

# FINAL DRAFT

## Trade in Devil's Claw (*Harpagophytum procumbens*) in Germany – Status, Trends and Certification

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The Food and Agriculture Organisation of the United Nations  
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BY

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**TABLE OF CONTENTS**

<b>1</b>	<b>Acknowledgements.....</b>	<b>4</b>
<b>2</b>	<b>Background.....</b>	<b>6</b>
<b>3</b>	<b>Introduction.....</b>	<b>8</b>
<b>4</b>	<b>Methods.....</b>	<b>9</b>
<b>5</b>	<b>Trade of Products Derived from Devil's Claw in Germany.....</b>	<b>10</b>
5.1	<b>Import of <i>Harpagophytum</i> spp. Raw Material.....</b>	<b>10</b>
5.2	<b>Intermediate Trade within Germany and to Third Countries.....</b>	<b>13</b>
5.3	<b>Production of Finished Herbal Products Containing <i>Harpagophytum</i> spp..</b>	<b>14</b>
5.4	<b>Retail Trade.....</b>	<b>15</b>
5.4.1	Pharmaceutical Market.....	16
5.4.2	Non-Pharmaceutical Market.....	16
5.4.3	Veterinary Pharmaceutical Market.....	16
5.5	<b>Market Trends.....</b>	<b>17</b>
5.5.1	Pharmaceutical Market.....	17
5.5.2	Non-Pharmaceutical Market.....	17
<b>6</b>	<b>Licensing and Certification of Devil's Claw.....</b>	<b>19</b>
6.1	<b>'Traditional Pharmaceuticals' and Related Legal Provisions.....</b>	<b>19</b>
6.2	<b><i>Harpagophytum</i> spp. in the European Pharmacopoeia.....</b>	<b>19</b>
6.3	<b>Certification of Wild-Harvested African Devil's Claw.....</b>	<b>20</b>
6.3.1	Organic Certification.....	20
6.3.2	Product Quality Certification and Management Certification.....	21
6.4	<b>Demand and Potential.....</b>	<b>22</b>
<b>7</b>	<b>Cultivation of <i>Harpagophytum procumbens</i>.....</b>	<b>24</b>
<b>8</b>	<b>Discussion and Conclusions.....</b>	<b>26</b>
8.1	<b>Import of <i>Harpagophytum</i> spp. Raw Material into Germany.....</b>	<b>26</b>
8.2	<b>Listing of <i>Harpagophytum zeyheri</i> in the European Pharmacopoeia.....</b>	<b>26</b>
8.3	<b>Potential of Certification of Products Based on <i>Harpagophytum</i> spp.....</b>	<b>27</b>
8.3.1	Organic Certification.....	27
8.3.2	Product Quality Certification and Other Certification Systems.....	29

<b>8.4</b>	<b>Wild-collection versus Cultivation.....</b>	<b>30</b>
<b>8.5</b>	<b>Discussions about a possible CITES Listing of <i>Harpagophytum</i> spp.....</b>	<b>31</b>
<b>8.6</b>	<b>Conclusions.....</b>	<b>32</b>
<b>9</b>	<b>References and Contacts.....</b>	<b>34</b>
<b>9.1</b>	<b>References.....</b>	<b>34</b>
<b>9.2</b>	<b>List of Contacts.....</b>	<b>37</b>
<b>10</b>	<b>Annex.....</b>	<b>41</b>
<b>10.1</b>	<b>Devil's Claw Products Listed in German Pharmaceutical Trade.....</b>	<b>41</b>
<b>10.2</b>	<b>Devil's Claw Products Sold on the German Non-Pharmaceutical Market..</b>	<b>44</b>
<b>10.3</b>	<b>Devil's Claw Products Sold on the German Veterinary Pharmaceutical Market .....</b>	<b>46</b>
<b>10.4</b>	<b>Monograph of <i>Harpagophytum procumbens</i> (European Pharmacopoeia)....</b>	<b>47</b>
<b>10.5</b>	<b>Good Harvesting Practices (GHP) Guidelines for <i>Harpagophytum</i> <i>procumbens</i> in the Kalahari (RSA) (<a href="http://www.harpago.co.za">www.harpago.co.za</a>).....</b>	<b>49</b>

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## 2 Background

The African devil's claw (*Harpagophytum* spp., family Pedaliaceae) is a traditional medicinal plant from Southern Africa. It has been used in tribal medicine for many centuries, if not millennia (e.g. by the Khoisan people in the Kalahari in RSA and Namibia; Demeter-Hampshire 2002). But also in North America and Europe, especially in Germany, the plant and its healing effects have been known for nearly a century and have become increasingly popular during the last decade.

In its region of origin – the countries of Southern Africa, namely Namibia, RSA, Botswana, Zambia, Mozambique, Zimbabwe, and Angola (IHLENFELDT & HARTMANN 1970) – the plant and its populations have been facing an eventful development. For many centuries it was abundant in almost its total natural range area (HACHFELD & SCHIPPMANN 2000), but when farmers entered many regions in Southern Africa, they became annoyed by the plants 'devilish' dried fruit claws that often caused injuries with cattle and other livestock grazing on pasture grounds. Consequently, farmers began to fight this perilous 'weed' and uprooted it wherever it was in their way (HACHFELD & SCHIPPMANN 2000). The local extinction and almost region-wide reduction of devil's claw populations was an inevitable consequence. The situation has aggravated in recent years due to the increasing popularity of devil's claw products in Europe and intensive sourcing and local over-exploitation of *Harpagophytum* spp. in the range countries. However, it is difficult to assess the overall population of *H. procumbens*, because the species' natural distribution is very patchy (HACHFELD & SCHIPPMANN 2000).

In traditional South African tribal medicine, the devil's claw is appreciated as an effective medicinal plant capable of reducing the blood pressure and of curing disturbances of organs such as kidney, liver, bile with hardly any side effects (PAHLOW 1993; BERG & GENSTHALER 2001). It is also said to be used against malaria and skin cancer (SMITH et al. 1999). Contrary to the traditional African applications, modern western medicine and homeopathy use the plant chiefly to treat ailment of joints such as osteo-arthritis and rheumatism (CHRUBASIK & EISENBERG 1999; CHRUBASIK & SHVARTZMAN 1999; DAZ 2001). The devil's claw can also be used to fight diabetes, allergies (SMITH et al. 1999), and inflammations and to treat metabolic disturbances (PAHLOW 1993; LEVIEILLE et al. 2000).

'The' African devil's claw consists in fact of two distinct species, each with a number of subspecies: *Harpagophytum procumbens* (BURCH.) DC. ex MEISSNER (ssp. *procumbens* and ssp. *transvaalensis*) and *Harpagophytum zeyheri* DECNE (ssp. *zeyheri*, ssp. *sublobatum* and ssp. *schijffii*). *H. procumbens* lives in Namibia, RSA, Botswana and Zimbabwe, *H. zeyheri*'s range countries include also Zambia, Mozambique, and Angola (COLE & DU PLESSIS 2001). Both species can easily be discerned when alive but they are very difficult to distinguish when you only have dried tuber slices (BAGHDIKIAN et al 1997; LEVIEILLE et al. 2000). Most reports and descriptions tend to write '*Harpagophytum procumbens*' as a synonym of the African devil's claw. However, as this report will show that the role of *Harpagophytum zeyheri* on the international market has obviously been clearly underestimated, we use the expression *Harpagophytum* spp. unless statements unequivocally refer to one of the two species. *H. zeyheri* is regarded an 'adulterant' to *H. procumbens* collected in the northern parts of Namibia (SCHNEIDER 2000; other adulterants are described as well), where the natural ranges of both species overlap.

The exact composition of the devil's claw's medicinally active agents and the effects of each of them have not yet been fully uncovered. The plant's primary active agents are harpagoside (a glycoside) from which the plant's scientific name is derived, and a cocktail of further glycosides and flavonoids. These active agents can mainly be found in the secondary roots (store tubers), which are exclusively used as raw material for producing devil's claw products (BRADLEY 1992, cited in: SCHNEIDER 1997). Most tubers are harvested from the wild

in the devil's claw's range countries, especially in Namibia. Very often, this wild-collection is not carried out in a sustainable way, which has locally led to a considerable decrease in devil's claw populations. Sustainable wild-collection, however, can be achieved if only parts of the secondary tubers are cut, the taproot is not disturbed and the pothole is filled again after removing the tubers (COLE & DU PLESSIS 2001). Some projects targeting at the sustainable wild-collection of *H. procumbens* have been initiated, amongst others the well-described SHDC-Project (Sustainably Harvested Devil's Claw Project) in the Omaheke San region of eastern Namibia (LOMBARD, 2000; COLE & DU PLESSIS 2001). There have been several efforts to cultivate the plant; however, none of them has so far been really successful due to a variety of reasons. Therefore, *Harpagophytum* material from cultivation still contributes only a very small amount to the global trade in this species.

The sourcing of *Harpagophytum* spp. has also an important social dimension, as over 10,000 mostly tribal people (Omaheke-San, Nama Damara and others) in Namibia earn cash income from the wild-collection of devil's claw (LOMBARD 2000; COLE & DU PLESSIS 2001). It has been proven that the (semi-) wild harvesting of *Harpagophytum* spp. can be carried out in a sustainable manner (SCHNEIDER 1997, 2000). This method of sourcing devil's claw tubers is not only ecologically sustainable as it leaves time for the complete regeneration of the individual plant and permits natural propagation, but it also considers the social aspect of sustainability, providing a reliable source of income for a considerable portion of the rural and tribal population in some regions, especially in Namibia and South Africa.

### 3 Introduction

The African devil's claw is traded as 'Harpagophytum', "Harpagophyti radix' or 'Harpagophyti tuberi' (HACHFELD & SCHIPPMANN 2000). Germany is at present by far the biggest importing country and trade market for *Harpagophytum* products world-wide (HAMUNYELA 2002; SCHIPPMANN 2002). This fact has one of its roots in the times of colonialism, when Namibia, the main source country for the African devil's claw, was a German colony. In those times, many personal and trade relationships between both countries were established, some of which have been handed down from one generation to the next and are still alive to date. In 1904, a German farmer in Namibia was trained by the local population (San people) how to use the African devil's claw as medicine. He brought this knowledge to Europe and spread it (DAZ 2001). The German pharmacist Otto Heinrich Volk (1903-2000) lived in Namibia during World War II and came to know *Harpagophytum* and its medicinal applications; he started the pharmaceutical research in the devil's claw in the late 1930s. In the 1960s, he carried out a number of studies on the African devil's claw and made it known in Germany (U. EILERT, Schulbiologiezentrum Hannover, pers. comm.). However, the plant was at first no best-seller on the pharmaceutical market, until the phyto-pharmaceuticals' revival in the 1990s contributed to its rediscovery and to its commercial success (U. EILERT, Schulbiologiezentrum Hannover, pers. comm.). Besides traditional links and phyto-pharmaceutical fashions, the success of *Harpagophytum* in Germany may also be partly explained by the peculiarities of the country's pharmaceutical licensing system: contrary to many other countries, the German law offers the option to have traditionally used phyto-pharmaceuticals licensed as 'traditionelle Pharmaka', which – under certain circumstances – releases these products from the obligation to be sold in pharmacies and opens up the larger markets of drugstores, health food stores and ordinary supermarkets.

Taking this background into consideration, it becomes clear that sourcing of and trade in the devil's claw are controversial issues. They involve economic interests (collectors; trading / production companies; national / regional authorities), ecological interests and conservation concerns (represented by nature conservation organisations / NGOs), social interests (collectors; local and regional authorities) and health care interests (local / regional / international consumers and associations). There is still a lack of adequately strong scientific research into *Harpagophytum* spp. biology, sourcing, trade and markets for discussing and weighing the impacts of the different interests and implications. Germany as the largest importing country of *Harpagophytum* raw material is a prime target country for a market analysis. WWF Germany and TRAFFIC Europe – commissioned by the FAO Non-Wood Forest Products Programme – have carried out a study on the German devil's claw market. The authors hope that this report on the results of the research and the discussion will help to deepen our understanding of the complexity of the devil's claw market and the ecological, social and economical interests involved in the sourcing of and the trade in *Harpagophytum* spp.

#### 4 Methods

In order to assess the German devil's claw market, a list of products containing agents / ingredients derived from *Harpagophytum* spp. and being sold on the German pharmaceutical and non-pharmaceutical markets was compiled (cf. Annexes 10.1 – 10.3). Subsequently, questionnaires were developed including the most important guiding questions listed in the ToRs of the FAO plus some further and more detailed questions to get additional background information. For each of the four main groups of experts (pharmaceutical industry; pharmacists; retail trade; certification organisations) a slightly different questionnaire was developed, taking into account which type of questions was likely to be most efficiently answered by what group.

Research was either carried out by contacting the respective persons, organisations or companies by phone or by site-visits. During these talks, the questionnaires served as a guideline through the interview but they were used as flexible tools depending on each interlocutor's knowledge and readiness to talk. The respective questionnaire was sent out to those who preferred to answer the questions in a written form, which was, however, rather the exception. The results of these interviews were organised in 'information lots' and gave a mosaic image of the central questions to be dealt with.

In a final step, these 'information lots' were – together with information from relevant publications – worked up and condensed into this report. Chapters 5 - 7 cover the results of the research, chapter 8 reflects the authors' interpretations of these results and possible conclusions. Each statement other than of the authors' origin is verified by citations in brackets, either referring to the publications listed in chapter 9 or to information provided in communication by individual persons (cited as: (X. MODEL, pers. comm.)). Names of companies are cited where appropriate. In some cases, people or companies interviewed did not give their permission to publish the information under their or their company's name. As this wish has to be respected, the respective information is cited as: (Anonymous, pers. comm.).

In 1999 / 2000, Berit Hachfeld (University of Hamburg) and Uwe Schippmann (BfN) carried out a comprehensive study of the German market of *Harpagophytum procumbens*. Parts of this background study have been published (HACHFELD & SCHIPPMANN 2000). The complete report, however, is regarded as 'confidential' by the German Federal Agency for Nature Conservation (BfN).

## 5 Trade of Products Derived from Devil's Claw in Germany

### 5.1 Import of *Harpagophytum* spp. Raw Material

The majority of the German imports of African devil's claw raw material (dried, sliced roots) originate from Namibia (possibly over 80%), the remaining 15-20% from RSA, except for maybe a very small portion from Botswana (15 tonnes in 2001, according to the Agricultural Resources Board, Gaborone; BEN 2002). It remains unclear, however, if imports from RSA contain mainly South African devil's claw and to what extent they are re-exports of raw material of Namibian origin.

Importing Company	Estimated Amount of Annual Imports [tonnes] <sup>1</sup>
Martin Bauer GmbH	200 (at least 20 tonnes from cultivation)
Extrakt Chemie GmbH & Co. KG <sup>2</sup>	200 (maybe only 100 – 150 tonnes are direct imports, the rest is purchased from Martin Bauer GmbH; 10-20 tonnes direct imports from cultivation) <sup>3</sup>
Salus-Haus GmbH & Co. <sup>4</sup>	40 (20 tonnes from cultivation)
Cornehls & Bosse GmbH	'several containers'
Alfred Galke GmbH	10 (5 tonnes from cultivation)
Kräuter Mix GmbH	10
Dr. Willmar Schwabe GmbH & Co.	??
Flachsmann AG Germany	?? (Imports via Flachsmann Switzerland)
<b>Estimated Total Annual Import in 2002 [tonnes]:</b>	<b>350-450</b>

**Table 1:** German companies importing *Harpagophytum* spp. raw material directly from source countries. Most of these imports are of Namibian origin. For sources of information see text.

Investigations proved at least eight direct importers of devil's claw raw material in Germany (Tab. 1), although it is very difficult to obtain exact data due to the lack of transparency of the German devil's claw market. Therefore, it is very likely that some more, most probably smaller, German trading companies also import *Harpagophytum* spp. raw drug directly from

<sup>1</sup> these import figures are the 'official data' provided from the companies; for the discussion of these data please refer to chapter 8.1

<sup>2</sup> full company name: Extrakt Chemie Dr. Bruno Stellmach GmbH & Co. KG; further on abbreviated as 'Extrakt Chemie'

<sup>3</sup> according to information provided by D. v. WILLERT

<sup>4</sup> full company name: Salus-Haus Dr. med. Otto Greither Nachf. GmbH & Co.; further on abbreviated as 'Salus-Haus'

the countries of origin. The by far largest importers are the Martin Bauer Group and Extrakt Chemie (Tab. 1).

The total amount of the raw material imported into Germany is difficult to assess, because most companies are reluctant to provide this information. In 2001, about 459 tonnes of *Harpagophytum* spp. raw drug were officially imported into Germany from Namibia and 95 tonnes from RSA (SCHIPPMANN 2002). Namibian export and German import data, however, differ widely (SCHIPPMANN 2002). For 2002, estimates sum up the total annual import of *Harpagophytum* spp. into Germany ranging from 300 (H.-J. HANNIG, Martin Bauer GmbH & Co. KG, pers. comm.) to around 650 tonnes (D. v. WILLERT, University of Münster, pers. comm.). All material is imported as dried raw material (sliced and dried roots); according to our information, no extracts are produced in the source countries.

### **Martin Bauer Group**

The Martin Bauer Group reports the import of around 200 tonnes of *Harpagophytum* spp. raw material per year (H.-J. HANNIG, Martin Bauer GmbH & Co. KG, pers. comm.; tab. 1). About 90 % of the material imported by the Martin Bauer Group from Namibia and RSA originates from wild-collection (H.-J. HANNIG, Martin Bauer GmbH & Co. KG, pers. comm.). The company either directly imports the raw material or buys it from intermediate traders like 'Grassroots Phytomed' in RSA (D. v. WILLERT, University of Münster, pers. comm.). Further trade partners have not been disclosed by the company.

The Martin Bauer Group has also started a cultivation pilot project in Namibia. Devil's claw is cultivated by contract farms delivering their harvest to the Martin Bauer Group. Cultivation restrictions on the part of the Namibian Government are not known of. The total annual yield was estimated at about 80 tonnes (Anonymous, pers. comm.). Supposedly, however, the actual annual harvest yield was considerably less in 2001 and 2002; Martin Bauer GmbH & Co. KG reports that currently about 20 tonnes are sourced from cultivation (H.-J. HANNIG, Martin Bauer GmbH & Co. KG, pers. comm.).

### **Extrakt Chemie**

Extrakt Chemie obtains about 200 tonnes of African devil's claw raw material annually; most likely, only 100-150 tonnes are direct imports from source countries, the rest is purchased from the Martin Bauer Group (D. v. WILLERT, University of Münster, pers. comm.: tab. 1). 90-95% of this material originates from wild-harvesting, only about 10-20 tonnes from cultivation (D. v. WILLERT, University of Münster, pers. comm.). Extrakt Chemie has not been prepared to disclose further details of its imports (SCHEELER, Extrakt Chemie, pers. comm.). Therefore it is not known what share or if any of the imported quantities of devil's claw are (organically) certified. From hints it may be possible to conclude that **Coetzee (Blackheath, RSA)** is involved in the *Harpagophytum* trade with Extrakt Chemie (SCHEELER, Extrakt Chemie, pers. comm.).

### **Salus-Haus**

Salus-Haus has been active in projects relating to the sustainable wild-collection and cultivation of devil's claw in Namibia, some years ago. However, the Namibian Government interfered with the cultivation, because they feared that the cultivation of *Harpagophytum procumbens* would deprive a considerable portion of the local population of their income (G. HARNISCHFEGGER, Schaper & Brümmer GmbH, pers. comm.). Salus-Haus has placed its stake on sustainable wild-collection since (R. FRANKE, Salus-Haus, pers. comm.). Today, Salus-Haus directly imports the *Harpagophytum* raw drug (about 40 tonnes/year; tab. 1) from Namibia and from RSA. About 20 tonnes are sourced from sustainable (but not certified; cf. chapter 6.3) wild-collection, and 20 tonnes from cultivation (R. FRANKE, Salus-Haus, pers. comm.). The cultivated *Harpagophytum* material is purchased from the farms of the GTZ-

project in RSA, in which D. v. WILLERT is involved (R. FRANKE, Salus-Haus, pers. comm.; cf. also Harpago-Avontuur 2000, annex 10.5). Salus-Haus has tried to purchase raw material sourced from CRIAA's 'Sustainably Harvested Devil's Claw' project, but the deal did not materialise (R. FRANKE, Salus-Haus, pers. comm.). The company aims at obtaining a safe basic devil's claw supply from cultivation projects and at covering the expansion demand through sustainable wild-collection (R. FRANKE, Salus-Haus, pers. comm.).

### **Cornehls & Bosse GmbH**

The company does not provide any detailed information on the quantity of annual *Harpagophytum* spp. imports, neither on the origin of the material (BARKMANN, Cornehls & Bosse GmbH, pers. comm.). The only information that could be obtained was that the company imports 'several containers' of devil's claw raw drug, predominantly from Namibia (BARKMANN, Cornehls & Bosse GmbH, pers. comm.). According to HACHFELD & SCHIPPMANN (2000), the contents of one container equals about 8 tonnes. As 'several' means in common parlance at least three, Cornehls & Bosse GmbH's annual devil's claw imports sum up to at least 24 tonnes, but are most probably higher.

### **Alfred Galke GmbH**

The company purchases about 10 tonnes of *Harpagophytum* spp. raw drug annually. The drug is imported from both Namibia and RSA (KARL, Alfred Galke GmbH, pers. comm.), but it remains unclear what quantity is imported from which country.

### **Kräuter Mix GmbH**

Kräuter Mix GmbH is a typical intermediate trading company with a very transparent structure and information policy. The *Harpagophytum* raw drug is purchased from traders in Germany (Cornehls & Bosse GmbH), and Switzerland (Phytopharm), but also directly imported from Namibia and RSA (from Niel Coetzee, Blackheath, RSA) (B. FRIEDMANN, Kräuter Mix GmbH, pers. comm.). Kräuter Mix GmbH usually buys lots of 2-3 tonnes and has an estimated annual '*Harpagophytum* spp. raw material turnover' of about 10 tonnes (B. FRIEDMANN, Kräuter Mix GmbH, pers. comm.; tab. 1).

### **Schwabe GmbH<sup>1</sup>**

The company buys an unknown amount of *Harpagophytum* spp. raw drug from traders. It remains also unclear if these trading companies are located in the devil's claw's source countries, in Germany or in a third country, because Schwabe has not been willing to provide any information (SCHMIED, Dr. Willmar Schwabe GmbH & Co., pers. comm.).

### **Flachsmann AG Germany**

The company imports the *Harpagophytum* raw drugs from Switzerland, either through Flachsmann AG Switzerland or through other traders domiciled in Switzerland (SCHMITZ, Flachsmann AG Germany, pers. comm.). Flachsmann AG was not prepared to provide any information with regard to the import quantities or to the origin of the raw drug (SCHMITZ, Flachsmann AG Germany, pers. comm.).

Other trading companies that are not yet involved in the trade in *Harpagophytum* spp. express their interest in entering this trade in the nearer future, such as **Schües & Nordström** (C. CAESAR, Schües & Nordström, pers. comm.).

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<sup>1</sup> full company name: Dr. Willmar Schwabe GmbH; further on abbreviated 'Schwabe'

## 5.2 Intermediate Trade within Germany and to Third Countries

Most trading companies importing *Harpagophytum* spp. raw drugs do not process the material into finished medicine or other final herbal products. Rather they produce extracts, sell either the raw drug or the extract to other companies in Germany or re-export the drug to third countries.

### Martin Bauer Group

The majority of the *Harpagophytum* drugs imported into Germany by the Martin Bauer Group are processed in the company-owned extraction facilities 'Finzelberg' (Andernach) and mostly sold to producers of pharmaceutical products, such as **Alsitan GmbH & Co. KG** or **Lichtwer Pharma AG** (H.-J. HANNIG, Martin Bauer GmbH & Co. KG, MANG, Alsitan GmbH & Co. KG and EFFENBERGER, Lichtwer Pharma AG, pers. comm.). Unprocessed, sliced devil's claw roots are sold for the production of devil's claw teas and herbal tea-mixtures to various companies. It remains unclear how much is sold as extract and how much as unprocessed raw material to other companies (H.-J. HANNIG, Martin Bauer GmbH & Co. KG, pers. comm.).

The Martin Bauer Group re-exports imported raw material as well as pre-processed products such as extracts to various countries world-wide (H.-J. HANNIG, Martin Bauer GmbH & Co. KG, pers. comm.); however, the company did not specify the destinations of its re-exports. The Martin Bauer Group states that there are product-specific differences with regard to the demand in Germany and third countries, however without specifying these differences (H.-J. HANNIG, Martin Bauer GmbH & Co. KG, pers. comm.).

### Extrakt Chemie

Extrakt Chemie provides 'Strathmann AG' with their devil's claw products (cf. chapter 5.3), which may account for about 150 tonnes dried raw material alone, as Strathmann AG, especially with its product 'Jucurba', is the secondmost successful supplier of devil's claw products on the German market (D. v. WILLERT, University of Münster, pers. comm.). Strathmann AG, however, state that only 65 tonnes of *Harpagophytum* raw material have been used for the 2001 production of *Jucurba* (SUCKERT 2002). Besides Strathmann AG, a number of other pharmaceutical companies such as **Astrid Twardy GmbH** (SCHRÖDER, Astrid Twardy GmbH, pers. comm.) obtain the *Harpagophytum* extracts from Extrakt Chemie. Extrakt Chemie itself is not prepared to provide any information with regard to their trading partners, their activities in the intermediate trade nor whether or not the company re-exports parts of the *Harpagophytum* spp. raw drug purchased (SCHEELER, Extrakt Chemie, pers. comm.).

### Salus-Haus

The importing company Salus-Haus processes the *Harpagophytum* drugs into finished herbal products and teas, which enter the market under the company's brand name or the name of its subsidiary 'Duopharm' or are produced for its Swiss affiliate 'Bioforce AG' (R. FRANKE, Salus-Haus, and A. RYSER, Bioforce AG, pers. comm.).

### Cornehls & Bosse GmbH

The company re-sells directly imported *Harpagophytum* raw material to other intermediate trading companies like Kräuter Mix (B. FRIEDMANN, Kräuter Mix GmbH, pers. comm.), to extract producers or to pharmaceutical companies. The company was not prepared to reveal further details (BARKMANN, Cornehls & Bosse GmbH, pers. comm.); re-exporting activities are likely but cannot be proven.

### **Alfred Galke GmbH**

Alfred Galke GmbH usually does not process the raw drug, except for the occasional cutting and pulverising of the material (KARL, Alfred Galke GmbH, pers. comm.). The company re-exports the un- or only semi-processed raw drug world-wide, depending on the demand; with regard to devil's claw re-export destinations, the company does not reveal any details (KARL, Alfred Galke GmbH, pers. comm.).

### **Kräuter Mix GmbH**

The company re-sells the purchased drugs without any further processing or extract production. The clientel is a variety of mostly small pharmaceutical companies in Germany (B. FRIEDMANN, Kräuter Mix GmbH, pers. comm.). However, Kräuter Mix also re-exports *Harpagophytum* spp. raw material on request, e.g. to the UK (B. FRIEDMANN, Kräuter Mix GmbH, pers. comm.).

### **Schwabe GmbH**

Schwabe has not been willing to provide any information on the company's trading activities (SCHMIED, Dr. Willmar Schwabe GmbH & Co.).

### **Flachsmann AG Germany**

The company produces extracts from the *Harpagophytum* spp. raw drug imported. These extracts are traded on the market (SCHMITZ, Flachsmann AG Germany, pers. comm.); however it remains unclear to which companies the extracts are sold.

In addition to these importing companies active in re-exporting devil's claw raw drug or semi-processed products and in the intermediate trade within Germany, an unknown number of other trading and producing companies is involved in the intermediate trade within Germany.

## **5.3 Production of Finished Herbal Products Containing *Harpagophytum* spp.**

The German market of finished herbal products containing *Harpagophytum* spp. is complex. Currently, 57 pharmaceutical products marketed by 46 different companies are sold (cf. Annex 10.1). Most companies obtain their material (and occasionally even the finished products) from either the importing companies, the extract producers or from other companies producing on a licence basis. As a result, it is often difficult for the companies to trace back the chain-of-custody in order to be able to clarify whether or not the raw material had been sourced from sustainable harvesting. Some examples to illustrate this:

- a. The company '**Roha Arzneimittel GmbH**' (further on abbreviated 'Roha') sells one devil's claw product (Zirkulin Teufelskralle Kapseln N; see Annexes 10.1 and 10.2) on the German market. However, this product is not produced by 'Roha' themselves, but by '**Swiss Caps AG**'. Therefore, 'Roha' does not know which extract is used for the production of the medicine and consequently it is impossible to determine how and where the raw material had been sourced. However, as 'Roha's' quality tests show, the product contains both *Harpagophytum procumbens* and *H. zeyheri*, which are sourced from wild-collection (P. BULLERMANN, pers. comm.).
- b. '**Strathmann AG**' is the second-most successful company on the German devil's claw market, especially with regard to their product 'Jucurba' (A. ZIRZOW, Strathmann AG, and D. v. WILLERT, University of Münster, pers. comm.). Strathmann AG does not produce its own products but obtains them from **Extrakt Chemie** that processes the imported dried raw material. However, it remains unclear what quantities are purchased by Strathmann AG (cf. chapter 5.2), what quantity Extrakt Chemie directly imports from the source countries and how much is obtained from the **Martin Bauer**

- Group.** Extrakt Chemie refused to clarify this question. Strathmann AG advertises the sourcing of sustainably harvested devil's claw drugs in its brochures and on the website, where CRIAA's sustainability project is presented (e.g. DREXELIUS & RÜCKERT, year n.a.), although obviously Strathmann AG's sustainably harvested drugs are not obtained from the harvest relating to the CRIAA project but from **Salus-Haus** (A. ZIRZOW, Strathmann AG, pers. comm.). In fact, the share of sustainably harvested *Harpagophytum* spp. raw material in Strathmann AG's total devil's claw consumption may be only small.
- c. **Bad Heilbrunner Naturheilmittel GmbH & Co.** (further on abbreviated 'Bad Heilbrunner') purchases the *Harpagophytum* spp. medicines it sells on the German market from **Astrid Twardy GmbH**. Astrid Twardy GmbH had produced these preparations on its own until mid-2002. Since then, Astrid Twardy has obtained the products from **Extrakt Chemie** (DITTRICH, Bad Heilbrunner, pers. comm.; SCHRÖDER, Astrid Twardy, pers. comm.). The percentage of sustainably harvested or possibly certified *Harpagophytum* raw drug is difficult to assess.
- d. **Lichtwer Pharma AG** (further on abbreviated 'Lichtwer') obtained the devil's claw raw material from their own cultivation project in Namibia, which provided almost all source material for the company's devil's claw product 'Revoltan Filmtabletten', almost 95% of which had been sold in Germany, the Netherlands and the UK. (EFFENBERGER, Lichtwer, pers. comm.) However, Lichtwer has recently sold its cultivation project and the product for the domestic market, most probably to Martin Bauer GmbH. The company, however, has still kept the international market and now obtains the raw material from Martin Bauer's extract facilities Finzelberg (EFFENBERGER, Lichtwer, pers. comm.).

With regard to the production of finished herbal medicine and other products derived from *Harpagophytum* spp., the pharmaceutical market cannot be clearly separated from the non-pharmaceutical market. Some of the products, such as 'Sanhelios Teufelskralle Kapseln N' (Börner GmbH, Berlin), are produced for both markets and sold in pharmacies as well as in drugstores. According to the authors' estimates, at least 20-30 different 'soft pharmaceuticals' and teas or tea-mixtures based on *Harpagophytum* spp. are produced for the German non-pharmaceutical market (cf. annex 10.2); the exact number is difficult to assess, because the majority of these products is not officially listed.

#### 5.4 Retail Trade

In the mid-1990s, the African devil's claw became a 'fashion drug' against degenerative diseases of joints and bone articulation (U. EILERT, Schulbiologiezentrum Hannover, pers. comm.). At first, devil's claw medicine was almost exclusively sold as accredited medicinal preparations in pharmacies. In recent years, the market has more and more been shifting towards selling devil's claw products as 'soft pharmaceuticals' in health food stores, drugstores and supermarkets. Possible reasons for this development are:

- Aggravation of the pharmaceutical licensing in EU-countries since 2001. For many pharmaceutical producers, the production of such a product does not pay any more, because licensing is a costly process (MANG, Alsitan GmbH & Co. KG, pers. comm.).
- Auto-medication increases due to cuts in the reimbursement of the costs for medicine by German health insurance companies (U. EILERT, Schulbiologiezentrum Hannover, pers. comm.).

It is almost impossible to assess financial turnover and sales figures of the German retail trade in *Harpagophytum*-products (U. EILERT, Schulbiologiezentrum Hannover, pers. comm.). According to the authors' research, the *Harpagophytum*-products achieving the highest sales

figures at the German market are - among the over-the-counter drugs – **Ratiopharm GmbH's** 'Teufelskralle-ratiopharm Filmtabletten' and – among the behind-the-counter drugs – 'Jucurba' from **Strathmann AG** (U. BREIDER, Ratiopharm, A. ZIRZOW, Strathmann AG, and D. V. WILLERT, University of Münster, pers. comm.).

#### 5.4.1 Pharmaceutical Market

The pharmaceutical market for *Harpagophytum* products is comparatively easy to assess except for when it comes to sales figures. The strict criteria and processes for obtaining a licence to sell a product on the German pharmaceutical market (cf. chapter 6.1) help to increase the transparency of this sector. The presently 57 *Harpagophytum* medicines produced by 46 different companies and licensed for the German pharmaceutical market are mostly sold in pharmacies. Many pharmacies, however, do not only offer these pharmaceuticals, but also products designed for the non-pharmaceutical market.

#### 5.4.2 Non-Pharmaceutical Market

During the last two years, the market for *Harpagophytum* spp. products has obviously experienced a shift from the pharmaceutical sector with products almost exclusively available in pharmacies to an open market expanding into the territory of drugstores and supermarkets, being sold as 'traditional pharmaceuticals' (MANG, Alsitan GmbH & Co. KG, pers. comm.).

Today, devil's claw products can be found in German drugstores like '**IDEA Drogerie**', health food stores like '**Neuform**' and supermarkets like '**ALDI**'. As a consequence, some devil's claw products have entered mass-production. ALDI has started to sell its sole devil's claw product, 'St. Benedikt Teufelskralle-Kapseln' produced by **Pro Dimi Markenprodukte GmbH & Co.**, in early 2001 (KELLER, Pro Dimi Markenprodukte GmbH & Co., pers. comm.). This could mean a new dimension for the sales figures of *Harpagophytum* products, because large wholesalers such as ALDI sell almost exclusively goods produced in mass-production.

According to **KD - Kaiser's Drugstore GmbH**, which offers three *Harpagophytum* products for sale in KD-shops, the non-pharmaceutical market for devil's claw products is still moderately but continuously growing (SCHULTE, KD Kaiser's Drugstore GmbH, pers. comm.).

#### 5.4.3 Veterinary Pharmaceutical Market

Veterinary medicine is a special – and most probably a niche – market for *Harpagophytum* spp. products. Veterinary pharmaceutical products do not have to be produced in compliance with the monograph of the European pharmacopoeia. They are often traded as fodder supplements for animals (G. ALBER, Navalis Nutraceuticals, pers. comm.). The number of products containing African devil's claw and having exclusively been developed for the veterinary pharmaceutical market is limited. In the official 'Delta Index' of veterinary pharmaceutical products in Germany, only two products containing *Harpagophytum* spp. are listed (see annex 10.3). This index does not claim to provide exhaustive information, therefore a number of additional products containing African devil's claw can be suspected. Further products are used in animal homeopathy (G. ALBER, Navalis Nutraceuticals, pers. comm.; see e.g. SCHNEIDER 2002).

However, numerous *Harpagophytum*-preparations originally developed for the market in human medicine are also used in veterinary medicine (G. ALBER, Navalis Nutraceuticals, pers. comm.). As in human medicine, the main applications are degenerative diseases of the

joints and bone-articulation. For the production of veterinary medicine, the drug need not be in conformity with the provisions of the respective pharmaceutical monograph; therefore, often lots were used that had a high percentage of *H. zeyheri* admixture (G. ALBER, Navalis Nutraceuticals, pers. comm.). The annual quantities of *Harpagophytum* raw material used to produce veterinary pharmaceutical products in Germany is unknown.

## 5.5 Market Trends

### 5.5.1 Pharmaceutical Market

The German pharmaceutical market for *Harpagophytum* spp. products does not seem to be growing any more. 'Roha' states that the sales figures of their sole devil's claw product, Zirkulin Teufelskralle Kapseln N, stagnated and now decrease (P. BULLERMANN, Roha Arzneimittel GmbH, pers. comm.). The demand for some *Harpagophytum* products has proved to decrease once they are not actively advertised any more (MANG, Alsitan GmbH & Co. KG, pers. comm.). The sales figures of **Alsitan GmbH & Co. KG's** (further on abbreviated 'Alsitan') *Harpagophytum* products have recently decreased (MANG, Alsitan, pers. comm.). The **Martin Bauer Group** also states that there was an increase in the market for *Harpagophytum* spp. pharmaceutical products until 2000/2001 but the market has stagnated since last year (H.-J. HANNIG, Martin Bauer GmbH & Co. KG, pers. comm.). This is at least partly explained by the stricter licensing procedures applied since 2000, which has increased the price of licensing for the companies (MANG, Alsitan, pers. comm.).

The leader of the German *Harpagophytum* spp pharmaceutical market, Ratiopharm GmbH, regards the African devil's claw market a typical 'trend market' (U. BREIDER, Ratiopharm GmbH, pers. comm.), a view which is supported by U. EILERT (Schulbiologiezentrum Hannover, pers. comm.). During the last 2-3 years, Ratiopharm's increase in *Harpagophytum* sales figures was enormous. At present, the product sales have stagnated and the market seems to be saturated (U. BREIDER, Ratiopharm GmbH, pers. comm.). According to Ratiopharm GmbH, the zenith of the development of *Harpagophytum* product sales figures on the German market has most probably been reached (U. BREIDER, Ratiopharm GmbH, pers. comm.). This estimate is based on market research data which reveal this trend.

According to other companies, however, a further slight increase of the demand can be prognosticated (R. FRANKE, Salus-Haus, pers. comm.).

### 5.5.2 Non-Pharmaceutical Market

As described above, the market for *Harpagophytum* products has shifted from the pharmaceutical market to the non-pharmaceutical market in recent years (MANG, Alsitan, pers. comm.). Most of the products developed for the non-pharmaceutical market seem to be successfully sold under the denomination of 'traditional pharmaceuticals' (cf. chapter 6.1), and some have recently entered mass-production being sold in big drugstore or supermarket chains like ALDI, Schlecker or IDEA Drogerie (cf. chapter 5.4.2).

**KD - Kaiser's Drugstore GmbH** state that the annual turnover in their *Harpagophytum* products is still increasing, and that 'Zirkulin' is their *Harpagophytum* product, for which the highest demand can be observed (SCHULTE, KD Kaiser's Drugstore GmbH, pers. comm.). A further increase in sales is expected.

A further trend of *Harpagophytum* spp. products shifting from the pharmaceutical and non-pharmaceutical medicines sector to the 'supplements' sector is regarded as unlikely (SCHRÖDER, Astrid Twardy GmbH, pers. comm.). According to SCHRÖDER (Astrid Twardy

GmbH, pers. comm.), supplements can be much faster developed and introduced to the market, but most probably devil's claw products would not be accepted as supplements, as they have always been applied in a medicinal context. So far, none of the authors' interlocutors knew of any devil's claw tea or tea-mixture being sold as 'supplement', but several experts could imagine such a produce (H. SCHILCHER, ZÄN and BAMBECKER, Hevert Arzneimittel GmbH & Co. KG, pers. comm.).

## 6 Licensing and Certification of Devil's Claw

### 6.1 'Traditional Pharmaceuticals' and Relating Legal Provisions

Contrary to the legal provisions in most other countries, the German legislation has earmarked certain 'soft' phyto-pharmaceutical products that have been in traditional use for a long time for being sold at the non-pharmaceutical market (MANG, Alsiton GmbH & Co. KG, pers. comm.). These pharmaceuticals are called 'traditional drugs' ('traditionelle Heilmittel').

The **German Medicines Law** ('Arzneimittelgesetz') basically regulates that pharmaceutical products have to be sold in pharmacies, even though herbal pharmaceuticals are mostly no prescription drugs (AESGP 1998). Exceptions are made for such pharmaceutical products (AESGP 1998) that:

- 1) are marketed exclusively for purposes other than curing or alleviating illnesses, injuries, aches and pains (Medicines Law, Article 44, Paragraph 1) or
- 2) contain specific substances without risk (Medicines Law, Article 44, Paragraph 2) such as natural or non-natural curative waters and salts (Sentence 1), healing earth [...] (Sentence 2) and plants and parts of plants or mixtures or distillates thereof as well as saps from fresh plants or plant parts if extracted without solvents except for water (Sentence 3).

Within the framework of the 5<sup>th</sup> amendment to the German Medicines Law, Article 109a has been amended resulting in a facilitated re-licensing procedure for traditionally used medicine, comprising a large group of herbal medicinal products. According to the German Medicines Manufacturers Association (BAH), several lists with more than 800 substances have been acknowledged by a special commission (BAH 2003). These lists are published by the Federal Institute for Drugs and Medicinal Products (BfArM); the areas of application are indicated by the addendum 'traditionell angewendet' (traditionally applied) (BAH 2003; German Medicines Law, Article 109a, Paragraph 3). According to SCHRÖDER (Astrid Twardy GmbH, pers. comm.), products can be re-licensed under the 'traditionally applied' provision if they were on the market before 1976 and, possibly, if it concerns products sold in GDR (former German Democratic Republic). The concentration of active agents is usually reduced in these products. **Astrid Twardy GmbH** sells one *Harpagophytum* product through its subsidiary **Renatura** on the non-pharmaceutical market under the 'traditionally applied' provision (SCHRÖDER, Astrid Twardy GmbH, pers. comm.).

### 6.2 *Harpagophytum* spp. in the European Pharmacopoeia

The first of the two devil's claw species used in Europe and listed in the European Pharmacopoeia was *Harpagophytum procumbens* (cf. annex 10.4).

In 2001, the **Martin Bauer Group** has started to push the pharmaceutical licensing for *Harpagophytum zeyheri* in the European pharmacopoeia (D. v. WILLERT, University of Münster, pers. comm.). The drive was explained by the fact that in reality both species are mixed in many devil's claw products and that at the time when *H. procumbens* had been licensed, both species could not be or were not differentiated (D. v. WILLERT, University of Münster, pers. comm.). This request has been approved; *Harpagophytum zeyheri* has officially listed in the European pharmacopoeia (Pharmeuropa 2002) on January 1, 2003 (B. KELLER, BfArM, pers. comm.). The listing has officially been substantiated by the need to cover all *Harpagophytum* products on the market and to meet the fact that the drug of the two different species cannot easily be distinguished by a botanical identification

(Pharmeuropa 2002). In fact, the percentage of *H. zeyheri* in mixed dried raw material imports has obviously increased over the last couple of years (B. FRIEDMANN, Kräuter Mix GmbH, pers. comm.). The potential consequences of this listing are discussed in chapter 8.2.

### 6.3 Certification of Wild-Harvested African Devil's Claw

Certification is a procedure by which written assurance is given that a product, process or service is in conformity with certain standards (ISO/IEC 1996, cited in WALTER 2002). According to WALTER (2002), four different categories of certification schemes have mainly become important for non-wood forest products: 1) **Organic Certification**; 2) **Product Quality Certification**; 3) **Social Certification**; and 4) **Forest Management Certification**. With regard to the devil's claw, it is mainly organic certification and product quality certification, which are at present of prime importance, at least from the German point of view. In the source countries, social certification may play a certain role as well given the fact that the devil's claw is chiefly collected by poorer groups in society, with a considerable percentage of tribal population. In addition, **Management Certification** schemes such as ISO 9000 may be of some importance for German companies. This chapter seeks to analyse – with regard to *Harpagophytum* spp. – the *status quo* of certification schemes already in operation and the certification schemes desired by German companies and / or the German market(s).

#### 6.3.1 Organic Certification

Organic certification with relevance to the European market is usually carried out in compliance with the provisions and standards of the Council Regulation on Organic Farming (EEC) No. 2092/91 of the European Union. Some international certification organisations also certify according to the US-standard 'National Organic Program' (NOP). Some of these companies have their own inspectors or inspection teams in South Africa (such as IMO and ECOCERT), checking on collectors and trade flow (U. HELBERG, pers. comm.).

The actual percentage of organically certified devil's claw material is a controversial issue. Whereas most experts state that the certification of *Harpagophytum* spp. sourcing is still relatively uncommon, the Martin Bauer Group estimates that about 50% of the material entering the German market has been certified (H.-J. HANNIG, Martin Bauer GmbH & Co. KG, pers. comm.). Maybe these 50% should reflect all material that has either been certified or sourced from sustainable harvesting with criteria equalling those of organic certification.

Most internationally renowned certification organisations are not involved in the certification of *Harpagophytum* spp. sourcing, trade or production of medicine (e.g. INAC). To the knowledge of the authors, only two projects relating to the sustainable wild-harvesting of *Harpagophytum procumbens* include an acknowledged certification.

1. The first project comprises the wild-collection of the African devil's claw on about 10,000 ha farmland in North-Western RSA, which has been certified for the **Martin Bauer Group** by **ECOCERT** (H.-J. HANNIG, Martin Bauer GmbH, pers. comm.). The annual harvest yield from this pilot project sums up to about 10 tonnes dried raw material (R. ORDOWSKI, ECOCERT International, pers. comm.).
2. The second project has been initiated by the service NGO CRIAA. Its 'Sustainably Harvested Devil's Claw Project' (SHDC) includes an 'Organic Certification' by **Soil Association (UK)** (COLE & DU PLESSIS 2001; E. SCHNEIDER, pers. comm.). The 'CRIAA-Standard' of production also takes care of activating and guaranteeing benefit sharing mechanisms. It remains unclear which importing company purchases the certified drugs from this project. According to B. DICKSON (FFI, pers. comm.) the

annual harvest yields from this project are presently very low and may not exceed 3 tonnes.

No further certification of devil's claw sourcing and trade is known of. Possible reasons will be discussed below (cf. chapter 8.3). Almost all *Harpagophytum* spp. raw material imported by Salus-Haus supposedly originates from sustainable wild-collection. However, the sourcing is not certified (R. FRANKE, Salus-Haus, pers. comm.). E. SCHNEIDER (pers. comm.) states that there is a number of small traders in Namibia who organise sustainable wild-collection of *Harpagophytum procumbens*. However, the majority of these traders are almost unknown to the public, because they do not have the financial means (unlike CRIAA) to advertise their sustainably sourced raw material or go for certification.

According to HELBERG (Helberg Consult, pers. comm.) the certification process for the sustainable wild-harvesting of *Harpagophytum procumbens* is too costly to be considered by most trading companies.

### 6.3.2 Product Quality Certification and Management Certification

The (German) pharmaceutical market has its own, rather strict rules with regard to product quality certification. It works on basically two levels: on the company level and on the product level. Every company producing pharmaceuticals in Germany is obliged to have a licence called 'Herstellungserlaubnis' (**operating or producing licence**; German Medicines Law, Article 13). The prerequisites to obtain the licence depend on a variety of factors, such as the qualification of the head of production and the equipment of production facilities. The specifications required for a standard pill for instance are less strict than for the production of sterile medicine (MANG, Alsitan, pers. comm.). Not only prescription drugs but also OTC-drugs are subject to have a production licence (H. SCHILCHER, ZÄN, pers. comm.).

The licensing is in the hand of the provincial bureaus of investigation ('Landesuntersuchungsbehoerden') affiliated with the provincial governments. The umbrella association of these bureaus of investigation is the German Federal Institute for Pharmaceuticals (BfArM).

The operating licence is a management certification scheme specific to the pharmaceutical sector and independent of **ISO 9000** (MANG, Alsitan, pers. comm.). However, the certification scheme covers all the requirements to be met for obtaining an ISO 9000 certification. For this reason, an additional certification according to ISO 9000 is redundant (H. SCHILCHER, ZÄN, pers. comm.). Nonetheless, some pharmaceutical companies (such as e.g. Strathmann AG) are getting certified according to ISO 9000 due to marketing reasons (MANG, Alsitan, pers. comm.).

On the product-level, the **drug monographs** have to be primarily considered. These are either published in the European pharmacopoeia or in the German pharmacopoeia ('Deutsches Arzneibuch'). *Harpagophytum procumbens* has first been listed and described in the German pharmacopoeia and later been adopted by the European pharmacopoeia. *Harpagophytum zeyheri* has been listed in the European pharmacopoeia in 2002 (cf. chapter 6.2). In the pharmacopoeia(s) the crucial quality characteristics such as the concentration of active substances, concentration of coliforms, aflatoxins or other contaminations are regulated. The drugs used for the production of a pharmaceutical product have to be compliant with the monograph; only then the pharmaceutical product gets the certificate to be sold on the market (B. FRIEDMANN, Kräuter Mix GmbH, pers. comm.). The manufacturing process of a product has to be described in detail upon applying for a product licensing; this process has to be kept for production once the licence has been issued (B. FRIEDMANN, Kräuter Mix GmbH and MANG, Alsitan, pers. comm.).

An analysis documenting the compliance of the drug with the monograph is sometimes already provided by the contractor. These analyses have to be carried out by an accredited laboratory that has to have a licence to do the analyses. Another option for producing companies is to obtain lot-samples from the trader(s) and carry out the quality control tests in their own laboratories (MANG, Alsitan, pers. comm.).

Another category of certification schemes are 'good practices' guidelines such as **GMPs** (Good Manufacturing Practices) or **GLPs** (Good Laboratory Practices). These schemes relate to product or production quality. The respective guidelines are issued by various organisations, such as WHO. These guidelines are – as such – of minor importance to most German pharmaceutical companies, because the only document that is officially acknowledged is the operating / production licence (H. SCHILCHER, ZÄN, pers. comm.). However, GMPs and GLPs do have a certain influence, because these standards are expected to be met for the assignation of an operating and production licence (BfArM).

Good practices guidelines relating to product quality do also comprise those guidelines that aim at the product quality of the sourced raw drug (also called 'starting material'). Several relevant guidelines have been or are being developed, among these the European Good Agricultural Practices (**GAP**) guideline "Points to consider on Good Agricultural and Collection Practice for Starting Materials of Herbal Origin", developed and issued by the European Agency for the Evaluation of Medicinal Products (EMEA) and WHO's **GACP** guidelines (Good Agricultural and Field Collection Practises for Medicinal Plants), the target publication date of which is late 2003 (EMEA 1999; WHO in preparation). These guidelines concentrate on product quality, but they also include some – few – provisions on social and ecological sustainability issues. These guidelines have in common that they are no legally binding documents, but rather voluntary reference lists for companies relating to best handling and sourcing practices.

In 2002, the German Medicines Manufacturers Association (BAH – Bundesverband der Arzneimittelhersteller) has developed an **audit scheme** for its members. This audit scheme tries to translate the basic ideas and 'points to consider' of the EMEA guideline into action. It is made up of a catalogue of questions the importing company should ask its contractor in the source country in order to improve sourcing conditions and methods and, as a result, product quality. This 'Standard Process Instruction for an Audit Scheme on the Cultivation and Collection of Medicinal Plants' has been developed by representatives of German pharmaceutical companies trading in medicinal plants, with the collaboration of the German Federal Agency for Nature Conservation (BfN), WWF Germany and TRAFFIC Europe. Among these companies were also some importing companies of *Harpagophytum* spp. raw material, namely Martin Bauer GmbH and Kräuter Mix GmbH. The main target of the audit scheme is also product quality, but the concerns of nature conservation are more explicitly addressed than in the comparable EMEA guideline. The final document of the audit scheme will be shortly available for BAH members and its publication is envisaged (B. STEINHOFF, BAH, pers. comm.).

#### 6.4 Demand and Potential

Evidently, the pharmaceutical industry has a certain demand for certified *Harpagophytum* spp. material. Despite the demand, some producers (e.g. **Navalis Nutraceuticals**) have so far not taken steps to include devil's claw medicals or teas in their production line, because of the uncertainty involved in the sourcing of the raw material and the lack of guarantees to certify that the drug originates from sustainable harvesting (G. ALBER, Navalis Nutraceuticals, pers. comm.). Other producers (e.g. Salus-Haus, Strathmann AG) advertise that their

*Harpagophytum* raw material was sourced from sustainable wild-collection; however, this material has either not or most likely not been certified. Strathmann AG has one of the most successful devil's claw medicines on the market ('Jucurba') and claims that the sustainable sourcing of the drug is very important for the company ('Jucurba' advertising flyer, edited by Strathmann AG); however, the company procure all of its *Harpagophytum* material from one intermediate trader and the source of this material is unknown.

According to **Salus-Haus**, bio-certification of devil's claw is too expensive and hardly worthwhile to consider given the fact that in Germany it is not legal to advertise such a certification upon the sale of pharmaceutical products (R. FRANKE, Salus-Haus, pers. comm.). The relevant provisions are regulated in the 'Heilmittelwerbeengesetz' (German Law on Advertising Drugs). Amongst other provisions, it is not authorised by the law in force to advertise in public medicinal products through certificates, and scientific or expert publications or respective indications (Article 11, German Law on Advertising Drugs).

Despite the disadvantage of higher costs for training, controlling and certification, large companies like the **Martin Bauer Group** prognosticate an increase in the demand for certified *Harpagophytum* spp. raw material and products over the next couple of years (H.-J. HANNIG, Martin Bauer GmbH & Co. KG, pers. comm.). An increase in the share of certified devil's claw material will, according to the Martin Bauer Group, most probably have no significant effect on the company's profit margin and the structure of trade; higher procurement costs will be compensated by higher retail prices (H.-J. HANNIG, Martin Bauer GmbH & Co. KG, pers. comm.).

## 7 Cultivation of *Harpagophytum procumbens*

The cultivation of the African devil's claw has been tried several times, but these efforts had to face considerable obstacles and they still do. A fundamental problem in cultivating *Harpagophytum* spp. is its extremely low germination rate (DE JONG 1985, cited in KUMBA et al. 2002). Therefore, it was tried to propagate the species through slippings. Specimens propagated that way did, however, not produce primary roots and could therefore only be harvested once (D. v. WILLERT, University of Münster, pers. comm.). At the University of Durban, a working group tried to propagate *Harpagophytum procumbens* through cell-cultures. The experiment produced about 50,000 plants, however again without the formation of primary roots (D. v. WILLERT, University of Münster, pers. comm.). A disadvantage of this method may also be its high operating costs and the required inurement of the seedlings before planting (D. v. WILLERT, University of Münster, pers. comm.).

At the Institute of Ecology at the University of Münster, Germany, the working group of Prof. von Willert succeeded to break the inhibition of germination through the application of gibberellic acid. Generative propagation was possible that way; almost 100% of the seedlings took root (D. v. WILLERT, University of Münster, pers. comm.). The institute initiated a cultivation project on a farm in RSA, where *Harpagophytum procumbens* has been cultivated in co-operation with the German GTZ and Salus-Haus (Harpago-Avontuur 2000). The aim of the project was to establish the cultivation in rural areas outside the range of rich farms (D. v. WILLERT, University of Münster, pers. comm.). The project aims at the production of the drug directly in or in the vicinity of poorer settlements in order to create a direct income for the local population and improve the working conditions. In this region, the wild harvesting of devil's claw has mainly been carried out by women who have to cover distances of up to 20 kilometres on foot to reach the area where the devil's claw grows. Another focus of the project is laid upon efforts to establish a cultivation method of devil's claw without irrigation (OLIVIER et al. 2000; v. WILLERT et al. 2002), which is especially important in semi-arid areas, because one recurrent point of criticism was the usually high consumption of water for such cultivation projects. D. v. WILLERT states that the yield per plant could be increased by 8-10 times and that the drug could be harvested all year. According to estimates of R. FRANKE (Salus-Haus, pers. comm.), the increase in harvest yield is lower than 8-10 times; he states, that the tubers increase their volume if the water supply is higher, the content of harpagosid, however, reduces.

Meanwhile, Salus-Haus and GTZ are not actively involved in this project any more, after the end of the fixed-term PPP-project (D. v. WILLERT, University of Münster, pers. comm.). Subsequently, problems with the intermediate financing had occurred; as it takes at least three years before the cultivated plants can be harvested, the local population would have to have been financially supported during the first years of the project, for which no donor could be found (D. v. WILLERT, University of Münster, pers. comm.). Today, the harvest yields from this project of about 30-40 tonnes of devil's claw raw material are directly exported to **Salus-Haus** (20 tonnes; R. FRANKE, Salus-Haus, pers. comm.) and to **Extrakt Chemie** (10-20 tonnes; D. v. WILLERT, University of Münster, pers. comm.). However, also **Bioforce AG**, Switzerland, claims to import from this cultivation project parts of the company's demand in devil's claw raw drug (A. Ryser, Bioforce AG, pers. comm.). It remains unclear if these are direct imports of raw material or if extracts are obtained from Salus-Haus.

The Martin Bauer Group co-operates with Grassroots Phytomed, Kapstadt in RSA (D. v. WILLERT, University of Münster, pers. comm.). Martin Bauer GmbH estimates that the market share of both *Harpagophytum* spp. raw material sourced from cultivation and for certified material will increase over the next couple of years (H.-J. HANNIG, Martin Bauer GmbH & Co. KG, pers. comm.).

It remains unclear at this stage whether (H.-J. HANNIG, Martin Bauer GmbH & Co. KG, pers. comm.) or not (D. v. WILLERT, University of Münster, pers. comm.) there is a cultivation project for *Harpagophytum* spp. that has obtained a certification for organic production in Namibia or RSA. BERG & GENSTHALER (2001) mention that the cultivation project of George Betti on the Eahero Farm (Okahanja) in Namibia has been certified according to the provisions of the EU-Regulation. Both H.-J. HANNIG (pers. comm.) and D. v. WILLERT (pers. comm.) suppose that it will not be difficult to obtain such a certification if needed. The total market share of certified devil's claw material sourced from cultivation is unknown (H.-J. HANNIG, Martin Bauer GmbH & Co. KG, pers. comm.). It may be estimated at between 10 and 20 %.

Cultivation of medicinal plant species is usually an interesting option for the companies involved in the production of herbal medicine. However, cultivation always involves a number of risks, such as social hardships for marginalized people who had collected plants from the wild and are suddenly faced with the fact that the wild-collected material doesn't sell any more (LOMBARD & DU PLESSIS 2003). This and other risks of cultivation will be discussed in chapter 8.4.

## 8 Discussion and Conclusions

### 8.1 Import of *Harpagophytum* spp. Raw Material into Germany

As the analysis of the current import volumes of *Harpagophytum* spp. into Germany shows (cf. chapter 5.1), the trade in these species is still not transparent. Most importing companies are reluctant to provide any data relating to exact import or export volumes of *Harpagophytum* spp. In addition, the discrepancies in data and estimations are considerable, as it is reported from previous trade reports on *Harpagophytum* spp. in Germany (SCHIPPMANN 2002). Most importing companies purchase the raw material from Namibia but an increasing volume seems to be imported from RSA. An increase from an annual 6 to 95 tonnes has been reported for the period 1999-2001 (SCHIPPMANN 2002). However, LOMBARD & DU PLESSIS (2003) estimate the quantity of *Harpagophytum* raw drug actually harvested in RSA at below 50 tonnes per year. Consequently, the rest of RSA's exports are in fact re-exports of raw material sourced in and imported from Namibia or Botswana.

It is very difficult to find out if the information on the current import figures (cf. tab. 1) provided by the companies is true or not. In the case of Martin Bauer GmbH, the reported 200 tonnes seem to be rather low. But these data can, as other trade figures on *Harpagophytum* spp. imports, not be proven and verified because Germany has still no trade monitoring system for *Harpagophytum* (SCHIPPMANN 2002) and the permit system in Namibia also seems to cover only part of the actual quantities harvested and exported. Countries like Switzerland do not appear in *Harpagophytum* trade statistics although the German company Flachsmann AG obviously purchases devil's claw raw drug from a Swiss importing company.

Taking all these uncertainties into account, it may be safe to conclude that Martin Bauer's estimate with regard to the annual German *Harpagophytum* import volume of 300 tonnes is considerably too low and D. v. WILLERT's estimate of 650 tonnes is almost certainly too high (cf chapter 5.1). In 2002, the actual import quantity has most likely been in the magnitude of the previous year's figures, which means around 500-550 tonnes.

### 8.2 Listing of *Harpagophytum zeyheri* in the European Pharmacopoeia

The official licensing of *H. zeyheri* is a very recent development and could have a significant impact on the sourcing of and trade in African devil's claw. Experts discuss the potential consequences of this development controversially. It may even be questionable if the official listing of the species is legally correct, because it refers to the monograph of *H. procumbens*, which, however, does not mention *H. zeyheri* (E. SCHNEIDER, pers. comm.).

In terms of sustainability of devil's claw sourcing and trade, negative consequences of the listing of *H. zeyheri* could be:

1. The species still lives in rather large populations in Northern Namibia and in the southern parts of Angola. Unsustainable harvesting of the poverty-stricken majority of people living in southern Angola could lead to a fast over-exploitation of *H. zeyheri*, which is cheaper than *H. procumbens* and therefore very attractive to German importing and producing companies.
2. The potential increase in sourcing *H. zeyheri* could force down the market price of *H. procumbens* and consequently endanger the efforts to establish sustainable sourcing methods and fair trade principles in *Harpagophytum procumbens* wild-collection projects in Namibia and RSA (E. SCHNEIDER, pers. comm.).

3. *H. zeyheri* seems to have a lower concentration of harpagoside compared to *H. procumbens* (although the final scientific proof of a lower medicinal efficacy of *H. zeyheri* is still lacking; E. SCHNEIDER, pers. comm.). The species can therefore either be used as an admixture to pharmaceutical products based on *H. procumbens* or it could be used for the non-pharmaceutical market, where demands relating to pharmaceutically active agent concentrations are lower. For these reasons, *H. zeyheri* could become even more interesting for the German importers and medicine producing companies as the market of *Harpagophytum* products in Germany seems to shift from the stagnating or decreasing pharmaceutical market to the increasing non-pharmaceutical market (cf. chapter 5.5).

Positive aspects of the listing of *H. zeyheri* could be:

1. The harvesting pressure on *H. procumbens* in some regions of Namibia and RSA may decrease following a potential increase in the sourcing of *H. zeyheri*.
2. The knowledge gained from projects on the sustainable sourcing of and trade in *Harpagophytum procumbens* could be transferred to similar projects on the sourcing of and trade in *H. zeyheri* in the North of Namibia, in Angola or other range states, which would enable the local population in these regions to participate in such projects based on sustainable sourcing and benefit sharing.

Rumors say that a reaction to the listing of *H. zeyheri* can be observed and that van-loads of raw material are shipped from Angola and Northern Namibia to the traders in the South. However, the further development in the sourcing of *H. zeyheri* will strongly depend on the market development in consumer countries such as Germany. If the pharmaceutical market for devil's claw products decreases further and the German non-pharmaceutical market is able to keep its boom going for a while, it is possible that *H. zeyheri* will soon be preferred by parts of the trade market. If the devil's claw boom has reached its peak in Germany, *H. zeyheri* will probably not be an interesting alternative for the trading and pharmaceutical companies, unless other markets for products with reduced pharmaceutical requirements can be opened and developed, provided it is legal to use larger amounts of *H. zeyheri* in the products on these potential markets.

### 8.3 Potential of Certification of Products Based on *Harpagophytum* spp.

#### 8.3.1 Organic Certification

Certification, namely 'bio-certification', has become a buzzword in Germany in recent years. Many different kinds and forms of certification have since sprung up, making it occasionally difficult even for experts to keep track of the developments. So far, organic certification of devil's claw wild-harvesting in the source countries is rather the exception than the rule (cf. chapter 6.3). One of the most important reasons may be that organic certification is costly: several thousand US dollars have to be paid for the certification of one project (U. HELBERG, Helberg Consult, pers. comm.). In addition, most exporters charge an extra sum for trading in certified raw material, because of the additional work required for compulsory documentation. If a site or a project only yields smaller quantities of tradable raw material, obtaining a certification is not cost-effective for the companies; from the economical point of view, the costs for certification should not exceed 2% of the turnover achieved with the certified material (U. HELBERG, Helberg Consult, pers. comm.). Therefore, companies like Salus-Haus, for which the sustainable sourcing of the raw material used for production is very important and part of the company's policy, have decided to avoid an 'official' organic certification scheme, and rather invest in controlling and guaranteeing that their material is obtained from sustainable sourcing; the criteria are as strict as those to be met for an organic

certification (R. FRANKE, Salus-Haus, pers. comm.). The company has developed a manual to train collectors and intermediate traders. The latter is important, because these traders are trained to distinguish dried primary roots from secondary tubers and to refuse buying primary roots. In addition, wild-collection intervals for each area are fixed at five years to allow full regeneration of the plants (R. FRANKE, Salus-Haus, pers. comm.).

Another problem occurring in the sustainable sourcing of African devil's claw from the wild is, according to U. HELBERG (Helberg Consult, pers. comm.), that the inspectors of certification companies usually control the collectors and the flow of goods. The populations of the species collected are mostly not assessed, either because it is too much work or because of the inspectors' lack of knowledge. Inspection and certification is also not able to prevent the intrusion of other (unregistered) harvesters into the collection area and the potentially unsustainable harvesting following such practices (U. HELBERG, Helberg Consult, pers. comm.). This seems to be a major problem also in devil's claw sourcing. There is a number of projects that promote the sustainable harvest of *Harpagophytum procumbens* in Namibia and RSA, but it is hardly possible to establish an effective monitoring and control system. Besides, the knowledge of the species, its population status and ecology based on scientific research is still insufficient (LOMBARD & DU PLESSIS 2003), a fact which has, amongst others, lead to the withdrawal of the 1999 proposal to list *Harpagophytum procumbens* on CITES Appendix II (CITES 2002; cf. chapter 8.5).

Organic certification, however, may also have a considerable potential. According to U. HELBERG (Helberg Consult, pers. comm.) and to several market analyses carried out in Europe, the demand for ecologically produced goods increases, especially in countries like Germany and Austria, where the share of goods based on organically certified starting materials is relatively high (about 2.3 %). An increase of this market by an annual 20% is expected over the next couple of years. However, this refers mainly to the food-market and probably less to the market for herbal medicine, as for medicinal products direct advertising of organic certification on product labels is prohibited by the German Law on Advertising Drugs (cf. chapter 6.4). A good potential for organic certification is already observed in teas and tea-mixtures, for which customers in Germany tend to demand 'bio-certification' more often than for other products (U. HELBERG, Helberg Consult, pers. comm.). As a result, the demand of organic certification of devil's claw may increase, because – contrary to the pharmaceutical market – the German *Harpagophytum* market for 'soft pharmaceuticals' like teas is still growing. Also large companies such as Martin Bauer GmbH estimate that the demand for organically certified devil's claw raw material will increase over the next couple of years (H.-J. HANNIG, Martin Bauer GmbH, pers. comm.). The trend in phyto-pharmaceuticals seems to favour organic certification (U. HELBERG, Helberg Consult, pers. comm.). This may become more realistic, if methods are found how to reduce the costs for certification to allow a cost-effective certification also for smaller projects and sites. Such a reduction could be achieved by an internal control system of the respective companies. 'Internal control system' means that the companies themselves are in charge of monitoring and controlling collectors, collection practices and flow of goods. The development of an audit scheme for the sustainable harvesting of medicinal plants developed by the BAH (cf. chapter 6.3) is a first step in this direction. The associated companies will have a kind of guideline which questions to ask and possibly how to develop respective questionnaires in order to assess the most important parameters for sustainable sourcing, including product quality, plant populations and sourcing areas and basic social criteria. If this system is ameliorated and stricter criteria introduced by the companies, certification may be less costly over the long term, because inspectors of the certification companies will only have to survey the controlling and monitoring activities performed by the companies.

Some European and North American companies even have developed their own organisation and sourcing criteria, which are occasionally stricter than what is required by the respective US-American/Canadian or EU regulations to be complied with. An example of a

company on the German market is 'Naturland' (U. HELBERG, Helberg Consult, pers. comm.; see also annex 10.6).

In short, there is a certain potential for organic certification of devil's claw starting materials, however with possible draw-backs to come. The chances for organic certification of *Harpagophytum* starting material can be increased if:

- the costs of certification can be reduced
- smaller companies succeed in forming associations for a 'joint certification'
- the demand of organically certified herbal medicine in consumer countries increases the way it is prognosticated.

Potential draw-backs for the organic certification of *Harpagophytum* starting material are:

- a success in the large-scale, commercial cultivation of *Harpagophytum procumbens*
- a further decrease in the demand of *Harpagophytum* products on the pharmaceutical market without a further increase of the non-pharmaceutical market
- a further decline in the natural populations of *Harpagophytum procumbens*
- a fast shift from the wild-collection of *H. procumbens* to *H. zeyheri* without establishing adequate sourcing structures

### 8.3.2 Product Quality Certification and Other Certification Systems

As described in chapter 6.3 there is a whole variety of possible certification schemes that are of potential interest to companies trading in botanicals and producing herbal medicine. The results of our research show that management certification according to ISO 9000 is of minor importance to the companies, because the German law requires an equivalent anyway and the ISO 9000 certification of companies in the source countries is of no obvious relevance for marketing issues or legal requirements.

Certification schemes relating to product quality such as 'good practices' seem to be of some importance. GLPs and GMPs have some influence on the development of legal provisions. 'Good practices' guidelines relating to sourcing of the raw material such as 'Good Agricultural Practices' (GAP) or 'Good Wild Collection Practices' (various abbreviations) seem to become increasingly important. In recent years, China, Japan, and the European Union have developed such guidelines and the World Health Organization (WHO) is about to develop a similar document. Product quality is a number one criterion for the pharmaceutical companies. Regulations on this issue have become stricter in recent years and the companies were forced to adapt. These product quality certification schemes have started to take also some ecological and social aspects of sustainability into consideration. These are usually still poorly addressed, but the awareness among most stakeholders involved in medicinal plants sourcing, trade and production gradually increases that ecological and social aspects of sourcing and trade are relevant parameters for product quality as well.

So it may be hoped that these guidelines be amended to better meet those issues. If this happens there is quite some potential in these 'soft' product quality guidelines, because they

can easily build a link towards organic certification systems and promote a participatory structure of these systems, where the companies themselves take over the responsibility for the monitoring and documentation of raw material sourcing. However, the real potential of these guidelines largely depends on the companies; the influence of the consumer and even of authorities is rather limited.

Social certification systems such as Fair Trade have not yet been widely recognized in many consumer countries such as Germany. Whereas environmental issues have been entering public awareness during the last 20 years, the idea of equal benefit sharing and Intellectual Property Rights is relatively new and it seems to be still less prominent in public perception. On the political level it appears to be a difficult issue for many governments and authorities in consumer countries, also in Germany. Consequently, there is still no need, neither any legal requirement nor a strong moral obligation, for most companies to react and consider fair trade and social responsibility as important. However, especially in products as the African devil's claw, the potential for such certification systems seems to be relatively high. First fair trade certification initiatives relating to *Harpagophytum* have already taken place (LEITH, year n.a., cited in WALTER 2002).

#### 8.4 Wild-collection versus Cultivation

Wild-collection vs. cultivation of medicinal plants is a very controversial issue. There are good arguments for both methods, depending on the point of view and the main interests of the respective stakeholder. This short discussion, focussing on *Harpagophytum procumbens*, cannot provide a comprehensive discussion encompassing all relevant parameters of this controversy, but seeks to illustrate a few – potential – chances and dangers of cultivation.

D. v. WILLERT (University of Münster, pers. comm.) favours the cultivation of devil's claw, because it could contribute to an increase in the financial revenues for the poorer population in RSA and Namibia, establishing direct trade links to exporters or even to importing companies thus cutting out the intermediate trade. Another advantage of cultivation would be its effectiveness and the reduced consumption of source material. According to a calculation of D. v. WILLERT, about 650 tonnes of *Harpagophytum* raw material are annually imported into Germany; as each plant is supposed to provide about 65 grams of dried raw drug, this would sum up to an annual demand of about 10 Mio plants. In cultivation, the harvest yield per plant is up to 10 times higher, which would reduce the annual demand to about 1 Mio plants.

A cultivation project is usually also easier to control. This may be especially relevant with regard to irrigation and water quality, because wild-collected devil's claw raw material is occasionally severely contaminated by microorganisms such as *E. coli*. (A. Ryser, Bioforce AG. pers. comm.). In addition, chances for the harvesters in cultivation projects may be higher to in fact earn their fair share in the trade. However, such cultivation projects again run the potential risk of being becoming dependent on an international import company, if the projects cannot be protected by community support and, if necessary, by national or international non-profit organisations.

Having analysed the German devil's claw market it seems to be doubtful if the total import volume is really around 650 tonnes per year or, as we suppose, considerably lower. Also the claimed 10-fold increase in harvest yield per plant through cultivation seems to be hard to believe (R. FRANKE, Salus-Haus, pers. comm.). So these calculations may reflect the upper limit of the potential increase in harvest yield, but they are most probably not likely to be achieved in reality. On the other hand, cultivation offers the chance of a 'controlled decentralisation' of devil's claw raw material sourcing and trade. The plant can – the suitability of the biotic and abiotic factors of the location provided – be cultivated in places

where the income from the harvest is most needed by the local population (D. v. WILLERT, University of Münster, pers. comm.). Again, this seems to be a rather theoretic approach. In reality and despite all efforts to establish the sustainable collection of *Harpagophytum* spp., the traders and pharmaceutical companies in Germany are primarily interested in obtaining the raw drug at the best possible quality with the lowest possible costs. So far, the wild-collection of *Harpagophytum* spp. is both more reliable and cheaper than drugs sourced from cultivation projects. However, this may change in the future. It is very likely, that – once large-scale cultivation yields constant and reliable harvests in sufficient quantities – the costs of cultivation will decrease. Together with the potential decrease in the wild populations of *Harpagophytum procumbens* a fast and fundamental shift from wild collection to cultivation could be the consequence, if *H. zeyheri* from wild harvesting is no cheaper alternative.

A serious point of criticism relating to the cultivation of medicinal plants is the fact that the income of several thousands of collectors is in danger, who may not be able to find work in cultivation projects. This danger seems to exist for many of the collectors and mainly for the tribal population, whereas others may profit from the cultivation as an even easier way of sourcing compared to wild-collection. Those who profit over the long-term could again be large farms, because they have the financial means to cover periods of lower financial revenues (A. Ryser, Bioforce AG, pers. comm.). R. FRANKE (Salus-Haus, pers. comm.) presumes that cultivation will not reduce the number of people involved, because jobs such as weeding have to be continuously performed. However, it seems to be very unlikely that the cultivation of *Harpagophytum procumbens* will provide a livelihood for as many people in Southern Africa as the sustainable wild harvesting will be able to provide (B. DICKSON, FFI, pers. comm.). And it is not for sure, that large-scale cultivation will in fact be established in the range countries. Rumors have already spread that such cultivation projects could best be carried out in countries like Morocco. The conditions are comparable, but it will be much cheaper, as Morocco is closer to the consumer countries and probably easier accessible.

For the wild populations of *Harpagophytum procumbens* such a development could be positive news, because the pressure on them may (at first) decrease. For many people living from the sourcing of *Harpagophytum* spp. from the wild, it would be a disaster (LOMBARD & DU PLESSIS 2003), because at present the wild harvesting is often carried out in regions where there is not much else to do to make a living. And on the long term, this would not even guarantee the protection of the natural populations of *Harpagophytum procumbens* in the range countries, because once the species cannot be harvested and sold on the market any more, the plant loses its economic value. Consequently, the danger increases that people lose their interest in protecting the species and its habitats, which could be disastrous given the fact that habitat alteration is one of the key factors that endanger the wild populations of *Harpagophytum* spp. (E. SCHNEIDER, pers. comm.).

## **8.5 Discussions about a possible CITES Listing of *Harpagophytum* spp.**

The German proposal made for CoP11 (in 2000) to list *Harpagophytum procumbens* on Appendix II of CITES has created a big fuss among all stakeholders in the range countries and the consumer countries involved in the sourcing of and trade in *Harpagophytum procumbens* and the production of herbal products based on this species. The proposal was withdrawn under the pressure of the range countries, which obviously had not been adequately and timely included in this process. At CoP11 the decision was made to require from Namibia and the other range states of *Harpagophytum procumbens* a report including all available information relating to the trade, management, regulation measures and the biological status of *Harpagophytum procumbens*. This information was submitted before CoP12 and the Plants Committee wrote a report (CITES 2002).

From this and other reports it becomes clear that there is still a fundamental lack in reliable data on the biology and population development of *Harpagophytum procumbens*, but also in reliable trade data, which is again shown by this report.

The listing of *Harpagophytum procumbens* or *Harpagophytum* spp. on CITES is still an issue discussed. But at present, as it is also stated by the CITES secretariat, it seems to be more effective to put all effort into an intensified co-operation between the different interest groups involved. In addition it seems to be crucial to find ways to increase the transparency of the *Harpagophytum* market and intensify research. A listing of the genus or of *Harpagophytum procumbens* on CITES Appendix II or III may be an issue to discuss at a later stage and it should be accompanied by strong efforts to explain what a CITES listing and the different appendices mean.

After the CITES proposal, the range countries noticed a reduced demand shown in the export figures in 2000 (HAMUNYELA 2002; LOMBARD & DU PLESSIS 2003). This could possibly be explained by 'safety purchases' by the importing companies during the previous year, leaving considerable quantities on stock in 2000. The large increase of German import quantities in 2001 would also account for this interpretation. During their interviews with German companies the authors of this report experienced that the controversy about the proposed or a future 'CITES-listing' is no topic for them any more.

## 8.6 Conclusions

From the interviews made for this report and from discussions with various experts in the fields of medicinal plants, especially devil's claw, and certification, some summarising conclusions may be drawn:

1. The trade in *Harpagophytum* spp. is characterised by a lack of transparency; trade data often do not match.
2. Scientific research into *Harpagophytum* spp. is still insufficient; the population status is poorly assessed.
3. *Harpagophytum* spp. can be – but is frequently not - harvested in a sustainable way; German importing and pharmaceutical companies very often do not exactly know where the material they use is sourced from.
4. *Harpagophytum zeyheri* has been listed in the European pharmacopoeia. This may have considerable but not yet calculable effects on the market.
5. The German pharmaceutical market for *Harpagophytum* spp. has obviously reached its peak.
6. The non-pharmaceutical market for *Harpagophytum* spp. is still increasing. However, it is difficult to say if *Harpagophytum* spp. is a 'fashion drug' or if it will become established on the German and possibly other markets.
7. Organic certification of *Harpagophytum* spp. sourcing is still rare; the demand for such certification is estimated to increase in consumer countries during the next couple of years.

8. Good practices guidelines (product quality certification) relating to medicinal plant collection are most likely becoming more important in the future; their potential influence is probably underestimated at present.
9. Social certification systems are not yet demanded by most consumers and by authorities and associations in consumer countries.
10. Large-scale cultivation of *Harpagophytum procumbens* has not yet reached a commercial stage; however, it cannot be excluded that such cultivation could be successful. It might be necessary to be extremely careful with large-scale cultivation, especially in terms of social sustainability but also in terms of ecological effects on the wild populations of *Harpagophytum procumbens*.

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## 9.2 List of Contacts

This list comprises all individual people and companies (importing and producing companies; certification organisations; consultant offices) and the respective representative(s) contacted during the research for this reports.

<b>Company</b> <b>Registered Office</b>	<b>Name of Contact Person</b>
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<b>Astrid Twardy GmbH</b> <b>Flörsheim / Main</b>	Mrs. Schröder
<b>Bad Heilbrunner Naturheilmittel GmbH &amp; Co.</b> <b>Bad Heilbrunn</b>	Mr. Dittrich
<b>BAH – Bundesverband der Arzneimittelhersteller e.V.</b> <b>Bonn</b>	Barbara Steinhoff
<b>BfArM – Bundesinstitut f. Arzneimittel und Medizinprodukte</b> <b>Bonn</b>	Konstantin Keller
<b>BfN – Bundesamt f. Naturschutz, Bonn</b>	Uwe Schippmann
<b>Bioforce AG</b> <b>Roggwil, Switzerland</b>	Andreas Ryser
<b>BSC Öko Garantie GmbH</b> <b>Nürnberg</b>	Albrecht Benzing
<b>Cornehls &amp; Bosse GmbH</b> <b>Hamburg</b>	Mr. Barkmann

<b>ECOCERT International</b> <b>Osterrode</b>	Iris Förster
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<b>GTZ – Gesellschaft f. Technische Zusammenarbeit</b> <b>Eschborn</b>	Hans-Joachim Rabe
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<b>Hevert Arzneimittel GmbH &amp; Co. KG</b> <b>Nussbaum</b>	Mrs. Bambecker
<b>IMS Health GmbH</b> <b>Frankfurt / Main</b>	Miss Mark
<b>INAC (Intl. Nutrition and Agriculture Certification)</b> <b>Witzenhausen</b>	Mrs. Orth
<b>KD Kaiser's Drugstore GmbH Hamm</b>	Mr. Schulte
<b>Kräuter Mix GmbH</b> <b>Abtswind</b>	Barbara Friedmann
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<b>Martin Bauer GmbH</b> <b>Vestenbergskreuth</b>	Hans-Juergen Hannig
<b>Mercabio Consult</b> <b>Polling</b>	Udo Censkowsky
<b>Navalis Nutraceuticals</b> <b>Stuttgart</b>	Gabriele Alber
<b>Pro Dimi Markenprodukte GmbH &amp; Co.</b> <b>Dortmund</b>	Mr. Keller
<b>Ratiopharm GmbH</b> <b>Ulm</b>	Ulrike Breider
<b>Roha Arzneimittel GmbH</b> <b>Bremen</b>	Peter Bullermann
<b>Salus-Haus Dr. med. Otto Greither Nachf. GmbH &amp; Co.</b> <b>Bruckmühl</b>	Rolf Franke
<b>Schaper &amp; Brümmer GmbH</b> <b>Salzgitter</b>	Götz Harnischfeger
<b>Schües &amp; Nordström GmbH &amp; Co. KG</b> <b>Hamburg</b>	Clemens Caesar
<b>Strathmann AG</b> <b>Hamburg</b>	Anja Zirzow
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<b>Dr. Willmar Schwabe GmbH</b> <b>Karlsruhe</b>	Mr. Schmied
<b>ZÄN – Zentralverband der Ärzte für Naturheilverfahren e.V.</b> <b>München</b>	Heinz Schilcher