all under 20%.

Additionally, anecdotally we know that there is now quite considerable variation in wages across Europe. At the time of writing a salesperson in Switzerland (not part of EU, but in the single market), can have a salary twice that of a salesperson selling the same product in Italy or Spain. Therefore the impact on cost of where you hire people may be considerable, particularly if it is amplified by payroll taxes. This will also need to be balanced against corporation taxes if profits are to be taken in Europe.

The difficulty with respect to payroll taxes, and similarly with the discussion on labor law, is that when employing people in the EU and UK it is really best to go for talent where the talent is. Sometimes that may mean the on-cost is considerably higher, but if that person is going to generate an extra $xM, what then? Corporation Taxes: Again there is considerable variation when it comes to corporation tax

*Please note this information is largely illustrative of variation, and was believed to be accurate at time of the first edition of this e-book and may have subsequently changed. For detailed advice check with a local advisor*.

1. Malta, 35

2. Luxembourg, 29.22

3. France, 28

4/5/6/7.Belgium, 25 /Austria / Netherlands / Spain, 25

8/9. Italy, 24 /Greece, 24

10. Denmark, 22/

11. Sweden, 21.4

12/13. Portugal, 21 / Slovakia, 21

14/15/16. Finland, 20 /Estonia, 20 /Latvia, 20

17/18/19/20. Britain, 19 / Czech Republic, 19 / Slovenia, 19 / Poland, 19

21. Croatia, 18

22. Romania, 16

23/24. Germany, 15 / Lithuania, 15

25/26. Cyprus / Ireland 12.5

27. Bulgaria, 10

28. Hungary, 9

(expressed as percentages, highest to lowest)

## LANGUAGE & CULTURE

The culture, language, and history of Europe is colourful and diverse. Understanding these complexities will greatly aid your ability to make impact in your launch.

**Language complexities.** The "international language" of healthcare is English. This is helpful for US companies, and also Chinese and Japanese. It is also true that many, if not most clinicians speak English. However, it is often considered wise that if you have distributor managers it is helpful, if not essential for them to speak other European languages dependent upon where your main centres of business are.

In the authors' experience, the Nordic countries and the Netherlands are very happy doing business in English. It is sometimes joked that many people in these countries speak better English than the English! These countries are very international in their outlook and it is our opinion that doing business in English will have very few disadvantages.

In Germany, most professionals speak excellent English, though it is true to say that a native German speaker will understand the subtleties of the culture better, and if you decide that this is going to be your most productive market then it may be advisable to have a native speaker or someone who speaks German fluently.

In Spain and Italy the average standard of English may be described as more challenging than northern Europe. Most distributors and senior people will speak reasonable and often very good English. This may need to be a factor in your choice of distributor.

If you are considering France as a major market we would strongly recommend a fluent French speaker in your team. English is quite widely spoken in France, but it is our experience that doing business in France. is severely impaired by not speaking French.

**The culture** of Europe is, as previously mentioned, diverse. This is also reflected in business practice. Understanding the subtleties of culture may make the difference between success and failure anywhere in the world. This is no less so in Europe.

Some countries have a more formal approach to business communication (Germany for example), some more relaxed (Italy). Similarly timeliness has a high value in Northern European countries, but less so in Southern Europe. In many countries meetings are rarely conducted before 10:00AM or after 3:00PM. This may be important to understand from your "person on the ground" if you think a breakfast meeting is a good idea!

The essential approach is one that most international people take; do not assume the cultural norms of your country will always play out in another country. That said, the universal principles of honesty, respect and humility play well with most people wherever they are, do they not?

How many of you who have worked in large corporations have heard the phrase "people are our greatest asset", only then to see practices that contradict the statement? The people you choose to assist you with your launch are absolutely mission critical. Whether these are advisors, distributors or employees it is essential that you engage the very best. Experienced people have told us stories of "slap-dash" recruitment processes that have resulted in serious damage to the business.

## AVOIDING MISTAKES IN RECRUITING YOUR TEAM

You really must have people on the ground. They might be permanent staff, or they might be interim, but essentially they need to be accountable to YOU!

A number of CEOs have told us they tried to run distributors in Europe without anyone directly representing them and they have all said that it did not work well. There may be a few exceptions, but the consensus seems to be that if you are serious about selling your product in Europe, you need at least one person there to run the distributors, preferably more than one, if not a team.

Where there are highly technical products it makes sense to have a team of applications specialists/ customer training managers and/or service engineers to ensure the customer is properly using the product. If the product is improperly supported this could cause lasting damage to your product and brand, that will not only cause long term damage in Europe, but could also leak back to your domestic market.

### Where do you start then?

First, decide what sort of person you want to represent you in Europe? It is far better to do this dispassionately and objectively rather than fit a role around a person whom you happen to know. Ask yourself what sort of person works well in your company in the domestic market. This may provide a template, with the caveat that it may be that you decide that when taking into account cultural and market conditions it needs to be someone quite different from anyone you have currently. The following areas may help:

- **Company cultural fit**— This person(s) is/are working remotely from the main company, and therefore it is even more important that they accurately represent the values and professionalism that you represent in your home market. They need to "get" what you as a company are about, and be thoroughly aligned.
- **Attitude**— Every company says it wants someone who is self-motivated (is there any other type of motivation?!), but the truth is you want someone that is really excited about taking your job. Before they take the job they need to really be able to articulate to you what it is about your opportunity that interests them. However, beware that this may not happen on the first meeting! Germans, in particular, can be somewhat circumspect until they are convinced it is right for them. This should not put you off, and is a great example of understanding the culture of the markets in which you are operating.
- **Experience**—Determine what experience is important. In the opinion of the authors, attitude should outweigh experience every time, but there will be certain experience such as market knowledge that will ensure your launch is successful. The caution here is not to be blinded to the previously mentioned factors just because someone has great experience in your sector. No experience can really make up for poor attitudes!

Now you know what you need, what next? Answer; choose a really good aligned recruiter. Yes, one of the authors of this guide is a recruiter of many years experience, but vested interest is not the reason this is advised. It is what our clients have experienced. Yes a bad recruiter can be as bad, or worse, than no recruiter, but a good one will ensure that you have choice of the best talent on offer.

Also it is also advisable for you to ask any potential recruiter to sell you the role as they see it. Tell them you would like to speak to them tomorrow at a certain time and you would like them to sell you the job as though you were an applicant. If they cannot or will not do this do not use them! You need to be sure that when they (or any of their colleagues) speak to a candidate they have the best chance of securing that candidate's interest. They will need to keep selling your role to the candidate right the way through the process, including offer evaluation. If they are not good at what they do they will lose you the best candidates to your competitors. We will shortly be publishing a paper called *'12 questions you should ask before engaging a recruiter'*, which should help you choose the right one.

Competition for good people is fierce anywhere, but particularly so in Europe. If you genuinely want the best you will not waste time or valuable resources on trying to do this yourself or trying to find the cheapest recruiter. We know lots of cheap recruiters – they are all useless, and that is why they are cheap! If you value your business you do not use cheap lawyers, patent attorneys or accountants.

Definitely do not use "cheap and easy" recruitment solutions – you will invariably pay a heavy price.

# SUMMARY - DO'S & DON'TS

## Do

- **Go for it! Europe is a potentially very lucrative market for you. If your product is good in your domestic market it stands a good chance of working in Europe.**
- **Plan your route to market and vigorously test your assumptions. If you use distributors have a thorough vetting procedure in place for their selection.**
- **Understand the varying healthcare systems across Europe and how that impacts reimbursement, and understand the reimbursement challenges for your product type in each country.**
- **Understand the variability in labor law and tax and how this will impact the business.**
- **Get real about potential localized barriers to entry and figure how you can navigate these and set targets that take these into account.**
- **Get the very best of advisors. Cheap ones will damage your credibility and business.**
- **Be relentless in your pursuit of the best talent to run your European business.**

## Don't

- **Ignore any of the advice above and hope you will just get lucky!**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Nigel founded **Remtec Talent Management Ltd** in May 1998, with an objective to provide the very highest level of specialist recruiting services to the Life Sciences and Medical Technology industries. Prior to founding Remtec, Nigel held a variety of roles (Clinical Applications, Sales, and Marketing Management) within the Life Science and Medical Device industries (Sarstedt, Medtronic, Caledonian Medical/Angeion).

Since founding Remtec, Nigel has assisted many companies large and small with the acquisition of "mission critical" talent. He is particularly interested in the challenges companies have with product launches into Europe and has had numerous conversations with clients about those challenges and this was the inspiration for the publication of this e-book guide.

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Claude has around 35+ years experience in Healthcare and well over 30 years in a business capacity.

He has held a variety of positions for a number of Blue Chip Healthcare companies including Baxter International, Guidant Corporation and St Jude Medical. His experience is wide-ranging and covers a number of roles in Sales and Marketing , Export Sales and Sales Effectiveness all of which were held at either operational, management, strategic or executive level. Claude founded Sospiro Associates Limited in 2012 as a boutique management consultancy, using his broad skillset to help small and medium sized companies manage and navigate the complexities of market entry and business development in an ever changing landscape.

During this time Claude has worked with a number of companies across numerous therapeutic areas including Oncology, Venous Vascular, Respiratory , Therapeutic Hypothermia, Nutrition, Wound Healing, Aesthetics, General Surgery , Medical Robotics as well as in his chosen areas of speciality, Cardio-Pulmonary, Structural Heart and Interventional Cardiology. In his spare time Claude likes to cook, he takes an active interest in health, fitness and nutrition and is currently in-training for a number of Triathlons and maybe the occasional marathon.

# DICTIONARY OF ACRONYMS

| | |
|---|---|
| CCGs | Clinical Commissioning Group |
| CE Mark | Conformité Européenne |
| FDA | Food and Drug Administration |
| GDP | Gross Domestic Product |
| HCP | Healthcare Professional |
| HRGs | Hospital Resource Groups |
| IP | Interventional Procedures |
| KOL | Key Opinion Leaders |
| MDR | Medical Device Regulation |
| MTEP | Medical Technology and Evaluation programme |
| NICE | National Institute of Health and Clinical Excellence |
| RCT | Randomised Control Trial |
| TA | Technology Appraisal |

## *What our readers have to say about this guide:*

*"I enjoyed reading it as it provides a great recap of the hurdles and to do's when entering Europe, we live in such a diverse ' European union' and that is what makes Europe exciting too... Having worked for the past 20 years in EMEA in Medical Devices, I relate very much to the topics covered in your book."*

*"The company who wants to enter in Europe need first to understand how to organize their strategy in regards about what you are describing. Any company who wants to launch a medical device should read your guide."*

*"Very interesting and insightful reading for me, sure we will gain from it when we start moving in that direction."*


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