8.6 Case study 6: Availability of herbal, homeopathic and anthroposophic medicinal products

Member states	EU27
Data sources	Consultation with industry organisations (ECHAMP, EUCOPE, AESGP) Published reports and legislation

8.6.1 Background

This case study looks at the availability of herbal medicinal products, as well as homeopathic and anthroposophic products. These are three distinct product groups regulated through distinct provisions. In the case of homeopathic products, regulation is primarily through Articles 14 and 16.2 of the Directive 2001/83/EC (described in more detail in the next sections), while in the case of herbal medical products these involve the simplified procedure introduced in Directive 2004/24/EC on Traditional Herbal Medicinal Products (THMPD). The three product groups do however share some attributes:

- individual manufacturers often produce both herbal medicinal products and homeopathic products;
- it is widely recognised that national medical traditions differ with regard to how these product groups are perceived; and
- in the case of herbal medicinal products and homeopathic products, respective industry organisations note that there are availability problems across the EU linked to the differences in national approaches as well as ineffective or inconsistent application of European provisions.

This case study aims to investigate in more depth the potential availability problems concerning these products. It is important to note that the case study looks at the availability of the products as medicinal products for human use, rather than more broader availability on the market, for instance as food supplements.

Definitions

Herbal products are defined by Directive 2004/24/EC on Traditional Herbal Medicinal Products (THMPD) as products "exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations"[130]. The Directive defines *traditional* herbal medicinal products as products fulfilling the following criteria:

- they have indications exclusively appropriate to traditional herbal medicinal products which, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment;

[130] Article 1 of Directive 2004/24/EC on Traditional Herbal Medicinal Products

- they are exclusively for administration in accordance with a specified strength and posology;
- they are an oral, external and/or inhalation preparation;
- the data on the traditional use of the medicinal product are sufficient; in particular the product proves not to be harmful in the specified conditions of use and the pharmacological effects or efficacy of the medicinal product are plausible on the basis of long-standing use and experience[131].

Homeopathic products are defined as products "prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the Member States"[132]. This means, in practice, that they are products consisting of diluted doses of substances, which in larger quantities would create the symptoms in a healthy person.

Anthroposophic medicinal products are products that use natural substances and require "heat, rhythmic preparation and potentising methods"[133]. It is important to note that regulatory framework concerning anthroposophic products is more fragmented and, as a result, there are no harmonised definitions of such products across the EU, nor systematic data on such products. This means that the focus in the sections below will be primarily on herbal and homeopathic products, however, where information is available, anthroposophic products will also be considered.

Market size

According to AESGP (Association of the European Self-Medication Industry), the total market size for herbal medicinal products[134] was approximately EUR 6bn in 2010[135], while ECHAMP (European Coalition on Homeopathic and Anthroposophic Medicinal Products) estimated the total sales (at ex-factory prices) of homeopathic products in the same period to be EUR 1,035bn[136]. Although this constitutes less than one percent of the EU pharmaceutical market[137], sales of such products remain significant and warrant an exploration of the availability issues associated with these product groups.

8.6.2 Availability problems

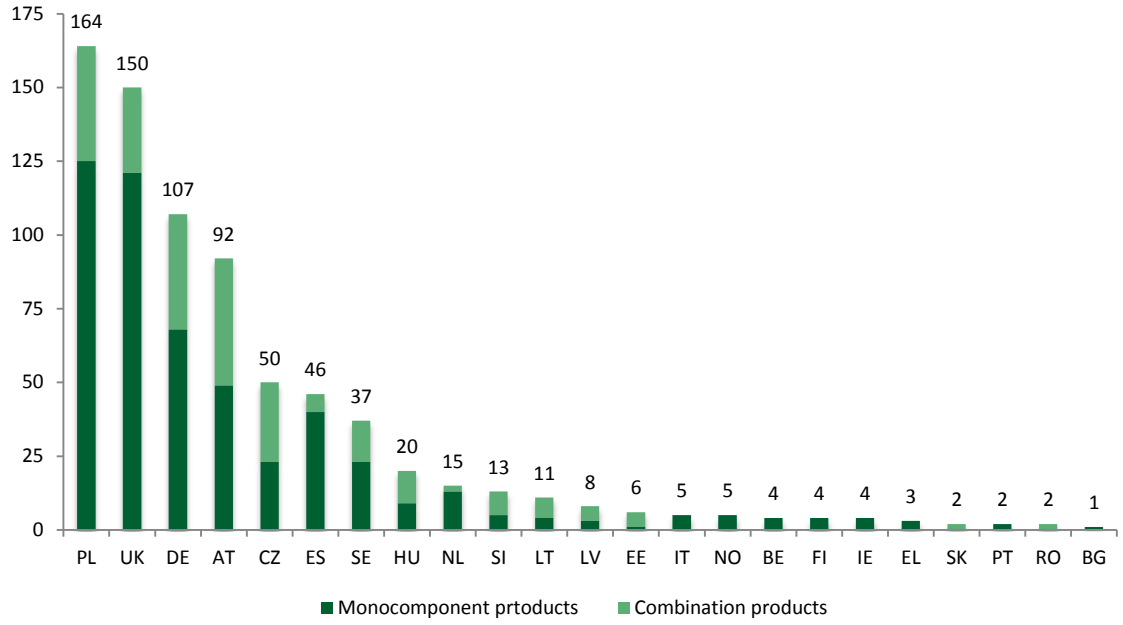
The following sections outline existing evidence concerning the availability of herbal medicinal products, as well as homeopathic and anthroposophic products.

[131] Article 1 of Directive 2004/24/EC on Traditional Herbal Medicinal Products
[132] Article 1 of Directive 2001/83/EC
[133] See http://www.echamp.eu
[134] Where terms "herbal medicinal products" or "homeopathic medicinal products" are used these are meant to describe products authorised explicitly as medicinal products
[135] Presentation of the Chair of the AESGP Herbal Medicinal Committee
[136] ECHAMP (2012), 'The Availability of Homeopathic and Anthroposophic Medicinal Products in the EU'
[137] EFPIA (2012), 'The Pharmaceutical Industry in Figures – Key Data 2012'

Availability of herbal medicinal products

The key issue noted by industry stakeholders with regard to the availability of (traditional) herbal medicinal products is the limited use of the simplified procedure (introduced in the Directive 2004/24/EC). This is illustrated in the figure below, provided by AESGP:

Figure 25: Number of registrations of traditional herbal medicinal products under Directive 2004/24/EC until December 2011



Source: AESGP

The above figure shows that the differences in the number of registrations do not necessarily correspond to the size of the national market. Poland, UK, and Germany are three of the larger EU markets, but there were also considerably more registrations in Austria and Czech Republic than, for instance, in Italy or France (although not included in the above figure, according to AESGP there were in total four registrations in France).

As industry stakeholders point out, however, there are differences in the way individual Member states approach herbal products and one can also expect that the demand for herbal products may not necessarily correspond to the sizes of individual markets. As noted by the WHO[138], in 2002 (prior to the establishment of the simplified registration procedure), Germany held the largest share of the European herbal medicinal product market with 39% of the market, followed by France (29%), Italy (7%), Poland (6%) and the UK (6%). Although these are all large Member States, the fact that the market share in France and Germany is more than triple that of the remaining five countries, suggests that herbal products play a much larger role in these two Member States.

[138] See http://apps.who.int/medicinedocs/en/d/Js4950e/1.html#Js4950e.1.1

When comparing these figures to the pattern in the number of registrations shown above, one can notice potential discrepancies. The size of the market for herbal medicinal products in Germany is not reflected in the fact that the number of registrations in Poland and the UK (both markets with potentially substantial demand for such products, but not nearly as high as in Germany) is considerably higher, More significantly, the low number of registrations in France, compared with the fact that total demand for such products was second only to Germany, suggests that there may be potential availability problems associated with few registrations in France. To a lesser extent this may also be the case in Italy.

More broadly, it is important to note that the above sections interpret availability strictly within the context of the procedure introduced in the THMP Directive. This means that in some Member States (such as France and Italy) where there may be demand for herbal medicinal products, some products might not be registered through the THMP procedure. However, this does not necessarily imply that the products are not on the market, as they may be available as, for instance, food supplements. Finally, it is important to also note that availability issues concerning herbal medicinal products have not been recognised by other stakeholder groups. This suggests that the potential availability issues are unlikely to be acute ones. Nevertheless, the substantial disparity between the number of registrations warrants a closer examination of potential drivers. These are explored in more detail in Section 3.

Availability of homeopathic and anthroposophic products

With regard to the availability of homeopathic and anthroposophic products, a PwC study commissioned by ECHAMP examined a selection of products in five Member States (Bulgaria, France, Germany, Romania, and Spain) and noted, among others, that:

- There were moderate differences in availability, with most products being readily available in Germany, followed by France and Spain;
- Homeopathic medicinal products with no therapeutic indication are difficult to obtain directly (without ordering), but they can usually be delivered to order;
- There are generally no major issues regarding availability of homeopathic medicinal products for specific symptoms;
- Direct availability (without ordering) of anthroposophic products is generally worse than in the case of other homeopathic products

The above results, although they refer to only a subset of Member States, suggest that there are indeed some differences in availability of these products across the EU. However, as noted by industry stakeholders, and also analogous to herbal medicinal products, there are likely to be national differences in demand for such products.

Generally, according to ECHAMP data, sales of homeopathic and anthroposophic products as a percentage of total pharmaceutical market and per inhabitant are higher in France and Germany than in Bulgaria and Romania, two of the new Member states investigated in the aforementioned PwC study. Taking this to reflect the demand in these Member States, this would be consistent with the findings concerning availability, suggesting that Member States with higher demand for such products would also be ones where such products are more

available. On the other hand, on some metrics, the homeopathic market in Bulgaria appears to be larger in relative terms than that of Spain (i.e. when looking at homeopathic product sales as a percentage of the pharmaceutical market or looking at the number of homeopathic prescribes per capita). This, coupled with the fact that availability appears to be more problematic in Bulgaria than Spain, suggests that limited availability could result in some of the demand for such products not being met in some Member States[139].

At the same time it is important to note that, in general, the ECHAMP study did not find availability in all Member States to be particularly problematic, with the products surveyed generally being available when ordered in advance, meaning that they were both authorised and marketed. Secondly, as in the case of herbal medicines, other stakeholders consulted as part of the study (i.e. National Competent Authorities across the EU) have not raised the issue of the availability of homeopathic products.

Finally, it is also important to note that availability and sales (used here as a proxy for demand), can be interdependent concepts, with lower perceived demand (i.e. lower sales) potentially resulting in unavailability (since the manufacturers, or regulators, could place lower value on getting such products on the market), but also lower availability (due to other factors), potentially resulting in lower sales, which can then be misinterpreted as lower demand. Therefore, data such as number of homeopathic prescribers is important in triangulating such findings. Given that in the case of homeopathic products, this data shows Bulgaria as a Member State with more demand for homeopathic products than Spain (or even France and Germany), it is valuable to explore potential drivers of unavailability.

8.6.3 EU Legal framework

For both herbal medicinal product and homeopathic products, industry associations note that the existing regulatory procedures are either ineffective or are incorrectly applied, contributing to unavailability problems. These potential problem drivers are outlined below.

Traditional herbal medicinal products

The 2004 Directive established the simplified traditional-use registration procedure, which does not require extensive documentation given that there is sufficient documentation of the medical use of the product in the previous 30 years, including 15 years within the EU[140]. The Committee for Herbal Medicinal Products (HMPC) at the European Medicines Agency (EMA) supports this process.

However, as noted by AESGP, there are a number of issues associated with this procedure:

- there are long registration times in some Member States (ranging from 9 to 32 months), which are seen as being the result of limited resources, low prioritization, and lack of familiarity with herbal products in some national agencies; and

[139] ECHAMP (2012), 'The Availability of Homeopathic and Anthroposophic Medicinal Products in the EU'
[140] See http://ec.europa.eu/health/human-use/herbal-medicines/index_en.htm

- access conditions in some Member States are viewed as restrictive, including high fees (same as for chemical entities), different advertising rules, and other restrictions in selected Member States (age or pack size restrictions).

The above points reflect the industry position, but they do show that there are differences in Member State approaches, which could explain in part the pattern of registrations shown in the figure above. Although the simplified procedure is a national one, allowing for variation in Member State approaches, the above points suggest that the current practices may fall short of the new procedure's goals of facilitating the movement of traditional herbal medicines and harmonising the national rules, with a potential bearing on the availability of these products. It needs to be emphasised again that these potential shortcomings relate to delays and small number of products authorised as traditional herbal medicinal products. This does not necessarily mean that the products are not available on the market (for instance as food supplements). Nevertheless, according to the definition of availability used in the study, these delays could be seen as availability problems as the products in question are not available in a pharmacy setting.

Homeopathic products

As in the case of herbal medicinal products, a simplified procedure is in place for homeopathic products (as outlined in Article 14 of Directive 2001/83/EC), but industry stakeholders note problems with this procedure. These include in particular:

- long waiting time to authorise products (12-25 months), attributed to the lengthy administrative procedures;
- perceived disproportionate burden associated with the decentralized procedure provided for in Article 13 of the Directive, resulting in it being very rarely used;
- inconsistent application of Article 16.2 of the Directive (allowing a Member State to adopt specific rules concerning homeopathic products outside of those covered in the simplified procedure in accordance of homeopathy principles practiced in that Member State). As a result in only a selection of Member States where it has been adopted have products been registered through this procedure.

As in the case of herbal medicinal products, these findings suggest that the existing legislative framework for homeopathic products may fall short of simplifying procedures and introducing more harmonization across the EU for these products.

It is important to also keep in mind that homeopathic products are not a homogenous group. The simplified procedure set out in Art. 14(1) concerns products with no therapeutic indication, with concentrations lower than 1:10,000 and does not cover injectables. Producers aiming to introduce such products on the market therefore need to rely on Member State implementation of Article 16(2), which, as noted above, remains fragmented across the EU. As a result, there is no clear and consistent EU registration procedure for homeopathic products not covered under Article 14(1) (products with indication, or higher concentration products). This in turn means that some products effectively cannot be registered as homeopathic products in some markets, or need to be registered as products without indication (given that they are not injectables and do

not exceed the aforementioned concentration levels). It is important to note, however, that at the moment only few such products exist.

8.6.4 Conclusions

The analysis shows that even taking into account the demand and use of (traditional) herbal medicinal products and homeopathic products, in some Member States fewer such products are registered or registration is more time consuming leading to (temporary) unavailability. Although availability problems concerning these groups of products have not been identified by the NCAs or other non-industry stakeholders, the implementation of existing EU provisions concerning these products could be further improved. These provisions aim to simplify the authorisation process and ensure more harmonisation across the EU, but the evidence collected as part of this case study suggests that more progress could be made in this direction. Given the demand for such products, there appears to be a need for further action in this area, which, according to consulted stakeholders, should focus on ensuring that the process of authorisation of herbal medicinal products and HAMPs is more consistent, both with the text of the existing provisions and between Member States. The consulted stakeholders did not however point to a particular good practice example, suggesting that at the moment there is not blueprint for an optimal approach to authorising such products.