Table of Contents

- Lay summary: Page 2
- Scientific discussion: Page 3
- Steps taken for assessment: Page 11
- Summary of Product Characteristics: Page 12
- Product Information Leaflet: Page 16
- Labelling: Page 18

Weleda Herb & Honey Cough Elixir

THR 00298/0291

UKPAR
WELEDA HERB & HONEY COUGH ELIXIR

THR 00298/0291

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Weleda (UK) Ltd a Traditional Herbal Registration Certificate for the traditional herbal medicinal product Weleda Herb & Honey Cough Elixir (Traditional Herbal Registration number: THR 00298/0291) on 29 April 2013. Weleda Herb & Honey Cough Elixir is available without prescription and can be bought from pharmacies and other outlets.

Weleda Herb & Honey Cough Elixir is a traditional herbal medicinal product used for the symptomatic relief of dry and irritating coughs, based on traditional use only. The active ingredients in Weleda Herb & Honey Cough Elixir are Aniseed (Pimpinella anisum L.) fruit, Elder flower (Sambucus nigra L.), Iceland moss (Cetraria islandica L.) thallus, Marshmallow (Althaea officinalis L.) root, Thyme (Thymus vulgaris L. & Thymus zygis L.) herb and White horehound (Marrubium vulgare L.) herb.

This registration is based exclusively upon evidence of the use of Aniseed fruit, Elder flower, Iceland moss thallus, Marshmallow root, Thyme herb and White horehound herb as traditional herbal medicines and not upon data generated from clinical trials. There is no requirement under the Traditional Herbal Registration Scheme to prove scientifically that the product works.

No new or unexpected safety concerns arose from this application and it was, therefore, decided that a Traditional Herbal Registration Certificate could be granted.
SCIENTIFIC DISCUSSION

TABLE OF CONTENTS

Introduction ........................................ Page 4
Pharmaceutical assessment ........................ Page 5
Preclinical assessment ............................... Page 8
Clinical assessment ................................ Page 9
Overall conclusions and risk assessment ....... Page 10
INTRODUCTION

The MHRA granted a Traditional Herbal Registration Certificate for the traditional herbal medicinal product Weleda Herb & Honey Cough Elixir (THR 00298/0291) to Weleda (UK) Ltd on 29 April 2013. This product is on the general sales list (GSL).

A product licence of right (PLR) was granted to Weleda (UK) Ltd for this product. The PLR was reviewed and a product licence (PL 00298/7619R) was granted to Weleda (UK) Ltd for this product on 27 April 1992. PL 00298/7619R was cancelled on 29 April 2013.

This THR application was made under Article 16.c of Directive 2001/83 EC in accordance with arrangements to transfer certain herbal products with a Marketing Authorisation to a THR (according to MHRA Guidance dated January 2009). The application falls within the simplified THR application Category A, as no significant changes have been made to the formulation of the product. No new data were submitted, nor was it necessary for this application, as the data are essentially identical to those of the existing product.
PHARMACEUTICAL ASSESSMENT

HERBAL SUBSTANCE: ANISEED FRUIT

Scientific name of the plant: *Pimpinella anisum* L.
Plant family: Apiaceae

The herbal substance is used in the already licensed product. It is, therefore, acceptable.

HERBAL PREPARATION: ANISEED FRUIT EXTRACT

Extraction solvent: Water

The herbal preparation is used in the already licensed product. It is, therefore, acceptable.

HERBAL SUBSTANCE: ELDER FLOWER

Scientific name of the plant: *Sambucus nigra* L.
Plant family: Adoxaceae

The herbal substance is used in the already licensed product. It is, therefore, acceptable.

HERBAL PREPARATION: ELDER FLOWER EXTRACT

Extraction solvent: Water

The herbal preparation is used in the already licensed product. It is, therefore, acceptable.

HERBAL SUBSTANCE: ICELAND MOSS THALLUS

Scientific name of the plant: *Cetraria islandica* L.
Plant family: Parmeliaceae

The herbal substance is used in the already licensed product. It is, therefore, acceptable.

HERBAL PREPARATION: ICELAND MOSS THALLUS EXTRACT

Extraction solvent: Water

The herbal preparation is used in the already licensed product. It is, therefore, acceptable.
**HERBAL SUBSTANCE:** MARSHMALLOW ROOT

Scientific name of the plant: *Althaea officinalis* L.
Plant family: Malvaceae

The herbal substance is used in the already licensed product. It is, therefore, acceptable.

**HERBAL PREPARATION:** MARSHMALLOW ROOT EXTRACT

Extraction solvent: Water

The herbal preparation is used in the already licensed product. It is, therefore, acceptable.

**HERBAL SUBSTANCE:** THYME HERB

Scientific name of the plant: *Thymus vulgaris* L. & *Thymus zygis* L.
Plant family: Lamiaceae

The herbal substance is used in the already licensed product. It is, therefore, acceptable.

**HERBAL PREPARATION:** THYME HERB EXTRACT

Extraction solvent: Water

The herbal preparation is used in the already licensed product. It is, therefore, acceptable.

**HERBAL SUBSTANCE:** WHITE HOREHOUND HERB

Scientific name of the plant: *Marrubium vulgare* L.
Plant family: Lamiaceae

The herbal substance is used in the already licensed product. It is, therefore, acceptable.

**HERBAL PREPARATION:** WHITE HOREHOUND HERB EXTRACT

Extraction solvent: Water

The herbal preparation is used in the already licensed product. It is, therefore, acceptable.
**HERBAL PRODUCT:**  
**WELEDA HERB & HONEY COUGH ELIXIR**

**Description and Composition of the Herbal Product**
Weleda Herb & Honey Cough Elixir is a clear to slightly turbid amber-brown syrupy oral solution. 5 ml of oral solution contains 4g of liquid extract from Aniseed, Elder flower, Iceland moss thallus, Marshmallow root, Thyme herb and White horehound herb and the excipients water, honey, sucrose, glycerol and citric acid monohydrate. The formulation is identical to that of the already licensed product. It is, therefore, acceptable.

**Manufacture of Herbal Product**
The manufacturing process is in line with that of the already licensed product and is satisfactory.

**Finished Product Specification**
The finished product specification is in line with that of the already licensed product and is satisfactory.

**Container Closure System**
The product is packed in 100 ml, amber, glass bottles with a white screw cap closure. This type of packaging has been used to store the already licensed product and is satisfactory.

**Stability of Herbal Product**
A product shelf life of 3 years for product stored in unopened containers was applied to the already licensed product and is appropriate when the storage precautions ‘Do not store above 25°C’ and ‘Store in original package’ are applied. Once the container is first opened a shelf life of 1 month applies.

**Summary of Product Characteristics, label and Patient Information Leaflet**
All product literature is in line with that of the already licensed product, with some details amended in line with other products registered under the THR scheme.

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.

**ASSESSOR’S OVERALL CONCLUSION**
It is recommended that a Traditional Herbal Registration can be granted.
PRECLINICAL ASSESSMENT

INTRODUCTION
No new preclinical data have been supplied with this application and none is required for an application of this type.

Assurance has been given that the results of genotoxicity testing will be provided by the renewal date of the Traditional Herbal Registration.

PRODUCT LITERATURE
All product literature is satisfactory from a preclinical point of view.

ASSESSOR’S OVERALL CONCLUSION
It is recommended that a Traditional Herbal Registration can be granted.
CLINICAL ASSESSMENT

INTRODUCTION
The clinical particulars for Weleda Herb & Honey Cough Elixir are identical to those for the already licensed product. This is satisfactory.

PRODUCT LITERATURE
All product literature is medically satisfactory.

ASSESSOR’S OVERALL CONCLUSION
It is recommended that a Traditional Herbal Registration can be granted.
OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

QUALITY
Weleda Herb & Honey Cough Elixir is identical to an already licensed product. It is, therefore, pharmaceutically satisfactory.

PRECLINICAL
No new preclinical data were submitted and none are required for an application of this type. The results of genotoxicity testing will be provided before the THR is renewed.

EFFICACY
No clinical efficacy data are required for registration of Traditional Herbal Medicinal Products.

SAFETY
No new or unexpected safety concerns arose from this application.

BENEFIT-RISK ASSESSMENT
The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The benefit: risk balance is acceptable and a THR should be granted.
WELEDA HERB & HONEY COUGH ELIXIR

THR 00298/0291

STEPS TAKEN FOR ASSESSMENT

1. The MHRA received the Traditional Herbal Registration application on 28 February 2013

2. Following standard checks and communication with the applicant the MHRA considered the application valid on 5 March 2013

3. Following assessment of the application the MHRA requested information relating to the dossier on 27 March 2012

4. The applicant responded to the MHRA’s request providing further information on the dossier on 25 April 2013

5. A THR was granted on 29 April 2013
SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Weleda Herb & Honey Cough Elixir

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
5 ml of oral solution contains 4g of liquid extract from:
- Aniseed (*Pimpinella anisum* L.) (equivalent to 81 mg Aniseed fruit);
- Elder flower (*Sambucus nigra* L.) (equivalent to 81 mg Elder flower);
- Iceland Moss thallus (*Cetraria islandica* L.) (equivalent to 81 mg Iceland Moss thallus);
- Marshmallow root (*Althaea officinalis* L.) (equivalent to 81 mg Marshmallow root);
- Thyme herb (*Thymus vulgaris* L. & *Thymus zygis* L.) (equivalent to 81 mg Thyme herb);
- White Horehound herb (*Marrubium vulgare* L.) (equivalent 81mg to White Horehound herb).
Extraction solvent: Water.
Each 5ml of oral solution also contains 3.5 g sucrose.
For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM
Oral solution.
Clear to slightly turbid amber-brown syrupy liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
A traditional herbal medicinal product used for the symptomatic relief of dry and irritating coughs, based on traditional use only.

4.2 Posology and method of administration
For oral use.
Adults, the elderly and children over 12 years of age: Two 5ml spoonfuls (10ml) every 3–4 hours, undiluted or in a little water. Up to four doses can be taken daily.
Duration of use: 7 days
This use is not recommended for use in children under 12 years of age ( see Section 4.4, ‘Special warnings and precaution for use’). If the symptoms worsen or persist after 1 week, a doctor or qualified healthcare practitioner should be consulted.
4.3 **Contraindications**
Hypersensitivity to any of the active ingredients or to Apiaceae (Umbelliferae) (caraway, celery, coriander, dill and fennel) or to anethole or to members of the Lamiaceae family or to any of the excipients.
Obstruction of the bile duct, cholangitis, liver disease, ileus.

4.4 **Special warnings and precautions for use**
Do not exceed the stated dose.
If the symptoms worsen or persist after 1 week, a doctor or qualified healthcare practitioner should be consulted.
If dyspnoea, fever or purulent sputum occurs, a doctor or a qualified healthcare practitioner should be consulted.
The use of this product in children under 12 years of age is not recommended because there is no experience available.
Patients with active peptic ulcer, gallstones and any other biliary disorders should consult a doctor before using White horehound herb preparations.

Contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 **Interaction with other medicinal products and other forms of interaction**
None known.

4.6 **Fertility, pregnancy and lactation**
The safety of the product during pregnancy and lactation has not been established. In the absence of sufficient data the use during pregnancy and lactation is not recommended.
Studies on the effects on fertility have not been performed.

4.7 **Effects on ability to drive and use machines**
No studies on the effect of the product on the ability to drive and use machines have been performed.

4.8 **Undesirable effects**
Allergic reactions to aniseed affecting the skin or the respiratory system may occur. The frequency is not known.
Hypersensitivity reactions (including one case of anaphylactic shock and one case of Quincke edema) and stomach disorders have been observed with Thyme herb. The frequency is not known.

If other adverse reactions do occur a doctor or qualified healthcare practitioner should be consulted.

4.9 **Overdose**
No case of overdose has been reported.
5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Not required as per article 16c(1)(a)(iii) of Directive 2001/83/EC as amended

5.2 Pharmacokinetic properties
Not required as per article 16c(1)(a)(iii) of Directive 2001/83/EC as amended

5.3 Preclinical safety data
Tests on reproductive toxicity, genotoxicity and on carcinogenicity have not been performed.
An aniseed extract prepared with water was tested in an Ames test on *Salmonella typhimurium* strains TA98, TA100, TA102 and turned out as negative.
Results from non-clinical studies showed a weak mutagenic potential of anethole.
The genotoxic risks related to estragole is not considered to be relevant in the specified conditions of use due to the small amount present.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Water
Honey
Sucrose
Glycerol
Citric Acid, Monohydrate

6.2 Incompatibilities
None known.

6.3 Shelf life
Shelf life unopened:
3 years
Shelf life after first opening:
1 month

6.4 Special precautions for storage
Do not store above 25°C. Store in original package.

6.5 Nature and contents of container
Amber glass bottle with white screw cap closure.
100ml

6.6 Special precautions for disposal
There are no special precautions for disposal.
7 MARKETING AUTHORISATION HOLDER
Weleda (UK) Ltd
Heanor Road
Ilkeston
Derbyshire DE7 8DR, UK

8 MARKETING AUTHORISATION NUMBER(S)
THR 00298/0291

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
29/04/2013

10 DATE OF REVISION OF THE TEXT
29/04/2013
WELEDA HERB & HONEY COUGH ELIXIR

Traditional Herbal Medicinal Product

Liquid extracts from Aniseed, Elder flower, Iceland Moss, Marshmallow root, Thyme, White Horehound.

PATIENT INFORMATION

Read this leaflet carefully because it contains important information for you. Keep this leaflet. You may need to read it again.

Ask your pharmacist or qualified healthcare practitioner if you need more information or advice. You must contact a doctor or qualified healthcare practitioner if your symptoms worsen or do not improve after one week. If any of the side-effects get serious, or if you notice any side-effect not listed in this leaflet, please tell your doctor or qualified healthcare practitioner.

In this leaflet:

1. What this product is and what it is used for
2. Before taking this product
3. How to take this product
4. Possible side-effects
5. How to store this product
6. Further information

1. What this product is and what it is used for

Weleda Herb & Honey Cough Elixir is a traditional herbal medicinal product used for the symptomatic relief of dry and irritating coughs. This is based on traditional use only.

2. Before using this product

Do not take Weleda Herb & Honey Cough Elixir if you are allergic to any of the ingredients or to Apiaceae (Umbelliferae) (caraway, celery, coriander, dill and fennel) or to Anethole or to members of the Lamiaceae family (see Section 6), if you suffer from an obstruction of the bile duct, cholangitis (inflammation of the bile ducts), liver disease, ileus (intestinal obstruction) or if you are pregnant or breastfeeding or you are under 12 years of age.

- Consult your doctor, pharmacist or qualified healthcare practitioner if:
  - you have been told by your doctor that you have intolerance to some sugars
  - you have a peptic ulcer, gallstones or other biliary disorders

3. How to use this product

Directions: Weleda Herb & Honey Cough Elixir is for oral use. Shake the bottle.
Adults, the elderly and children over 12 years of age: Two 5ml spoonfuls (10ml) every 3 - 4 hours, undiluted or in a little water. Up to four doses can be taken daily.

Weleda Herb & Honey Cough Elixir is not recommended for children under 12 years of age. If you develop shortness of breath, a fever or coloured sputum while taking this product or if symptoms worsen or persist after one week, consult a doctor or qualified healthcare practitioner.

Each 5ml dose contains 3.5g of sucrose. This should be taken into account if you suffer from diabetes mellitus.

DO NOT EXCEED THE STATED DOSE
OVERDOSE
If you accidentally take too much of this product (overdose), consult your doctor or pharmacist as soon as possible and take this leaflet with you.

WHAT TO DO IF YOU MISS A DOSE
If you miss a dose of Weleda Herb & Honey Cough Elixir, just take the next dose when it is due. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side-effects
Aniseed may cause allergic reactions affecting the skin or respiratory system. Thyme may cause hypersensitivity reactions or stomach disorders. (One case of anaphylactic shock - a serious allergic reaction causing breathing difficulty and one case of Quincke oedema has been reported).
If you experience any unwanted effects consult your doctor, pharmacist or qualified healthcare practitioner.
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 GP's surgery or pharmacy, or call freephone 0808 100 3352 (available 10am-2pm Monday - Friday).

5. How to store this product
- keep out of the reach and sight of children
- do not store above 25°C
- do not use after the expiry date on the carton or label
- discard one month after first opening
- store in the original container
- return any unused medicine to your pharmacist for safe disposal

6. Further Information
Each 5ml of Weleda Herb & Honey Cough Elixir contains 4g of liquid extract from: Aniseed (Pimpinella anisum L.) (equivalent to 81mg Aniseed fruit); Elder flower (Sambucus nigra L.) (equivalent to 81mg Elder flower); Iceland Moss thallus (Cetraria islandica L.) (equivalent to 81mg Iceland Moss thallus); Marshmallow root (Althaea officinalis L.) (equivalent to 81mg Marshmallow root); Thyme herb (Thymus vulgaris L. and Thymus zygis L.) (equivalent to 81mg Thyme herb); White Horehound herb (Marubium vulgare L.) (equivalent to 81mg White Horehound herb).
Extraction solvent: Water.
Other ingredients: Purified Water, Honey, Sucrose, Glycerol, Citric Acid Monohydrate.
Pack Description: Weleda Herb & Honey Cough Elixir is a clear to slightly turbid, amber-brown syrupy liquid with a characteristic aromatic herbal/aniseed odour and sweet taste presented in an amber glass bottle. One pack size of 100ml is available.
THR holder and manufacturer: Weleda (UK) Ltd., Heanor Road, Ilkeston, Derbyshire DE7 8DR, UK.
THR 00298/0291.

Braille version
To request a copy of this leaflet in Braille or large print, or to listen to an audio version, please call free of charge: 0800 198 5000 (UK only).
Please be ready to give the following information:
Product name: Weleda Herb & Honey Cough Elixir.
Reference number: THR 00298/0291.
This service is provided by the Royal National Institute for Blind people.

Leaflet last revised June 2013 1/081532/1
LABELLING

Label:

A traditional herbal medicinal product used for the symptomatic relief of dry and irritating coughs. Based on traditional use only.

Active Ingredients: Each 5ml of oral solution contains 4g of liquid extract from: Aniseed (Pimpinella anisum L) (equivalent to 81mg Aniseed fruit); Elder flower (Sambucus nigra L) (equivalent to 81mg Elder flower); Iceland Moss thallus (Cetraria islandica L) (equivalent to 81mg Iceland Moss thallus); Marshmallow root (Althaea officinalis L) (equivalent to 81mg Marshmallow root); Thyme herb (Thymus vulgaris L. and Thymus zygis L) (equivalent to 81mg Thyme herb); White Horehound herb (Marumium vulgare L) (equivalent to 81mg White Horehound herb).

Extraction solvent: Water.

Directions: Adults, the elderly and children over 12 years of age: Two 5ml spoonfuls (10ml) every 3 - 4 hours, undiluted or in a little water. Up to 4 doses can be taken daily.

Weleda Herb & Honey Cough Elixir is not recommended for children under 12 years of age.

Shake the bottle

Keep all medicines out of the reach and sight of children

Discard one month after opening. Do not store above 25°C. Store in the original container. Do not use after the expiry date stated. Read the enclosed leaflet before use. Contents 100ml
Carton:

Weleda Herb & Honey Cough Elixir

ORAL SOLUTION

A traditional herbal medicinal product used for the symptomatic relief of dry and irritating coughs.
Based on traditional use only.

Active ingredients: Each 10ml of oral solution contains 4g of liquid extract from: Arsenical (Pimpinella anisantha L.) (equivalent to 8mg Arsenical) Bitter Wild Thyme (Thymus vulgaris L.) (equivalent to 8mg Thyme), Marshmallow root (Althaea officinalis L.) (equivalent to 8mg Marshmallow root), Thyme herb (Thymus vulgaris L. and Thymus zygis L.) (equivalent to 8mg Thyme herb), White Horehound herb (Marrubium vulgare L.) (equivalent to 8mg White Horehound herb).

Extraction solvent: Water.
Other ingredients: Purified Water, Honey, Sucrose, Glycerol, Citric Acid, Monohydrate.

Keep all medicines out of the reach and sight of children.

Do not use after the expiry date stated on the carton and label.

Remove one month after opening.

Do not store above 25°C.

Store in the original container.

A traditional herbal medicinal product used for the symptomatic relief of dry and irritating coughs.
Based on traditional use only.

A traditional herbal medicinal product used for the symptomatic relief of dry and irritating coughs.
Based on traditional use only.

MHRA PAR; WELEDA HERB & HONEY COUGH ELIXIR, THR 00298/0291 19