Spot the Difference

While Scandinavia as a region groups together Norway, Sweden, and Denmark, the three countries have very different rules and regulations when it comes to doing business

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What and where is Scandinavia? Locally, Scandinavia is defined as Norway, Sweden, and Denmark. If one includes Finland and Iceland, it becomes the Nordic region. All five countries have historical and cultural similarities due to their geographical location. However, Norway, Sweden, and Denmark have a strong history of unions and mutually intelligible languages, as well as close cultural ties.

These close ties enable these small countries to create synergies and operate within a bigger market. However, it has not always been plain sailing. Harmonisation within the region has not always been successful, with questions being raised about whether the differences between the countries have been fully considered. When doing business with other regions in the world, one should always be prepared for not only the social and cultural differences, but also the local laws and regulations. Problems tend to occur when they are assumed to all be the same.

Identifying Regional Differences

When combined, many other less formal differences add to the misconception of the Scandinavian region. Country stereotypes exist: Danish decision-making hierarchy, bacon production, love of bike riding, and rye bread. Sweden is known for its democracy, manufacturing the Volvo, its love of meatballs, and IKEA. Norway sits somewhere between the two on democratic rights and decision-making, but they are renowned for their cross-country skiing ability and Viking history. The Norwegians and Swedes are more obsessed with rules, whereas the Danes think these are more 'open to interpretation' (although hopefully not when it comes to pharmaceuticals).

With all these clearly identifiable differences, understanding why Scandinavia is still perceived as a single entity is difficult. This is certainly not reflected within the pharma industry. The countries which make up the area are part of different regional groups – Sweden and Denmark are part of the EU, whereas Norway is part of the European Economic Area. As a result, some variations exist between the local regulations and between the views of the regulatory agencies across the region. Despite the contrasts in their views, they cooperate across some areas. For instance, the medicines agencies across Scandinavia, as well as Finland and Iceland, have published a guideline on Nordic packages with FAQs and answers (1-2). The guideline sets out the differences and what the authorities have decided is possible with regard to common medicinal product packs with text in two or more local languages. For example, the Danish Medicines Agency does not always assess the package leaflet and labelling, mock-ups, or layout of the material components in connection with approval of a new application for a medicinal product or a change to a product with effect on the packaging material. Instead, they take random samples of packs on the Danish market and assess those for compliance with the regulation. On the other hand, in Sweden and Norway, for every new application for a new medicinal product or a change to a product with effect on the packaging material, the package material components are assessed and should be approved by the authority. On packages in Denmark and Norway that contain products affecting the ability to drive or use machines, a warning triangle on the outer packaging material component (eg, on the carton) should be present. However, this is not accepted in Sweden.

Over-the-counter (OTC) medicinal products are another example. Those suffering from a respiratory tract disorder with excessive or thickened mucus secretion may wish to use a drug containing acetylcysteine, which reduces the thickness of the mucus, making it easier to cough up. In Denmark, people can buy effervescent tablets containing acetylcysteine as an OTC product or even outside the pharmacies at some retailers. In Sweden, a prescription is needed to buy this medicine, and, in Norway, some of the products containing acetylcysteine are available as an OTC product, while others are prescription medicine. As can be seen, the variation in local regulations can have a major impact on the pathway and approach a company needs to take when thinking about their route to market.

Ethical Advertising

However, the differences do not stop there. Stringent rules are also in place regarding the advertising rules and marketing compliance required. The rules of advertising medicinal products to the general public and healthcare professionals (HCPs) are defined by law in all Scandinavian countries. Additionally, all countries have their own ethical

rules stating a number of minimum standards which must be complied with, alongside the applicable laws and regulations. The ethical rules are defined in collaboration between the pharma industry and the HCPs, details of which can be found in the Nordic Compliance overview (3).

Then, there are differences in the definition of certain terms when used in a particular circumstance. The term HCP, with respect to advertisements, is different in the Scandinavian countries. They are summarised in Table 1.

Packaging Compliance

Due to the rules of advertising differing for the HCP and the general public, being sure which of those segments the target group for advertising belongs to is essential, as this may differ between the Scandinavian countries.

Besides the differentiation with regard to the definition of HCPs, there are also differences in relation to the rules of advertising and sponsorship, for example, in terms of sponsorship of participation of HCPs in international congresses (travel expenses, registration fees, and hospitality). In Denmark, a pharma company may sponsor events and pay for the HCP's travel expenses, registration fee, and hospitality at international congresses, provided that certain conditions are met. In Sweden, pharma companies cannot pay for HCPs' travel or accommodation within Sweden or abroad. In Norway, financing participation, travel, or board for HCPs attending events abroad which have been organised by a third-party is not permitted.

The final difference highlighted is compulsory text, which is included in advertising material for medicinal products. As one can imagine, this is a minefield. There are variations regarding font size as well as content requirements. In all of the Scandinavian countries, advertising for medicinal products is required to contain some 'non-promotional' information about the product, referred to as 'compulsory text' or 'minimum information'. This information should be easily readable. In Sweden, the text must be a minimum font size of 7.5, while, in Denmark, point 6 is considered sufficient, and, in Norway, the font must simply be 'easily readable'. Since it has been established that there is no such thing as a 'Scandinavian', what are the fundamental points that organisations need to know to allow them to successfully navigate each regulatory framework? Each country within the Scandinavian region is unique, with their own customs, laws, and approaches. Therefore, knowledge is essential in making certain that the relevant and appropriate path is taken to secure regulatory approval and ensure compliance within the regulatory framework. The challenge that many pharma companies face is having access to the right knowledge and expertise. For large companies, this resource may exist internally via dedicated resources within local offices. However, for small to medium size

	Denmark	Norway	Sweden
Doctors/physicians	✓	✓	✓
Dentists	✓	✓	✓
Veterinarians	✓	✓	
Pharmacists	✓	✓	✓
Nurses	✓	✓	
Veterinary nurses	✓		
Pharmaconomists (Danish pharmacy technician)	✓		
Midwives	✓		
Bioanalysts	✓		
Clinical dieticians	✓		
Radiographers	✓		
Social and health workers	✓		
Students within the aforementioned professions	✓	✓	
Aqua medicine biologist		✓	
Other personnel with healthcare or distribution			✓

Table 1: The differences in the definition of HCP when used in a particular circumstance in advertisements across Scandinavian countries

"It is said to 'never assume,' and this should always be an organisation's mantra when approaching regulations across different country locations"


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companies, internal resources are often somewhat limited. Even if they do have an internal expert, their responsibilities may focus on other areas, leaving little time to provide advice on anything outside of their immediate responsibility.

This leaves companies in a quandary. How do they cover for the skills they need, but do not necessarily have, within their organisation? It makes sense to focus internal resources more effectively. Most staff are multiskilled, and, therefore, understanding their key strengths and ensuring they are able to channel these is crucial. Aligning staff skills and expertise with the overall organisational business plan is also essential. This may mean one's internal resource focusses on core business while outsourcing new product development or vice versa.

The most important thing is to recognise where the gaps in expertise lie. One should start by undertaking a gap analysis to better understand the skills shortfall and local requirements and identify the most effective method of streamlining resources. There is a strong argument that gaining an external view of one's internal structure will provide a neutral view and, therefore, allow one to better implement a change management plan.

Thus, before an internal set-up can be optimised, there needs to be a good external network of experts to call upon when specialist knowledge is required. Such support can be utilised in many ways, whether it be through using independent consultants or employing the services of a larger provider who is able to offer ongoing advice or long-term maintenance of established products. The options are endless. Once this is identified, finding the right specialist to help a company successfully navigate their target location's regulatory framework is much easier.

It is clear across all countries (not just Scandinavia and the Nordics) that no one size fits all. It is said to 'never assume,' and this should always be an organisation's mantra when approaching regulations across different country locations. The important thing is to have the right knowledge, whether that be a permanent internal resource or access to an external specialist.

References

1. Visit: lakemedelsverket.se/upload/foretag/humanlakemedel/Produktinformation/Guideline-on-Nordic-packages.pdf
2. Visit: lakemedelsverket.se/upload/foretag/humanlakemedel/Produktinformation/QnA-April-2018-english.pdf
3. Visit: enli.dk/media/49728/nordic-compliance-june-2018.pdf

About the author

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