



INNOVATIVE INTEGRATED TRAINING IN HEALING PLANTS BUSINESS

IO3 - The Total Business Plants Training Material

Module No. 4

“Business start-up in the sector of medicinal plants”

FyG Consultores



Unit 5: Legal issues, funding and networking

- **Summary**

Unit 5 “Legal issues, funding and networking” gives needed knowledge about legal facts and issues in countries related to the specific industry. At the same time in this part the learner can find information that helps with getting funds and financial support from different sources. Topic such as networking is also presented and explained in an easy way.

- **Learning outcomes**

- ✓ **Knowledge, understanding and professional skills:**

1. Get familiar with necessary legal and funding aspects.
2. Behave and create business based on legal rules
3. Creating successful networking

- ✓ **General and transferable skills:**

1. Plan and follow the business planning steps.
2. Show excellent written and oral communication skills.
3. Work alone or with team and set up activities that lead to the main goal.
4. Understand legal and fund terms related with European countries

Before you start your Medicinal Plants Business you already know you have to prepare many documents, do special research and prepare your business plan. Additionally, of course you have to make sure you are allowed to do your business in this specific sector and in the specific place (city, country etc.)

The European Union legislation for medicinal products is very complex and the base is related to the need of marketing authorization which needs to take place before having the medicines in the market. The main purpose of this is to protect public health by encourage high quality, efficacy and safety. All main requirements and procedures are presented in regulations which are contained in the “Rules Governing Medicinal Products in the European Union”. Many figures are included which are supported by other publications such as Good Manufacturing Practice (GMP) guidelines. (www.omicsonline.org)

Medicinal plants have been used for many years in all parts of the world by young people and older generation as well. Even so, strict regulation of herbal medicines in a legal environment was introduced in the 20th century. The EU regulatory framework includes specific requirements for herbal medicinal products (HMP) which are independent from their legal status: traditional herbal medicinal product (THMP) or products based on clinical evidence - well established use (WEU).

Knowing how hard it could be for you, we would like to present some information regarding legal issues and funding.

- **Legal issues**

The law of European pharmaceutic allocate herbal products as “normal” medicinal products if they claim to prevent illness or if they are conduct with a view to restoring, correcting or modifying physiological functions. Depending on the application and preparation of the product it can be used

differently. For example, peppermint tea could be treated as food or medicine. Another example is senna extract, which product need to be declared a medicine by virtue of its pharmacological action.

The component of herbal medicinal products and changes that are happening constantly make an impact on regulatory assessment. Additionally, it is a challenging aspect for health agencies and national authorities.

For long time herbal, medicinal products have been part of cultural heritage and this may be one reason why herbal medicinal products continue to be extensively used in Germany – that is the country where this market is growing very fast.

Recent studies present that more than 70% of the German population admitted that they used natural herbs/medicines, and apart from that for most of them as a first choice they used herbal medicinal products in the treatment of minor diseases or disorders.

When total European market is 39%, the German one holds the biggest part share by value, followed by France (29%), Italy (7%), Poland (6%) and the United Kingdom (6%). Herbal medicinal products are found among the top 200 of the 2000 most prescribed medicines that were reimbursed by state-supported health insurances in the year 2000. As an example, we can present, a product composed of *saccharomyces* yeast used for the symptomatic treatment of diarrhoea holds rank 51 with 1.5 million prescriptions, where the most popular brand antidarrhoeal, loperamide, is placed at 145 with 851 000 prescriptions. From the other hand the most important herbals are ginkgo leaves, hypericum, ivy (*Hedera helix*), mistletoe, hawthorn, saw palmetto and horse chestnut.

Presented data shows that creating a professional herbal medicines plants business you have to have in mind that those are rightly classified as medicinal products because they are used as such. At the same time its crucial to know that there are herbal medicines that may present risks even when properly used. Such risks for humans and animals are mostly moderate and can be avoided by appropriate labelling with description.

The problem that can be observe is that there is a potential interaction between herbal medicinal products with conventional medicines. The most visible example is hypericum. In this case the risk has to be carefully diagnosed. It's critical to balance the potential benefits and clearly labelled the product for consumer and health professionals in order to protect public health.

“These specific challenges were acknowledged at the Eighth International Conference of Drug Regulatory Authorities (ICDRA), in Bahrain in 1996. WHO Member States were encouraged to establish groups of experts for herbal medicines in their own countries and regions and to update national legislation in order to allow registration of herbal medicinal products. This was reconfirmed at the Ninth ICDRA in Berlin in 1999”. (<http://apps.who.int/medicinedocs/en/>)

Summarizing all facts, European experience shows that herbal medicinal plants are appropriately assigned to the group of medicinal products. It is caused by the fact that the used is the same as any other medicine. The risk that might appear must be identified and labelled as it is with any other medicine material.

➤ **Funding and networking**

European Union every year presents funding in the form of credit and grants for many different sectors. Main areas that can be covered by the EU funds are: education, health, ecosystem, consumer protection, environmental protection, entrepreneurship, agriculture, social and humanitarian aid. All

funding programs are managed according to very strict rules and legislations, which help to make sure that there is a control and proper check. The control is mainly addressed to the topic related with funds – how are they used, for who and when. Funds need to be spent in a transparent way – available for everyone. EU funding process is very complex, as there are various types of programs which are led by different parties. Each project has specific target group to which it can be addressed. Projects are divided by subject, age, special target group and location.

More than 76% of the EU budget is managed by the Member States. It includes structural funds that finance regional legislations, trainings, social support, as well as agriculture area (support for farmers as well).

Two main types of funding (www.eubusiness.com)

Grants – it refers to a specific project. Most of the time following a public announcement known as a 'call for proposals'. In this case part of the funding is sent by the EU and other part from another source.

Public contracts – Contracts cover a specific area such as: technical assistance and training, consultancy, conference organisation, IT equipment purchases etc. Awarded through calls for tenders.

28 EU Commissioners have an obligation and responsibility to ensure that all funds are spent properly and used in a proper way. There are also many EU funds that are managed at a country level – those are under the national governments control for checks and annual audit.

Beneficiaries of the funds:

- Small businesses
- Non-governmental & civil society organisations
- People that want to create a social entrepreneur
- Groups that have an idea but not enough financial support
- Young or adults with ideas
- Start-Ups
- Niche groups
- Disabled

- Researchers

In EU budget, more than €53 billion has been made available between 2007 and 2013 for research, principally connected with the seventh plan programme (FP7). Grants are available in the form of co-financing for research related to cooperation, ideas, people, capacities & nuclear research.

- Farmers

Many people that have a farm – farmers are not aware of the benefits that they have. Most of them are eligible to receive a direct payment to support their income. As any other support it requires to follow some rules which are for example: respect standards related to environmental protection, animal welfare and food safety.

Two main types of funding:

- Lifelong Learning Programme – study and learning opportunities through Erasmus, support for students, teachers, individual / ERASMUS+

- Youth in Action Programme – possibilities to go abroad for work or volunteer action

The market in Europe is very wide – can touch all kind of sectors. Medical sector is connected with herbal medicine plants which is diversified and well documented. The fact is that in Europe, both licensed and unlicensed medicinal plants/herbal products are available for the customer. From the point of view of both the dietary supplements and OTC drugs, the market for HMAP products is considered one of the leading sectors in Europe. In 1994, the annual turnover from the sale of OTC herbal medicines amounted to USD 6 billion which increased to USD 7.5 billion, growing at a rate of between 10 to 15% annum in 1997. The sales volume of the European market for licensed herbal medicines was estimated at higher than USD 475 million in 1997 with three ginkgo (*Ginkgo biloba*) products attracting the highest sales volume. There has been a drop in the sale of ginkgo products in Germany, one of the most developed herbal markets, in the last 10 years (sales dropped from 9.9 million in 1993 to 8.5 million in 1997). Conversely, some other herbs witnessed increased sales. An example is St. John's wort (*Hypericum perforatum*) which saw sharp sales increases from 2.6 to 8.5 million between 1993 and 1997. The leading herbal products recording the highest sales were derived from ginkgo, ginseng, garlic, St. John's wort, evening primrose and Echinacea.

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