

PAN-EUROPEAN SPECIALTY PHARMA BUSINESSES



PERFECTING
YOUR GAME
FOR SUCCESS
IN EUROPE

“Of all the hazards, fear is the worst.”

Sam Snead

Introduction letter from the authors

Since 1979, the European Parliament has been elected every five years, most recently in May 2014. The 751 Members of Parliament represent more than 500 million citizens in 28 member states. The largest country – Germany – has 96 representatives for a population of more than 80 million, while the smallest – Estonia, Cyprus, Luxembourg and Malta – each have 6 seats for their populations of between 0.5–1.3 million inhabitants. The elected politicians are generally well-known and it is relatively straightforward to identify and reach out to them.

After adoption of the ‘Orphan Regulation’ by the European Parliament on December 16, 1999, biopharma companies can submit applications for orphan designation to the European Medicines Agency (EMA). In order to qualify, a medicine must be intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating with prevalence in the EU of not more than 5 in 10,000. Hence, orphan drugs can address up to 250,000 patients across Europe.

In some cases though, there may be between only 5 to 100 patients per country – which across all of Europe would roughly equate to the number of Members of the European Parliament! Imagine you have the daunting task of identifying these patients – this is when the limitations of traditional affiliate-based organizations are exposed. To use a golfing analogy, companies have too often been hitting the ball without really knowing where the putting green is.

Recently we have seen the creation of hybrid organizational models, where a number of large pharma and smaller biotechs have successfully pioneered pan-European specialty pharma businesses, enabling them to map out their course and pitch directly towards it.

This report summarizes our experience as pioneers of pan-European specialty niche organizations, starting in the year 2000. To continue the golfing analogy, we will outline the importance of knowing the history of the game to learn future strategy, how to plan the perfect round, preparing the organizational set-up and approach, and exploring what it takes to deliver success when you step up to the first tee, including the ‘perfect shot’ of customer-centric and borderless organizations. During our work, we have been confronted with traditional beliefs about the pharma business in Europe which turned-out to be misconceptions, and we have summarized these at the end in “Achieving the perfect round: A European story in 9 holes”

We are convinced our clients are now faced with many specialty pharma products that are best addressed by pan-European, customer-driven biopharma businesses, which can result in ‘big tournament wins’ commercially. The legendary 1930s golfer Tommy Armour said: “Every golfer scores better when he learns his capabilities.” This is also true for successful biopharma entrepreneurs in Europe.

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The history of the game

Good golfers know about the history of the game; they need to know what has gone before to be able to prepare for future success. The analogy also applies in our industry.

The European pharmaceutical specialty business is now driven by regulations implemented by the European Medicines Agency, and clinical guidelines established by European Medical Societies. But it was not always like this.



Surveying the course

There was a time where regulatory process, promotional regulations and therapeutic guidelines were organized on a national basis. During the last 20 years, the EU has increasingly centralized and harmonized regulatory procedures and promotional practices; even access and reimbursement processes are interdependent and increasingly similar.

While the processes vary across the EU, the standard set by the UK's National Institute for Health and Care Excellence (NICE) 15 years ago, and the reference pricing system have reduced the variability of reimbursement process outcomes across Europe. The result: national processes have lost importance – as have national organizations.

Europe:
National
affiliates in
1990



Choosing the right clubs

In response to increasingly uniform regulations and more comparable pricing processes, national organizations did not add enough customer value to justify duplications; many pharmaceutical companies clustered their commercial outlet by language borders and some smaller markets were attributed 'opportunistically'.

In addition, clinical practice guidelines, opinion leader networks and scientific societies also function across borders. Smaller countries are often highly centralized and have significant sales potential due to the patient concentration in a few hospitals. For example, by adding Swiss and Austrian customers to the German list, only five of the latter remain in the top 10 centers. Indeed, the Vienna General Hospital in Austria has the most patients treated per annum of the German speaking hospitals, which should be reflected in trade-off decisions when it gets to resource allocation, **and the picture becomes even more telling when reviewing the European top 10 list.**

Europe:
Country cluster organization



Source:
Publically available
annual hospital reports
2012

German Location of Account (Nr beds)	Top 10 German (D) / Austrian (AT) / Swiss (CH)	Top 10 European
1. Berlin	1. Berlin D	1. Belgrade SER
2. Munich	2. Munich D	2. Berlin D
3. Stuttgart	3. Vienna AT	3. Helsinki FIN
4. Heidelberg	4. Stuttgart D	4. Oslo NOR
5. Hamburg	5. Heidelberg D	5. Prague CZ
6. Hannover	6. Geneva CH	6. Munich D
7. Leipzig	7. Innsbruck AT	7. Budapest HU
8. Münster	8. Graz AT	8. Vienna AT
9. Cologne	9. Hamburg D	9. Stockholm SWE
10. Freiburg	10. Klagenfurt AT	10. Rome ITA

Cluster organizations quickly learned that competence was more important than passport; and that national population was not predictive of account size and importance. An inverse correlation developed between clinical specialization and the need for national support organizations: the more specialized a business was, the more it benefited from a transnational set up.

PLANNING THE PERFECT ROUND



The question in terms of Europe is, are you playing a different course per country or selecting one strategy for the whole region? Where passports have traditionally driven European organizational design, the question could be asked: **“Why can’t Europe be run as one single organization led by patient potential per hospital?”**

There are many reasons why this could be the winning approach, especially in highly specialized competitive settings. The following tips could be valuable to playing the course perfectly.

Tip #1 Maximize product and disease competence not language competence

Cultural and demographic diversity within many European countries necessitate several languages to be spoken within each nation, e.g. Spain, Italy, Belgium, Switzerland, Finland and the Netherlands. Therefore passports do not always drive (language) competence, and a competent answer in English is better than a miscommunication in any other language, particularly if European guidelines drive national therapeutic recommendations in practically all hospital specialties.

While customer interactions always happen in local language, and English being the “Latin of our times” – why not take advantage of that, if it allows for expert up-skilling? EU statistics claim that 51% of all Europeans understand English; 95% of the hospital based physicians in Europe read English publications; and 90%+ of those under 55 speak English.

Tip #2 Win customers by putting the most competent resource in front of them

Efficacious and safe products will always be the foundation of success, and competent and excellent services bring the competitive edge. Customer services reach highest quality at an affordable cost only when orchestrated on a European level: it is more effective to have three highly competent collaborators focused on one therapeutic area than multiple “country resources” that have to work ‘part-time’ across several medical domains.

“Organize all customer facing functions on a European basis –we (your most influential customers) are already organized that way”

This is not only a constant plea from key opinion leaders all over Europe for dealing with multiple company representatives on different levels, but it is also becoming an organizational imperative. If patients and doctors can reach insurers service hotline 24/7/365, then they can rightly expect the same level of communication from pharmaceutical companies too, which can only be efficiently organized on a transnational level.

Tip #3 Centralize based on disease, accounts and medical networks focus

European scientific societies set the tone for almost all national and regional therapeutic standards. The degree to which any organization will mirror the map of influence and patient potential will vary: an orphan drug will have a different approach than an injectable MRSA antibiotic or an oncology product. All have one common strategic goal: to serve European accounts best, ordered by number of patients per diagnosis and treatment, ensuring the biggest therapeutic and business impact.

CUSTOMER NEED	EUROPEAN	NATIONAL	REGIONAL / LOCAL
REIMBURSEMENT			
ACCESS TO BUDGET			
COMPETENT 24/365 MEDICAL INFO			
KEY OPINION LEADER MANAGEMENT			
CLINICAL TRIAL INVOLVEMENT			
COMPETENT SALES REPRESENTATION			

KEY MOST RELEVANT VERY RELEVANT RELEVANT

Tip #4

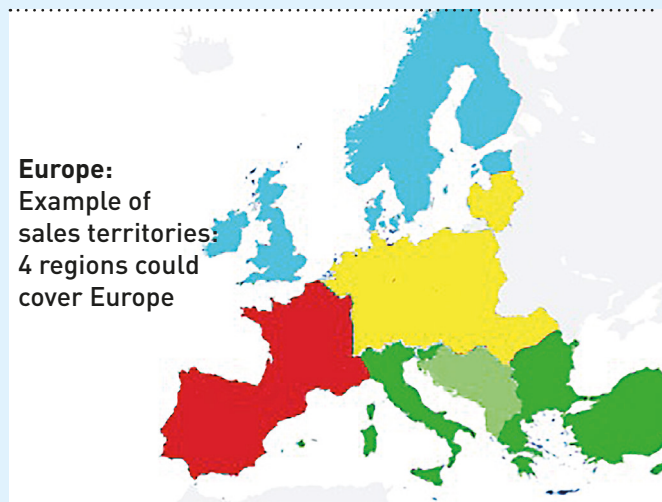
Get organized around customers, networks and competences

It's about therapeutic focus and customer proximity: the local representative must be trained and empowered to draw all organizational resources to the target (high potential) account to best present the product as the solution for the customer needs.

For example, the Aachen University Hospital in Germany will certainly be more effectively served if one understands the local network of referral not only within Düren, Germany but also within neighboring Maastricht in the Netherlands and Liège in Belgium. Why would the regional sales team not comprise German, Dutch and Belgian colleagues (all carrying a European Union passport already)?

The European sales territory of "Lower Rhine" may then encompass parts of North Rhine Westphalia, Limburg and (partially German speaking) Liège. Similar transnational teams may be found in the Savoya sales territory reaching from Torino to Geneva and Annecy, or in the Danube territory that reaches from Passau to Vienna. Not to mention the Nordic, Iberian or Eastern Europe areas.

Sales force reporting lines would then be to regional sales managers who implicitly invite to shared learning meetings at every sales reunion. Regional sales managers would report to a European sales head that evaluates and benchmarks best practices (and performances) across country borders. Most importantly, customer potential would automatically be determined on a European base, ensuring that investments and trade-offs follow a European target account logic rather than a country logic.



Tip #5

Start with the customer in mind – not the countries

Traditionally, biopharma companies have focused organizational set up on internal aspects, most often national organizations. Instead, we suggest initiating the build-up of pan-European specialty pharma businesses with a strong customer focus. A European customer target list will drive the design of a customer-facing organization based on competences. Then, it is the appropriate time to hire the European head and any regional competence teams reporting to that executive.

Traditional internal focus NATIONAL ORGANIZATIONS	Suggested customer focus PAN-EUROPEAN SPECIALTY PHARMA BUSINESS
1. Hire European Head	1. Establish European customer target list (including regulators and payers)
2. Hire big five country managers	2. Design customer-facing organization based on required competences (Who has what competence for which customer?)
3. Hire functional heads (mostly reporting to affiliate)	3. Hire European head
4. Hire national Key Account Managers / sales force reporting to affiliate	4. Hire regional competence team (Medical, MedInfo, Medical Liaison, KAM) reporting to European head

Biopharma companies establishing their presence for the first time, have a unique opportunity to optimize their legal, infrastructure and supply chain footprint from the very beginning. They have only one shot to make the right initial decisions on the legal set-up and other critical aspects. If done properly, they will successfully compete from the outset in the European pharmaceutical specialty market with the most effective and efficient pan-European business model.

If you want to play the perfect round of golf, it is helpful to get as much advice as possible about the course you are playing.

STEPPING UP to the first tee



Big pharma companies and smaller biotechs have successfully implemented pan-European business models for highly specialized products and customer groups. Eli Lilly, Actelion, Serono and Correvio are some examples of these pioneers.

Structuring a European business model in an established company is a significant change management undertaking: it puts many common beliefs (from “only national organizations understand customer needs and regulations” to “French customers want French management”) into question. This structural inertia may be the main reason why examples of successful projects have often been with previously unprofitable “niche products”.

In any case, it is vital to gain buy-in throughout the organization. You must secure unwavering support from the top executives for the initiative, from the conception of the idea through the lifespan of the organization. In hybrid organizations, as is often the case with large biopharma, the company affiliates must understand that the approach is mutually beneficial, and must be brought onboard

with the plan early on. Once the centralized approach has reaped success and the products start returning a tidy profit, the affiliates become interested again, potentially causing a destabilizing effect.

As outlined before, effective pan-European models should be designed to reflect the limited number of patients and stakeholders involved, and to consider country boundaries as a less important factor. Not only is a pan-European model much more effective at targeting and serving the specific needs of small, highly specialized customer groups, it will do so at a dramatically reduced cost, capitalizing on the fact that the very small field force requires no local infrastructure, and eliminating all duplicitous efforts (see real-life case study below).

Real-life case - qualitative rationale

- Information circulates faster and is more homogeneous and consistent across larger geography, enhancing decision speed and quality
- Optimal leverage of dedicated and scalable resources and capabilities to be used where and when appropriate
- Adequate critical mass and focus for creating the expertise and services the customers need, with less resources and investments
- Application of the 80/20 rule over a larger geography optimizes return on investment, with differentiating angle, e.g. customers associations
- Centralized functions and processes bring the organization closer to its customers and enable fast adaptations based on feedback received

Real-life case - quantitative impact:

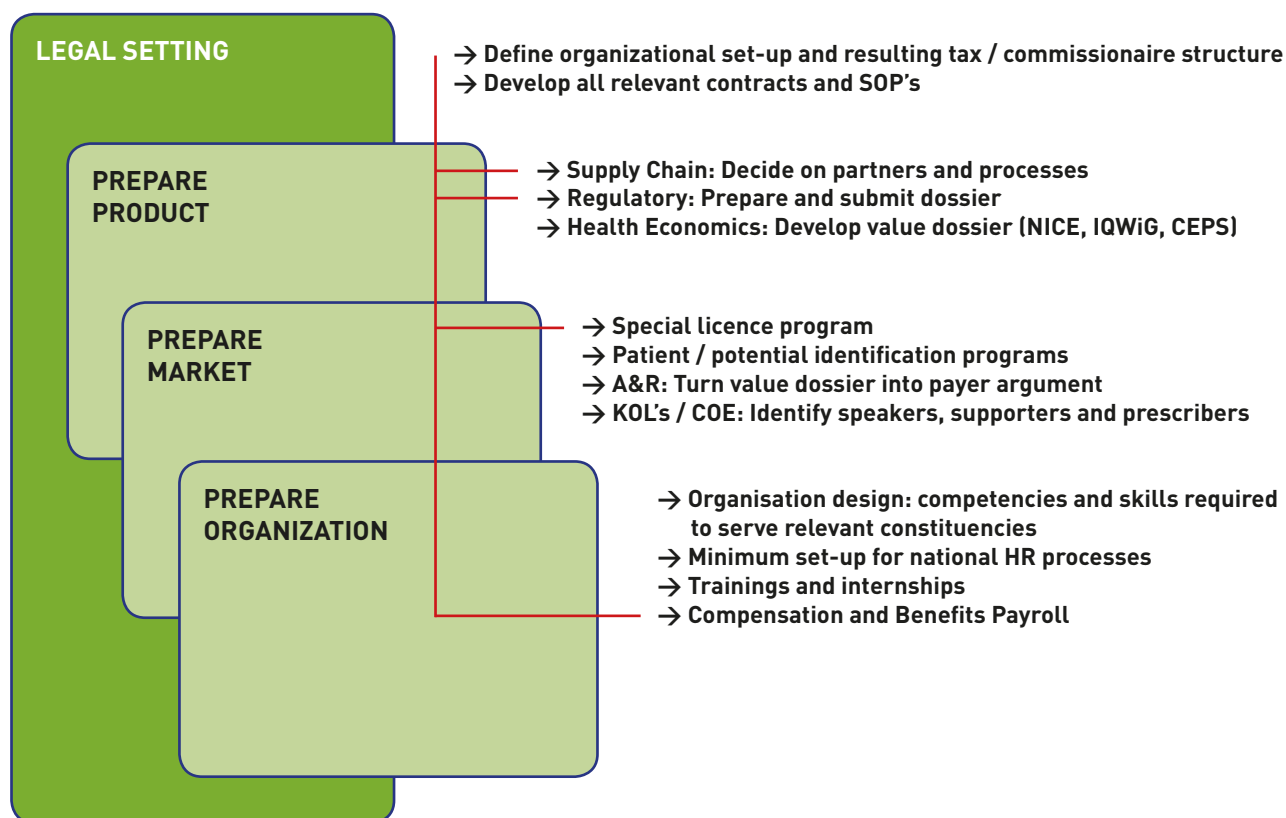
Pharma Business Unit undergoing business model transformation, results after 3 years post implementation

METRIC	DIRECTION	EXAMPLE %
Sales/Rep	↑	30%
Income/Rep	↑	40%
Opex/Sales	↓	15%
Opex/Sales Exp.	↑	40%
Sales/Marketing Exp.	↑	30%
Overall Headcount	↓	40%
Profit	↑	17%

Real-life case qualitative rationale and quantitative impact

The centralized approach integrates physicians across country borders, providing them with access to Europe's leading centers, facilitating education and best-practice sharing and improving patient outcomes. From the pharmaceutical company's perspective, it should develop stronger relationships with European-level KOLs, societies, payers, governing bodies and regulatory bodies. In addition, the organization can be up-scaled easily to take on new indications and new drugs for the same target group, thus introducing further efficiencies through economies of scale.

Start-up biotechs conquering Europe have to master an additional level of complexity. Before even being able to focus on product launch, they need to build their legal infrastructure, organizational set-up and resulting tax / commissionaire structure. SOPs reflecting relevant contracts can often be time-consuming, becoming a barrier



Interdependent processes when establishing European presence for the first time

The centralized pan-European model clearly seems to be the best option for commercializing narrow indication drugs to small specialized customer groups. From a business perspective, this model is likely to maximize profitability no matter how small the peak-sales expectations of the product, as outlined by Michael Stewart, Head of Actelion's Zavesca Global Business Unit (quoted from "How to commercialize Narrow-Indication Products", published in Pharma Magazine Nov/Dec 2012):

“We implemented a go-to-market model which allowed us to profitably commercialize a previously distressed product, achieve a four-fold increase in sales during the first three years after launch.”

ACHIEVING THE PERFECT ROUND: A EUROPEAN STORY IN 9 HOLES



*For 20 years, the European Union has had a unified regulatory approval process, with European medical societies setting the guidelines for treatment protocols from the North Sea to the black sea, from the North Cape to Cape Sunion... but still, pharmaceutical organizations continue to organize themselves as national or country cluster entities. **Here is a European story in 9 holes, uncovering misconceptions and revealing the reality to produce the perfect round.***

PAR FOR THE COURSE	BIRDIE OR BETTER
1. Regulatory process is uniform – but national markets are different	1. Regulatory process is uniform – all business is local
2. Access and reimbursement are national processes	2. Reimbursement is a national process in which 70% of all elements are uniform across Europe – Access is a regional or local process
3. Promotional rules are national	3. Promotional rules are uniform (in case of doubt: apply the French rules and you will be covered in all of EU)
4. National organizations know customer needs best	4. Competent organizations know customers' needs best
5. National organizations can make best trade-off decisions when it comes to resource allocation	5. A pan-European organization targeting European customers can make the best trade-off decisions
6. French customers want to interact with French pharma organizations	6. French (just as all other) customers want to interact with competent pharma organizations – they better speak the local language
7. Most European physicians do not speak English	7. (Almost) all hospital/specialty doctors read English publications. Quick and highest quality answers in English are more accepted than less competent answers in local language: A few countries will require local translation
8. National organizations can provide the highest quality service	8. Competent organizations can provide the highest quality service
9. Customer proximity requires a national (office) presence	9. Customer proximity requires local presence allowing local customers to access best company competence

Our European Ryder Cup team – authors and references

We have supported both large pharma organizations as well as start-up biotechs on pan-European specialty pharma businesses. In addition to facilitating fast decisions, we have also accelerated build-up and managed lean operations for our clients. Our consulting teams are led by biopharma executives with hands-on experience on the topic. The clients' desire for one-stop-shop solutions has triggered collaboration with complementary (services) partners, enabling us to address even the most complex issues such as supply chain/ logistics, Market Access and reimbursement and effective legal set up. As true Entrepreneurs, we partner with our clients for long-term success and believe as a team we can help our customers to plan and implement their European success strategy, following the advice of another legend of golf, Ben Hogan:

“Placing the ball in the right position for the next shot is eighty percent of winning golf.”

references (visit www.executiveinsight.ch/publications for download)

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