Pollinosan Hayfever tablets

NR 13668/0208

UKPAR

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POLLINOSAN HAYFEVER TABLETS

NR 13668/0208

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Bioforce (UK) Ltd a Homeopathic Marketing Authorisation for the homeopathic medicinal product Pollinosan Hayfever tablets (Homeopathic Marketing Authorisation number: NR 13668/0208) on 19 February 2013. This product is available without prescription and can be bought from pharmacies and other outlets.

Pollinosan Hayfever tablets is a homeopathic medicinal product used within the homeopathic tradition to relieve the symptoms of hayfever and other forms of allergic rhinitis. These indications are based on published scientific literature. The active ingredients in Pollinosan Hayfever tablets are *Ammi visnaga* (1x), *Aralia racemosa* (2x), *Cardiospermum halicacabum* (2x), *Larrea mexicana* (2x), *Luffa operculata* (6x), *Okoubaka aubrevillei* (2x) and *Galphimia glauca* (3x).

No new or unexpected safety concerns arose from this application and it was, therefore, decided that a Homeopathic Marketing Authorisation could be granted.
SCIENTIFIC DISCUSSION

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INTRODUCTION

The MHRA granted a Homeopathic Marketing Authorisation for the homeopathic medicinal product Pollinosan Hayfever tablets on 19 February 2013. This product is on the General Sales List (GSL).

The application was submitted in accordance with Article 16.2 of Directive 2001/83 EC, as amended, under the National Rules Authorisation Scheme. Pollinosan Hayfever tablets contain the homeopathic stocks *Ammi visnaga* (in a final dilution of 1x), *Aralia racemosa* (in a final dilution of 2x), *Cardiospermum halicacabum* (in a final dilution of 2x), *Larrea mexicana* (in a final dilution of 2x), *Luffa operculata* (in a final dilution of 6x), *Okoubaka aubrevillei* (in a final dilution of 2x) and *Galphimia glauca* (in a final dilution of 3x). The tablets are used to relieve the symptoms of hayfever and other forms of allergic rhinitis.

*Ammi visnaga, Aralia racemosa, Cardiospermum halicacabum, Larrea mexicana, Luffa operculata, Okoubaka aubrevillei* and *Galphimia glauca* are established homeopathic remedies and their traditional use in homeopathy is well documented. In support of this application to authorise Pollinosan Hayfever bibliographic information (including published homeopathic *Materia medica* provings of the individual stocks within the product) has been provided.
## PHARMACEUTICAL ASSESSMENT

### HERBAL SUBSTANCE: AMMI VISNAGA FRUIT

<table>
<thead>
<tr>
<th>Scientific/Latin name:</th>
<th>Ammi visnaga (L.) Lam</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synonym:</td>
<td>Daucus visnaga L.</td>
</tr>
<tr>
<td></td>
<td>Apium visnaga CRANTZ</td>
</tr>
<tr>
<td>English name:</td>
<td>Tooth Pick weed</td>
</tr>
</tbody>
</table>

### Manufacture

The *Ammi visnaga* plants from which the fruit is collected grow in Northern Africa. The fruit is collected when fully ripe then dried naturally and stored in a well ventilated warehouse, protected from light and humidity. Confirmation has been provided that the herbal substance is produced in line with the Guideline on Good Agricultural and Collection Practice (GACP)/HMPC guideline.

### Control

*Ammi visnaga* fruit is described in the German Homeopathic Pharmacopoeia (GHP) and the applicant refers to the test specifications mentioned therein. As *Ammi visnaga* is described in an official pharmacopoeia, the analytical tests do not require further validation.

Satisfactory Certificates of Analysis for the *Ammi visnaga* fruit have been provided.

### Container Closure System

Satisfactory details of the container closure system used to store the herbal substance are provided.

### Stability

A shelf-life for the herbal substance is not necessary because it is only a precursor of the active substance, the homeopathic stock.

### ACTIVE INGREDIENT: AMMI VISNAGA FRUIT HOMEOPATHIC PREPARATION

<table>
<thead>
<tr>
<th>Extraction solvent:</th>
<th>Ethanol 62 % (m/m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>General properties:</td>
<td>A golden yellow liquid with an aromatic odour and an aromatic taste</td>
</tr>
</tbody>
</table>

### Manufacture

A satisfactory description of the manufacturing process of the homeopathic preparation and flow diagram have been provided. *Ammi visnaga* fruit homeopathic preparation is manufactured according to method 4a of the GHP. The in-process controls are satisfactorily detailed. The ethanol and purified water used to prepare the mother tincture comply with the specifications of the Ph Eur. Certificates of Analysis for all materials used in the manufacture of the herbal preparation have been provided.

### Control

A satisfactory specification with appropriate tests and limits has been provided for the homeopathic preparation.
Appropriate analytical procedures are used to control the quality of the homeopathic preparation and these have been validated, as appropriate.

Certificates of Analysis have been provided for batches of the homeopathic preparation, demonstrating satisfactory compliance with the proposed specifications.

**Container Closure System**
Satisfactory details of the container closure system are provided and confirmation has been given that all components of the container closure system comply with current legislation relating to plastic materials and articles intended to come into contact with foodstuffs.

**Stability**
Stability studies have been carried out under ICH conditions. The results support the proposed shelf life of the homeopathic stock.

**HERBAL SUBSTANCE:** **ARALIA RACEMOSA UNDERGROUND PARTS**

<table>
<thead>
<tr>
<th>Scientific/Latin name:</th>
<th>Aralia racemosa L.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synonym:</td>
<td>Aralia</td>
</tr>
<tr>
<td>English name:</td>
<td>American Spikenard</td>
</tr>
</tbody>
</table>

**Manufacture**
The *Aralia racemosa* plants are cultivated in Switzerland. The fresh underground parts of the plants are harvested in the autumn. The fresh roots are washed before being processed.

Confirmation has been provided that the herbal substance is grown under organic conditions (according to EC Directive 2092/91) and is produced in line with the Guideline on Good Agricultural and Collection Practice (GACP)/HMPC guideline.

**Control of the Herbal Substance**
*Aralia racemosa* underground parts are described in the GHP and the applicant refers to the test specifications mentioned therein. As *Aralia racemosa* is described in an official pharmacopoeia, the analytical tests do not require further validation.

Satisfactory Certificates of Analysis for the *Aralia racemosa* underground parts have been provided.

**Container Closure System**
Satisfactory details of the container closure system used to store the herbal substance are provided.

**Stability**
A shelf-life for the herbal substance is not necessary because it is only a precursor of the active substance, the homeopathic stock.
ACTIVE INGREDIENT: ARALIA RACEMOSA HOMEOPATHIC PREPARATION

Extraction solvent: Ethanol 62 % (m/m)
General properties: A fine, white powder with a slightly aromatic odour and a sweetish taste

Manufacture
A satisfactory description of the manufacturing process of the homeopathic stock (which is a precursor of the homeopathic preparation) and the homeopathic preparation has been provided. *Aralia racemosa* homeopathic stock is manufactured according to method 3a of the GHP and the homeopathic preparation is manufactured according to method 6 or 7 of the GHP. The in-process controls are satisfactorily detailed. The ethanol and purified water used to prepare the homeopathic stock and homeopathic preparation comply with the specifications of the Ph Eur or the GHP. Certificates of Analysis for all materials used in the manufacture of the active ingredient have been provided.

Control
Satisfactory specifications with appropriate tests and limits have been provided for the homeopathic stock and homeopathic preparation.

Appropriate analytical procedures are used to control the quality of the homeopathic stock and homeopathic preparation and these have been validated, as appropriate.

Certificates of Analysis have been provided for batches of the homeopathic stock and homeopathic preparation, demonstrating satisfactory compliance with the proposed specifications.

Container Closure System
Satisfactory details of the container closure system are provided and confirmation has been given that all components of the container closure system comply with current legislation relating to plastic materials and articles intended to come into contact with foodstuffs.

Stability
Stability studies have been carried out under ICH conditions. The results support the proposed shelf life of the homeopathic stock. The same shelf life will be applied to the homeopathic preparation, which is appropriate.

HERBAL SUBSTANCE: CARDIOSPERMUM HALICACABUM AERIAL PARTS

Scientific/Latin name: Cardiospermum halicacabum L.
Synonym: Cardiospermum
English name: Ballon vine

Manufacture
The *Cardiospermum halicacabum* plants are cultivated in Switzerland. The fresh aerial parts are harvested in the summer, during the flowering period.
Confirmation has been provided that the herbal substance is grown under organic conditions (according to EC Directive 2092/91) and is produced in line with the Guideline on Good Agricultural and Collection Practice (GACP)/HMPC guideline.

**Control**

*Cardiospermum halicacabum* aerial parts are described in the GHP and the applicant refers to the test specifications mentioned therein. As *Cardiospermum halicacabum* is described in an official pharmacopoeia, the analytical tests do not require further validation.

Satisfactory Certificates of Analysis for the *Cardiospermum halicacabum* aerial parts have been provided.

**Container Closure System**

Satisfactory details of the container closure system used to store the herbal substance are provided.

**Stability**

A shelf-life for the herbal substance is not necessary because it is only a precursor of the active substance, the homeopathic stock.

**ACTIVE INGREDIENT:**

*CARDIOSPERMUM HALICACABUM AERIAL PARTS HOMEOPATHIC PREPARATION*

**Extraction solvent:** Ethanol 62% (m/m)

**General properties:** A fine, white, odourless powder with a sweetish taste

A satisfactory description of the manufacturing process of the homeopathic stock (which is a precursor of the homeopathic preparation) and the homeopathic preparation have been provided. *Cardiospermum halicacabum* homeopathic stock and homeopathic preparation are manufactured according to method 3a of the GHP. The in-process controls are satisfactorily detailed. The ethanol and purified water used to prepare the homeopathic stock and homeopathic preparation comply with the specifications of the Ph Eur or the GHP. Certificates of Analysis for all materials used in the manufacture of the active ingredient have been provided.

**Control**

Satisfactory specifications with appropriate tests and limits have been provided for the homeopathic stock and homeopathic preparation.

Appropriate analytical procedures are used to control the quality of the homeopathic stock and homeopathic preparation and these have been validated, as appropriate.

Certificates of Analysis have been provided for batches of the homeopathic stock and homeopathic preparation, demonstrating satisfactory compliance with the proposed specifications.

**Container Closure System**

Satisfactory details of the container closure system are provided and confirmation has
been given that all components of the container closure system comply with current legislation relating to plastic materials and articles intended to come into contact with foodstuffs.

**Stability**

Stability studies have been carried out under ICH conditions. The results support the proposed shelf life of the homeopathic stock. The same shelf life will be applied to the homeopathic preparation, which is appropriate.

**HERBAL SUBSTANCE:**

**GALPHIMIA GLAUCA LEAVES AND INFLORESCENCES**

**Scientific/Latin name:**

*Galphimia glauca* L.

**Synonym:**

Thryallis glauca.

**English name:**

Golden Thryallis

- Gold Shower
- Rain of Gold
- Shower of Gold
- Yellow Plumbago

**Manufacture**

The *Galphimia glauca* plants are cultivated in Central America. The leaves and inflorescences are harvested manually then dried naturally and stored in a well ventilated warehouse, protected from light and humidity.

Confirmation has been provided that the herbal substance is grown under organic conditions (according to EC Directive 2092/91) and is produced in line with the Guideline on Good Agricultural and Collection Practice (GACP)/HMPC guideline.

**Control**

*Galphimia glauca* leaves and inflorescences are described in the GHP and the applicant refers to the test specifications mentioned therein. As *Galphimia glauca* is described in an official pharmacopoeia, the analytical tests do not require further validation.

Satisfactory Certificates of Analysis for the *Galphimia glauca* aerial parts have been provided.

**Container Closure System**

Satisfactory details of the container closure system used to store the herbal substance are provided.

**Stability**

A shelf-life for the herbal substance is not necessary because it is only a precursor of the active substance, the homeopathic stock.

**ACTIVE INGREDIENT:**

**GALPHIMIA GLAUCA LEAVES AND INFLORESCENCES HOMEOPATHIC PREPARATION**

**Extraction solvent:**

Ethanol 62 % (m/m)
General properties:

A fine, white, slightly aromatic powder with a sweetish taste

A satisfactory description of the manufacturing process of the homeopathic stock (which is a precursor of the homeopathic preparation) and the homeopathic preparation has been provided. *Galphimia glauca* homeopathic stock is manufactured according to method 4a of the GHP and the homeopathic preparation is manufactured according to method 7 of the GHP. The in-process controls are satisfactorily detailed. The ethanol and purified water used to prepare the homeopathic stock and homeopathic preparation comply with the specifications of the Ph Eur or the GHP. Certificates of Analysis for all materials used in the manufacture of the active ingredient have been provided.

Control

Satisfactory specifications with appropriate tests and limits have been provided for the homeopathic stock and homeopathic preparation.

Appropriate analytical procedures are used to control the quality of the homeopathic stock and homeopathic preparation and these have been validated, as appropriate.

Certificates of Analysis have been provided for batches of the homeopathic stock and homeopathic preparation, demonstrating satisfactory compliance with the proposed specifications.

Container Closure System

Satisfactory details of the container closure system are provided and confirmation has been given that all components of the container closure system comply with current legislation relating to plastic materials and articles intended to come into contact with foodstuffs.

Stability

Stability studies have been carried out under ICH conditions. The results support the proposed shelf life of the homeopathic stock. The same shelf life will be applied to the homeopathic preparation, which is appropriate.

HERBAL SUBSTANCE: *LARREA MEXICANA AERIAL PARTS*

Scientific/Latin name: *Larrea mexicana* MORIC

Synonyms:

- *Larrea tridentata*
- *Larrea divericata* (MORIC)
- *Larrea glutinosa*

English name:

- Creosote bush
- Greasewood

Manufacture

The *Larrea mexicana* plants are cultivated in Mexico. The *Larrea mexicana* aerial parts are harvested manually then dried naturally and stored in a well ventilated warehouse, protected from light and humidity.
Confirmation has been provided that the herbal substance is grown under organic conditions (according to EC Directive 2092/91) and is produced in line with the Guideline on Good Agricultural and Collection Practice (GACP)/HMPC guideline.

**Control**

*Larrea mexicana* aerial parts are described in the GHP and the applicant refers to the test specifications mentioned therein. As *Larrea mexicana* is described in an official pharmacopoeia, the analytical tests do not require further validation.

Satisfactory Certificates of Analysis for the *Larrea mexicana* aerial parts have been provided.

**Container Closure System**

Satisfactory details of the container closure system used to store the herbal substance are provided.

**Stability**

A shelf-life for the herbal substance is not necessary because it is only a precursor of the active substance, the homeopathic stock.

**ACTIVE INGREDIENT:**

| LARREA MEXICANA AERIAL PARTS |
| HOMEOPATHIC PREPARATION |

**Extraction solvent:** Ethanol 62 % (m/m)

**General properties:** A fine, brownish, aromatic powder with a sweetish taste

A satisfactory description of the manufacturing process of the homeopathic stock (which is a precursor of the homeopathic preparation) and the homeopathic preparation has been provided. *Larrea mexicana* homeopathic stock is manufactured according to method 4a of the GHP and the homeopathic preparation is manufactured according to method 7 of the GHP. The in-process controls are satisfactorily detailed. The ethanol and purified water used to prepare the homeopathic stock and homeopathic preparation comply with the specifications of the Ph Eur or the GHP. Certificates of Analysis for all materials used in the manufacture of the active ingredient have been provided.

**Control**

Satisfactory specifications with appropriate tests and limits have been provided for the homeopathic stock and homeopathic preparation.

Appropriate analytical procedures are used to control the quality of the homeopathic stock and homeopathic preparation and these have been validated, as appropriate.

Certificates of Analysis have been provided for batches of the homeopathic stock and homeopathic preparation, demonstrating satisfactory compliance with the proposed specifications.

**Container Closure System**

Satisfactory details of the container closure system are provided and confirmation has
been given that all components of the container closure system comply with current legislation relating to plastic materials and articles intended to come into contact with foodstuffs.

**Stability**
Stability studies have been carried out under ICH conditions. The results support the proposed shelf life of the homeopathic stock. The same shelf life will be applied to the homeopathic preparation, which is appropriate.

**HERBAL SUBSTANCE:** LUFFA OPERCULATA FRUIT  
**Scientific/Latin name:** Luffa operculata L.  
**Synonyms:**  
- Luffa purgans MART.  
- Momordica operculata L.  
- Poppya operculata (L.) ROEM.  
**English name:** Sponge gourd

**Manufacture**
The *Luffa operculata* plants from which the fruit is collected grow in Brazil. The fruit is collected when fully ripe then dried naturally and stored in a well ventilated warehouse, protected from light and humidity.

Confirmation has been provided that the herbal substance is produced in line with the Guideline on Good Agricultural and Collection Practice (GACP)/HMPC guideline.

**Control**
The *Luffa operculata* fruit is described in the GHP and the applicant refers to the test specifications mentioned therein. As *Luffa operculata* is described in an official pharmacopoeia, the analytical tests do not require further validation.

Satisfactory Certificates of Analysis for the *Luffa operculata* fruit have been provided.

**Container Closure System**
Satisfactory details of the container closure system used to store the herbal substance are provided.

**Stability**
A shelf-life for the herbal substance is not necessary because it is only a precursor of the active substance, the homeopathic stock.

**ACTIVE INGREDIENT:** LUFFA OPERCULATA FRUIT MOTHER HOMEOPATHIC PREPARATION  
**Extraction solvent:** Ethanol 62 % (m/m)  
**General properties:** A fine, white, odourless powder with a sweetish taste

A satisfactory description of the manufacturing process of the homeopathic stock (which is a precursor of the homeopathic preparation) and the homeopathic preparation has been provided. *Luffa operculata* homeopathic stock is manufactured according to method 4a of the GHP and the homeopathic preparation is manufactured...
according to method 7 of the GHP. The in-process controls are satisfactorily detailed. The ethanol and purified water used to prepare the homeopathic stock and homeopathic preparation comply with the specifications of the Ph Eur or the GHP. Certificates of Analysis for all materials used in the manufacture of the active ingredient have been provided.

Control
Satisfactory specifications with appropriate tests and limits have been provided for the homeopathic stock and homeopathic preparation.

Appropriate analytical procedures are used to control the quality of the homeopathic stock and homeopathic preparation and these have been validated, as appropriate.

Certificates of Analysis have been provided for batches of the homeopathic stock and homeopathic preparation, demonstrating satisfactory compliance with the proposed specifications.

Container Closure System
Satisfactory details of the container closure system are provided and confirmation has been given that all components of the container closure system comply with current legislation relating to plastic materials and articles intended to come into contact with foodstuffs.

Stability
Stability studies have been carried out under ICH conditions. The results support the proposed shelf life of the homeopathic stock. The same shelf life will be applied to the homeopathic preparation, which is appropriate.

HERBAL SUBSTANCE:  OKOUBAKA AUBREVILLEI BARK AND BRANCHES

Scientific/Latin name:  Okoubaka aubrevillei F. PELLEGRIN & D. NORMAND.

Synonyms:  Okoubaka  

English name:  Okoubaka tree

Manufacture
The Okoubaka aubrevillei plants from which the bark and branches are collected grow in Cameroon. The bark and branches are collected manually then dried naturally and stored in a well ventilated warehouse, protected from light and humidity.

Confirmation has been provided that the herbal substance is produced in line with the Guideline on Good Agricultural and Collection Practice (GACP)/HMPC guideline.

Control
Okoubaka aubrevillei bark and branches are described in the GHP and the applicant refers to the test specifications mentioned therein. As Okoubaka aubrevillei is described in an official pharmacopoeia, the analytical tests do not require further validation.
Satisfactory Certificates of Analysis for the *Okoubaka aubrevillei* bark and branches have been provided.

**Container Closure System**
Satisfactory details of the container closure system used to store the herbal substance are provided.

**Stability**
A shelf-life for the herbal substance is not necessary because it is only a precursor of the active substance, the homeopathic stock.

**ACTIVE INGREDIENT:** *OKOUBAKA AUBREVILLEI BARK AND BRANCHES HOMEOPATHIC PREPARATION*

**Extraction solvent:** Ethanol 62 % (m/m)

**General properties:** A fine, white, odourless powder with a sweetish taste

A satisfactory description of the manufacturing process of the homeopathic stock (which is a precursor of the homeopathic preparation) and the homeopathic preparation has been provided. *Okoubaka aubrevillei* homeopathic stock is manufactured according to method 4a of the GHP and the homeopathic preparation is manufactured according to method 7 of the GHP. The in-process controls are satisfactorily detailed. The ethanol and purified water used to prepare the homeopathic stock and homeopathic preparation comply with the specifications of the Ph Eur or the GHP. Certificates of Analysis for all materials used in the manufacture of the active ingredient have been provided.

**Control**
Satisfactory specifications with appropriate tests and limits have been provided for the homeopathic stock and homeopathic preparation.

Appropriate analytical procedures are used to control the quality of the homeopathic stock and homeopathic preparation and these have been validated, as appropriate.

Certificates of Analysis have been provided for batches of the homeopathic stock and homeopathic preparation, demonstrating satisfactory compliance with the proposed specifications.

**Container Closure System**
Satisfactory details of the container closure system are provided and confirmation has been given that all components of the container closure system comply with current legislation relating to plastic materials and articles intended to come into contact with foodstuffs.

**Stability**
Stability studies have been carried out under ICH conditions. The results support the proposed shelf life of the homeopathic stock. The same shelf life will be applied to the homeopathic preparation, which is appropriate.
HOMEOPATHIC MEDICINAL PRODUCT: POLLINOSAN HAYFEVER TABLETS

Description and Composition of the Homeopathic Product
The finished product is a yellowish, biconvex tablet with a triangular stamp containing *Ammi visnaga* (in a final dilution of 1x), *Aralia racemosa* (in a final dilution of 2x), *Cardiospermum halicacabum* (in a final dilution of 2x), *Larrea mexicana* (in a final dilution of 2x), *Luffa operculata* (in a final dilution of 6x), *Okoubaka aubrevillei* (in a final dilution of 2x) and *Galphimia glauca* (in a final dilution of 3x). The excipients used to manufacture the homeopathic medicinal product are lactose monohydrate, pregelatinised starch and magnesium stearate. All excipients are considered to be compatible with the homeopathic stocks and do not influence the performance of the product.

All excipients used comply with their respective Ph Eur monograph. Certificates of Analysis for the excipients have been provided by the suppliers.

Manufacture
A flow diagram outlining the various stages of the manufacturing process and the in-process controls is provided. The critical steps of the process have been validated and the production process is considered validated.

Control of Homeopathic Product
The finished product specification is detailed and the tests and limits used were found to be satisfactory for a product of this nature.

Satisfactory details have been provided on all analytical procedures and these analytical procedures are valid.

Certificates of Analysis have been presented for batches of the drug product demonstrating little inter-batch variation.

Container Closure System
The product is presented in amber glass bottles (Type III glass) sealed with coated aluminium foil and closed with pilfer proof screw caps fitted with a polyethylene liner. Pack sizes of 80 or 120 tablets have been authorised, although not all pack sizes may be marketed. The components of the primary packaging system comply with current legislation relating to plastic materials and articles intended to come into contact with foodstuffs.

Stability
Stability studies were conducted under ICH conditions on product batches in the container type proposed for marketing.

The results of the stability study support the 60 month shelf for the product.

Summary of Product Characteristics, Labels and Patient Information Leaflet
The product literature for this product is pharmaceutically satisfactory.
A package leaflet has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

**CONCLUSION**

There are no objections to the granting of a Homeopathic Marketing Authorisation from a quality point of view.
NON-CLINICAL AND CLINICAL SAFETY ASSESSMENT

SAFETY OVERVIEW
A review of the literature and an Expert opinion on the non-clinical and clinical safety of the product has been provided.

Toxicity data were available for three of the individual stocks; *Ammi visnaga, Larrea mexicana* and *Luffa operculata* and the applicant addressed all relevant aspects of safety as required, providing calculations of the concentration of stocks in the finished product to demonstrate that the risk of toxic effects is low.

Evidence of adverse effects experienced in clinical studies of products similar to Pollinosan Hayfever tablets and products containing one or more similar stocks (*Galphimia glauca, Cardiospermum, Aralia racemosa, Luffa operculata* and *Okoubaka*) was submitted to demonstrate the safety of the product and, thus, the combination of stocks within the product. These data raised no safety concerns.

As genotoxicity data are not available in the published literature, assurance is provided that appropriate genotoxicity testing will be undertaken before renewal of the authorisation.

The SmPC, PIL and labelling are satisfactory in terms of safety.

CONCLUSION
There are no objections to the granting of a Homeopathic Marketing Authorisation from a safety point of view.
CLINICAL ASSESSMENT (NON SAFETY)

LEGAL STATUS
Aralia racemosa was already listed as a General Sales List (GSL) ingredient prior to the submission of this application. The remaining six homeopathic stocks were assessed for their suitability for GSL status during assessment of this application. As they met the relevant criteria, GSL has been granted for this product. Further details are provided in this report.

INDICATION
The applicant has proposed the following indication:

“A homeopathic medicinal product used within the homeopathic tradition to relieve the symptoms of hayfever and other forms of allergic rhinitis.”

This indication is acceptable.

POSOLOGY AND METHOD OF ADMINISTRATION
The applicant has proposed the following

“Adults, the elderly and children over 12 years: Take 2 tablets 3 times daily before meals.

Maximum recommended daily dose is 6 tablets.

This product should not be used in children under 12 years.

For oral use only.”

This is acceptable.

EVIDENCE SUPPORTING THE PROPOSED INDICATION
Schedule 1A Parts 1 and 3 of SI 2006 No. 1952 The Medicines for Human Use (National Rules for Homeopathic Products) Regulations 2006 specifies the data that must be provided to support the use of the product in the indications sought.

The applicant has provided data to demonstrate that products related to Pollinosan Hayfever tablets have been marketed by Bioforce Ltd worldwide since 1985 and supplied in the UK since 1987.

Pollinosan HK (a liquid formulation) and Pollinosan HK Tablets were introduced onto the Swiss market in 1985 and the UK market in 1987 and contain the same homeopathic stocks at the same levels of potency as Pollinosan Hayfever tablets. Pollinosan Spray, an intranasal spray, was introduced onto the Dutch and Belgian markets in 2003.

In support of the proposed indication for Pollinosan Hayfever tablets, the applicant reported two clinical trials carried out by Bioforce investigating the use of Pollinosan HK Tablets, Pollinosan Spray and some of the homeopathic stocks in Pollinosan Hayfever tablets.
Bibliographic data (including published homeopathic *Materia medica* provings of the individual stocks within the product) and UK homeopathic practitioner statements supporting the use of the homeopathic stocks used in Pollinosan Hayfever tablets in the indications sought have also been provided. The applicant has therefore demonstrated that the combination of stocks in the product to be authorised has a recognised level of use within the UK homeopathic tradition in the indications sought. In support of the proposed dosage for Pollinosan Hayfever tablets the applicant has stated that it is consistent with dosages stated in bibliography and is consistent with homeopathic practice.

It is considered sufficient evidence has been submitted to justify the homeopathic use of Pollinosan Hayfever tablets to relieve the symptoms of hayfever and other forms of allergic rhinitis.

**ASSESSMENT OF SUITABILITY FOR GSL STATUS FOR STOCKS IN POLLINOSAN HAYFEVER TABLETS**

The only stock in Pollinosan Hayfever tablets that is on Schedule 1 of the General Sales List is *Aralia racemosa*. All of the other stocks are not included.

Section 51 of the Medicines Act 1968 states that “GSL may be appropriate for medicines which can, with reasonable safety, be sold or supplied otherwise than by or under the supervision of a pharmacist”. The term “reasonable safety” may usefully be defined as: “Where the hazard to health and the risk of misuse and the need for special precautions in handling are small, and where wider sale would be a convenience to the purchaser”.

The following assessment discusses the suitability of the indication of Pollinosan Hayfever tablets for GSL

1. **Hazard to health**
   There appears to be a low risk of hazard to health in the proposed indication.

2. **Risk of misuse**
   The risk of misuse of this product is considered to be low.

3. **Need to take special precautions in handling**
   There are no special precautions in handling this product other than keeping it out of the reach and sight of children (as with any other GSL medicine).

4. **Wider sales are convenient to the purchaser**
   This would apply.

It is considered that the above mentioned criteria have been met and that this product is suitable for GSL status.

**CONCLUSION**

There are no objections to the granting of a Homeopathic Marketing Authorisation from a clinical point of view.
OVERALL CONCLUSION AND RISK ASSESSMENT

QUALITY
The quality data submitted with this application are satisfactory.

NON-CLINICAL
No new non-clinical data were submitted and none are required for an application of this type.

HOMEOPATHIC USE AND SAFETY
The applicant has provided literature references supporting evidence to fulfil the requirements for this type of application. These references relate to the indications sought and are, therefore, acceptable.

The SmPC, PIL and labelling of the product are satisfactory.

RISK ASSESSMENT
The quality of the product is acceptable and no new non-clinical or clinical safety concerns have been identified.
**POLLINOSAN HAYFEVER TABLETS**

NR 13668/0208

**STEPS TAKEN FOR ASSESSMENT**

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The MHRA received an application under the Homeopathic National Rules Scheme (Article 16.2) on 1 September 2009</td>
</tr>
<tr>
<td>2</td>
<td>Following standard checks and communication with the applicant the MHRA considered the application valid on 16 September 2009</td>
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<tr>
<td>3</td>
<td>Following assessment of the application and a meeting of the Advisory Board on the Registration of Homeopathic products (ABRH) on 15 December 2009 the MHRA requested further information relating to the dossier on 23 December 2009, 20 April 2012, 28 June 2012 and 25 October 2012</td>
</tr>
<tr>
<td>4</td>
<td>The applicant responded to the MHRA’s requests, providing further information on the dossier on 13 October 2010, 5 December 2011, 11 June 2012, 6 August 2012, 15 November 2012 and 5 December 2012</td>
</tr>
<tr>
<td>5</td>
<td>A National Rules Marketing Authorisation was granted on 19 February 2013</td>
</tr>
</tbody>
</table>
SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Pollinosan Hayfever tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each tablet (250 mg) contains:

- Ammi visnaga 1x
- Aralia racemosa 2x
- Cardiospermum halicacabum 2x
- Larrea mexicana 2x
- Luffa operculata 6x
- Okoubaka aubrevillei 2x
- Galphimia glauca 3x

Contains lactose monohydrate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM
Tablet
Yellowish, biconvex tablet with a triangular stamp.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
A homeopathic medicinal product used within the homeopathic tradition to relieve the symptoms of hayfever and other forms of allergic rhinitis.

4.2 Posology and method of administration
Adults, the elderly and children over 12 years: Take 2 tablets 3 times daily before meals.

Maximum recommended daily dose is 6 tablets.

This product should not be used in children under 12 years.

For oral use only.

4.3 Contraindications
Hypersensitivity to any of the active ingredients or to any of the excipients.

4.4 Special warnings and precautions for use
Do not exceed the stated dose.
If the condition worsens, or if symptoms persist for more than 7 days, consult a doctor or qualified healthcare practitioner.

This product contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactose deficiency or glucose-galactose malabsorption should not take this medicine.

This product is not recommended for use in children under 12 years of age due to a lack of data on safety.

4.5 Interaction with other medicinal products and other forms of interaction
No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation
Pregnancy: There is no evidence of the safety of the product in human pregnancy, nor is there any evidence from animal studies.

The use of the product during pregnancy and lactation should be avoided unless under the guidance of a doctor.

Studies on the effects on fertility have not been performed.

4.7 Effects on ability to drive and use machines
Pollinosan has no influence on the ability to drive or use machines.

4.8 Undesirable effects
Frequency not known
Gastrointestinal disturbances e.g. nausea, stomach upset.
Allergic reactions e.g. rash

If symptoms worsen, or persist for more than 7 days, or if other adverse reactions not mentioned above occur, a doctor, pharmacist or a qualified healthcare practitioner should be consulted.

4.9 Overdose
None known.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Not applicable.

5.2 Pharmacokinetic properties
Not applicable.

5.3 Preclinical safety data
Not applicable.
6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Lactose monohydrate
Pregelatinised starch
Magnesium stearate

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
60 months.

6.4 Special precautions for storage
This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container
Amber glass bottles (Type III glass) sealed with coated aluminium foil and closed with pilfer proof screw caps fitted with a polyethylene liner

Pack sizes: 80 tablets
120 tablets

Not all pack sizes may be marketed.

6.6 Special precautions for disposal
No special requirements.

7 MARKETING AUTHORISATION HOLDER
Bioforce (UK) Ltd
2 Brewster Place
Irvine, Ayrshire
KA11 5DD, United Kingdom
Tel: 01294 277344
enquiries@avogel.co.uk

8 MARKETING AUTHORISATION NUMBER(S)
NR 13668/0208

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORIZAION
19/02/2013

10 DATE OF REVISION OF THE TEXT
19/02/2013
**Information**

**Important things you need to know**
- This product is a homeopathic medicinal product used within the homeopathic tradition to relieve the symptoms of hayfever and other forms of allergic rhinitis.
- This is a homeopathic medicinal product.
- This product is suitable for adults and children over 12 years.
- **Do not take this product if you are allergic to lactose or any of the other ingredients; see section 6.**
- Before you take this product: read section 2.
- Dosage instructions: see section 3.
- Talk to your doctor if your symptoms worsen or persist after 2 days of first using this product.
- Side effects are minor and rare; see section 4.
- Now read the rest of this leaflet carefully. Keep this leaflet. You may need to read it again.

**1. What this product is for**

Pollinosan is a homeopathic medicinal product used within the homeopathic tradition to relieve the symptoms of:
- Hayfever
- Other forms of allergic rhinitis

Hayfever and allergic rhinitis are conditions where the body’s immune system reacts abnormally to external irritants (allergens) such as pollen, animal dander (material shed from the body of animals) and dust. Symptoms include sneezing, blocked nose, runny and itchy nose, itchy eyes and throat.

**2. Before you take this product**

- Do not give this product to children under 12.
- Do not take this product:
  - If you are allergic to any of the ingredients in this product. (See section 6 Further Information).
  - If you have been told by your doctor that you have an intolerance to products containing lactose. This product contains lactose.
  - If you are pregnant or breastfeeding.

**3. How to take this product**

Adults, the elderly and children over 12 years: Take 2 tablets three times daily before meals.
Do not take more than 6 tablets a day.
**Not for use in children under 12.**
For oral use only.

If you take too much
- If you take too much and feel ill, talk to your doctor. Taking too much is unlikely to be harmful.

If you forget to take this product
- Don’t worry about the missed dose. Take the next dose as usual.

If you feel this product isn’t working
- See your doctor or qualified healthcare practitioner if your symptoms worsen or persist after 7 days of first using this product.

**Using**

Please turn over...
**Side effects**

4. Possible side effects

Like all medicines, this product can cause side effects, although not everybody gets them.

**Minor side effects**

The following minor side effects can occur when using this product. Their frequency is not known. This means that it is not known how often these reactions occur as there has not been enough reports to allow this information to be calculated.

**Digestive symptoms**
- Feeling sick (nausea)
- Digestive upsets such as sickness or diarrhoea

These are often short-lived and should get better on their own, however if they persist, talk to your doctor or pharmacist.

**Allergic reactions**
- Skin reactions such as a rash
- Stop taking the product if these occur.

If your symptoms worsen or persist after 7 days, if you are concerned about any side effects or you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

**Information**

5. How to store this product

- Keep out of the reach and sight of children.
- Do not use this product after the expiry date which is stated on the packaging. The expiry date refers to the last day of that month.
- This product does not require any special storage conditions.
- Do not use this product if you notice a change in colour. The tablets should be yellowish in colour.

6. Further Information

**What this product contains**

Each tablet contains:
- Aminophylline
- Aralo rogenosa
- Cardiochamomile (Kalecorubin)
- Larrone mexicana
- Luffa operculata
- Skawoles addiction
- Solferine globut

The other ingredients used for the tablet are lactose, pregelatinised starch and magnesium stearate.

**What this product looks like and the contents of the pack**

Pollinosan tablets are round and yellowish in colour with a triangular stamp. Pollinosan is available in packs containing 80 and 120 tablets. Not all pack sizes may be marketed.

**National Rules Authorisation Holder and Manufacturer**

**National Rules Authorisation Holder and Batch Release**

Biotest (UK) Ltd.,
2 Brewster Place,
Irvine, Ayrshire, UK
KA11 9DO

**Manufacturer**

Biotest AG, CH-9325, Bruggwil, Switzerland

NR No. 13668/0208

This leaflet was revised on 11/2012

**You should also know**

Biotest runs a helpline by phone and email which can provide you with further information.

Email: enquiries@biotest.co.uk
Phone: 0845 608 5858

You can help to make medicines safer by reporting any side effects to the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.
Alternatively, you can get a paper yellow card form from your doctor’s surgery or pharmacy, or call freephone 0800 100 3352 (available 10am - 2pm Monday - Friday).

You can get a larger print or audio version of this leaflet.

Call this number: 0845 608 5858.
LABELLING

Labels:

Pollinosan is a homoeopathic medicinal product used within the homoeopathic tradition to relieve the symptoms of hayfever and other forms of allergic rhinitis.

Directions for use:
Adults: Take 2 tablets three times daily before meals. Do not take more than 6 tablets a day. Not for use in children under 12.

Ingredients:

This product contains lactose. See leaflet for more information. Keep out of the reach and sight of children.

Technical Data

Batch:

Exp: