
**Workshop "Good Practices,
Standards and Certification of
Starting Materials"**

**- Contribution of the Herbal
Medicinal Products Industry
(AESGP) -**

**Dr. Barbara Steinhoff (BAH)
53rd GA Annual Congress
24 August 2005**

AESGP - European Self-Medication Industry

- **Composed of national associations as well as international companies**
- **Contributes to facilitation of consumers' access to high-quality, safe and effective consumer healthcare products**
- **Member of WSMI (World Self-Medication Industry)**
 - **Non-Governmental Organization Status at WHO**
 - **Co-operation with various international associations and federations**
 - **Consultative status to the United Nations**

WHO Documents (Traditional Medicine Programme)

- Preparation and finalization of WHO guidelines on GACP (October 2002, July 2003)
- Discussion of draft guidelines on contaminants and residues (July 2004)
- Scientific support to WHO Model Monographs on Selected Medicinal Plants, Vol. I - IV
 - ⇒ WSMI Observer Status as NGO

AESGP's Views on Good Practices

Major issues related to cultivation and collection of medicinal plants

- Adherence to internationally agreed conventions, e.g. WHO GACP Guidelines
- Involvement of member companies in promoting transparency about sustainable production / collection as far as possible
- Development of collaborative projects in terms of sustainability and nature protection (e.g. in the framework of Standards and Criteria)

AESGP's Views on Good Practices

The herbal industry considers sustainable use as important in order to

- ensure future supply of raw materials of good quality
- guarantee availability of herbal medicinal products as an important area of self-medication

Motivate member companies to utilize ecological and sustainable collection methods and to preserve traditional knowledge and intellectual property rights as far as possible

Problems of Practical Implementation

- Manufacturers of herbal medicinal products (HMP) do not source raw herbs, but buy extracts
- Several processing steps, complex trade chain
- Involvement of manufacturers, extract manufacturers, suppliers of raw material, wholesalers, traders, local buyers, etc.
- Mixture of plant material from different geographical origin
- Blending of different batches of extracts
- Problem of traceability and documentation

Problems of Practical Implementation

- Major issue for HMP manufacturers is to obtain sufficient information from suppliers
- Particularly in case of supply of small quantities
- Problem of responsibility for steps that cannot be fully controlled by HMP industry

Guidelines on GACP

1998 **Europam recommendations on Good Agricultural Practice (GAP)**

1999 / 2002 **EMEA Herbal Medicinal Products Working Party's "Points to consider on GACP" // HMPC draft**
2005

2003 **WHO Guidelines on GACP**

Examples for National Approaches

WSMI World Self-Medication Industry



AESGP Association of the European Self-Med. Industry



BAH German Medicines Manufacturers' Association

FAH - German Medicines Manufacturers' Research Assoc.



Working Group (1995) "Cultivation of Medicinal Plants"
Representatives of member companies and official institutions

Examples for National Approaches

- Practical implications of GACP for e.g. cultivators/ collectors, traders, manufacturers discussed in German industry's groups
- Quality Assurance System of pharmaceutical industry
 - ➔ obligation to evaluate suppliers on a regular basis ("audit")
- FAH: need for practical guidance based on official documents

Examples for National Approaches

Co-operation with

- German Committee for Medicinal, Spice and Aromatic Plants (Deutscher Fachausschuss)
- Worldwide Fund for Nature (WWF)
- TRAFFIC Europe
- German Federal Agency for Nature Conservation (Bundesamt für Naturschutz)
- German Medicines Manufacturers' Association (Bundesverband der Arzneimittel-Hersteller - BAH)

Examples for National Approaches

FAH Proposal for a Standard Operating Procedure (SOP) for Audits of Cultivation and Wild Crafting of Medicinal Plants

- Zeitschrift für Arznei- und Gewürzpflanzen
2003;8(2):83-88
- Journal of Herbs, Spices & Medicinal Plants
2003;10(3):109-125
- Workshop GACP
Bonn, 12 November 2003

FAH SOP Proposal

- Made by co-operative approach and consensus between parties involved
- Recommendation, not binding
- Proposal on how to prepare an operating procedure for auditing cultivation/collection of a specific plant

FAH SOP Proposal

Purpose

This SOP regulates the preparation of operating procedures for implementing and documenting inspections (audits) in the cultivation and collection of medicinal plants. The inspections are meant to verify the effectiveness of both common and plant- or culture-specific quality assurance measures. Furthermore, the activities and results of the inspections can be examined to determine whether the operating procedures fulfill the scheduled inspection requirements. For wild crafting, inspections should support information exchange on the sustainability of plants taken from nature.

FAH SOP Proposal

Consideration of sustainable use

Instructions for preparing an inspection questionnaire:

"(...) Protection of species and habitat and the sustainability of plants within the cultivation area were considered and that collection took place at the optimal time; considerate withdrawal must be guaranteed. (...)"

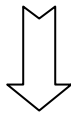
Certification

- **Quality Assurance System established within pharmaceutical industry (Art. 6 of GMP Directive 2003/94/EC)**
- **Audits on a regular basis**
- **Documentation on e.g. origin, cultivation/wild crafting, harvesting, use of pesticides, drying, further processing, etc.**
- **Application for marketing authorisation**

Medicinal Products / Food

Medicinal Product

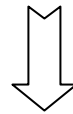
- cure
- alleviation
- prevention



**Marketing
Authorisation**
(2001/83/EC)

Foodstuff

all products which are not
medicinal products, e.g.
nutrition or consumption



**No Marketing
Authorisation**

Certification

- **No legally required documentation on quality assurance in the food area**
- **Certification system useful for food**
- **Medicines area: quality assurance to be documented within application for marketing authorisation**
- **No further certification required**
- **Additional costs and burden (auditing etc.) for farmers**

Conclusion

- **Adherence to legal provisions and internationally agreed conventions**
- **Sustainability and nature protection: Constructive discussion needed, but due to complex trade chains, problems of control exist**
- **Certification system not required for herbal medicinal products because well-working auditing and documentation system already exists**