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# Medicinal and Aromatic Plants: Legal Aspects in the European Union, in Italy and in some of its Regions

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'Europe is the main import region (medicinal and aromatic plants material) [1], with Germany that ranks fourth and third as importer and exporter, while Italy ranks eight as importer' (world level; volume). Different data sources, not always recent, indicate that the cultivated area for the EU medicinal and aromatic plants (MAPs) covers 69,640 hectares [2], with 11,490 farms (2005), while the Italian total production is approximately 3,000-4,000 tons/year [3]. At the European level MAPs are mainly cultivated in France [2], Spain, and in the East (Romania, Bulgaria). In Italy [4], the Piedmont Region concentrates by about one third of the national MAPs cultivated area.



Figure 1 – *Arnica montana* L. (Valle Cannobina, Province of Verbania, Piedmont Region, Italy).

The first part of the work involved the collection, and the analysis of the main regulations, and laws concerning the cultivation, and harvesting of MAPs at different levels (EU, Italy, Piedmont, and Valle d'Aosta Regions). In the second part some personal interviews to professionals, and civil servants of the examined regions will allow to obtain information on the effects of the considered laws, and quantify the amount of financial aids for MAPs.

In Italy the cultivation, gathering, and trade of medicinal plants [7,8], is still normed by the Law 99, 6<sup>th</sup> January 1931 ('*Disciplina della coltivazione, raccolta e commercio delle piante officinali*'). It defines the medicinal (officinal) plants, as 'medicinal, aromatic and used by perfume industry'. The law underlines: i) who gathers herbs must obtain the authorization card; ii) those who use medicinal plants must to obtain the diploma of herbalist. The list of declared medicinal plants is contained in two separate tables that distinguish between 'medicinal plants' and 'medicinal, aromatic and perfumery' sold outside the pharmacy (*Regio Decreto 19 Novembre 1932, n.772, Circolare Ministeriale n. 8/81*). Besides, the law indicates that all are permitted to gather and hold, without prior authorization, but only for personal or family use. Two specific rules are dedicated to gather and trade of *Matricaria chamomilla* L., and *Digitalis purpurea* L.. The most recent attempt to legislate about MAPs dates at year 2011, and includes restrictions, and certification of the products. Finally we remember that, while not compulsory, farms that provide the processing industry must comply with GAP (Good Agricultural Practices), and GWP (Good Wildcrafting Practices).

The work analyzes some laws/regulations concerning (mainly) the cultivation, and the gathering of MAPs, in the European Union (EU), in Italy and in some of its regions, Piedmont Region, and Valle d'Aosta Region, in the Northwest of Italy. This analysis should help to bring to the attention of public institutions, and private operators, some information that may be useful to develop and improve the cultivation of MAPs, also out of the considered context.

Within the *European Union* regulations, the EU policy for Rural Development (Reg. 1698/2005 EC) [5], co-finances by the INTERREG IIIC and Leader+ Programmes initiatives interesting also the cultivation of MAPs. They are known as 'European Community Initiatives', respectively regarding cross-border, transnational, and interregional co-operation, or 'innovative initiatives', managed at the regional level. Market surveys, training courses, purchase of drying equipments, making up 'signs of quality' to improve products, are several of the action supported. For the EU [6], it can be recalled the 'Guideline for Good Agricultural and Wild Collection Practice (GACP) of the European Herbs Growers Association (EUROPAM), that 'are intended to apply to the growing and primary processing practices of all such plants and their derivatives traded and used in the EU', and 'provide additional standards for the production and processing of raw materials. In this respect, they will be aimed at minimizing insufficient quality by prevention. The recommendations of this document are aimed at offering guidelines for natural regulations'. In addition, the guidelines are applied to production for humans and/or animals, and to organic production. To complete this synthetic framework of the EU legislation we remember the Directive 2004/24/EC, regarding herbal medicinal products (human use), while the Directive 2002/46/EC, in force from May 2011, regulates the dietary supplements (human use).

*Regional level.* The legislation of the Piedmont Region underlines the importance of MAPs for marginal [9,10], and mountainous areas, and to defend the environment. In this region, two laws governing this topic: i) the Regional Law 32/82 indicates the species for which gathering is absolutely forbidden (e.g. *Arnica Montana* L., *Achillea moschata* Wulfen), promoting the cultivation of MAPs with *ad hoc* financial aids; ii) the Regional Law n. 38/93 '*Norme relative alla coltivazione e alla commercializzazione delle piante officinali peculiari della Regione Piemonte*', promotes the cultivation with organic methods, training of farmers/operators, and the creation of botanical gardens also for dissemination purposes. In the *Valle d'Aosta* Region, the second considered region, almost entirely mountainous, the legislation for MAPs is very recent (Regional Law n. 2/2012). The law defines three categories of herbs: i) food for herbal use; ii) medicinal plants for food, and household use; iii) medicinal plants for medical use. The main aspects are: i) the cultivation, and gathering are free throughout the region, while the first processing can be performed by workers with suitable qualifications, and training courses; ii) to enhance the regional production through a logo indicating origin and quality.

This first phase of the work highlighted that: i) some public institutions (EU, Regions), show interest to the sector of MAPs, also reported by new laws; ii) the initiatives covered by the EU programs, did not proved very effective, at least in Italy, to improve the marketing/distribution (concentration of the farmers supply), and the quality of the production. Moreover, these initiatives are not always adequately known by the farmers, especially by small farmers.



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