



London, 12 January 2006  
Doc. Ref. EMEA/HMPC/11138/2006

**OVERVIEW OF COMMENTS RECEIVED ON  
DRAFT GUIDELINE ON GOOD AGRICULTURAL AND COLLECTION  
PRACTICE (GACP) FOR STARTING MATERIALS OF HERBAL ORIGIN**

**This document was valid from July 2005 until 9 July 2025.**

*Table 1: Organisations that commented on the draft Guideline as released for consultation*

	Organisation
1	AESGP
2	American Herbal Pharmacopoeia
3	Biologische Heilmittel Heel
4	Phytoconsulting
5	Herbal Forum
6	

Table 2: Discussion of comments

GENERAL COMMENTS - OVERVIEW		
<b>AESGP</b>		
Welcome this document.		
<b>AHP</b>		
All specific comments.		
<b>Biologische Heilmittel Heel</b>		
Document should have been published with a cover note indicating it had not changed significantly.		
There are no references in this document?		
<b>Phytoconsulting</b>		
Document should have been published with a cover note indicating it had not changed significantly.		
'General note' from original PtC removed?		
<b>Herbal Forum</b>		
Generally commend the publication of this guidance.		
Need clarification on the status of a PtC paper as opposed to a guideline?		
SPECIFIC COMMENTS ON TEXT		
1 INTRODUCTION		
Line no. + para no.	Comment and Rationale	Outcome
Paragraph 1	Make first sentence more positive than negative	Agreed
	Include 'in an appropriate manner' at end of last sentence	Not Agreed
Paragraph 3	Include the word 'may' in first sentence	Agreed

<b>2 GENERAL</b>		
<b>Line no. + para no.</b>	<b>Comment and Rationale</b>	<b>Outcome</b>
2.2	Replace last sentence to ‘prevent introduction and generation of pathogenic microbes’ [AHP].	Not agreed
2.3	Typo ‘ensure’.	Agreed
<b>4 PERSONNEL AND EDUCATION</b>		
<b>Line no. + para no.</b>	<b>Comment and Rationale</b>	<b>Outcome</b>
4.1	Define the term ‘food hygiene’.	Not agreed – this refers to regional and national guidance where this term may be defined differently.
4.7	Collectors cannot be expected to know anything specific about soil, shade and humidity conditions. They could generally know about the need for plants to be dried properly.	Partly agreed – the use of the term ‘sufficient’ covers the possibility that the level of knowledge may vary and the specific examples are removed.
<b>7 DOCUMENTATION</b>		
<b>Line no. + para no.</b>	<b>Comment and Rationale</b>	<b>Outcome</b>
7.7	Amend first sentence to ‘Batches of medicinal plant materials should be unambiguously and unmistakeably traceable to their sources. Therefore appropriate labelling and batch assignment should take place as early as possible.’	Agreed
	Clarify that the requirement to link each batch to a designated area applies to the farmer and not the pharmaceutical company	Not agreed – this provision is designed to ensure batch traceability and therefore is not limited to the farmer.
<b>8. SEEDS AND PROPAGATION MATERIAL</b>		
<b>Line no. + para no.</b>	<b>Comment and Rationale</b>	<b>Outcome</b>

8.1	<p>Amend first sentence to ‘Seeds should originate from plants that have been accurately identified to genus, species and if necessary, cultivar.’</p> <p>Clarify that tolerance/resistance to disease as referred to in the last sentence is ‘natural’ to avoid unintentional promotion of GMOs/selective breeding.</p>	<p>Agreed but reworded slightly.</p> <p>Agreed – included the word ‘naturally’ and included ‘where possible’.</p>
<b>9 CULTIVATION</b>		
<b>Line no. + para no.</b>	<b>Comment and Rationale</b>	<b>Outcome</b>
9.2.2	<p>Amend to ‘Water used for irrigation should not contain any substances (e.g. heavy metals, pesticides) or microbes that could impair the quality of the plant material’ in order to allow water from tanks/wells to be used.</p> <p>The term ‘national standards’ varies widely and may allow use of untreated water in some areas.</p>	Not agreed.
<b>11 HARVEST</b>		
<b>Line no. + para no.</b>	<b>Comment and Rationale</b>	<b>Outcome</b>
11.2	Due to the unavoidable nature of a certain amount of damaged material this sentence should also include a limit in accordance with a relevant pharmacopoeial e.g. Bearberry Ph. Eur.	Agreed in part – text amended.
<b>12 PRIMARY PROCESSING</b>		
<b>Line no. + para no.</b>	<b>Comment and Rationale</b>	<b>Outcome</b>
12.1	Include a statement that primary processing should be carried out as soon after harvesting as possible.	Agreed.

12.2	Include protection from insects also.	Agreed.
12.4	<p>Amend to ‘Adequate air circulation and protection from direct sunlight – if not specifically required – has to be ensured’ In order to allow water from tanks/wells to be used.</p> <p>Why not electric heat?</p> <p>Note need for proper air flow</p> <p>Include ‘Unless otherwise specified, medicinal plant material should be dried at not more than 45°C’.</p>	<p>Not agreed.</p> <p>Agreed, too prescriptive. Sentence deleted</p> <p>Agreed</p> <p>Not agreed, too specific.</p>