**STATE INSTITUTE FOR DRUG CONTROL**

**Šrobárova 48, 100 41 PRAGUE 10**

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***Czech Medical Herbs, s.r.o.***

***Ve Smečkách 1258/6***

***110 00 Prague 1 - Nové Město***

File No.: sukls121120/2013 DATE: 6 January 2014

Reference No.: skull/2014

Dispatched on a day of its handover for postal transport, as identified on the envelope by a postal service provider, on a day of sending the data message from the data box of the State Institute for Drug Control, on a day of its handover to the addressee in case of personal delivery.

**DECISION**

The State Institute for Drug Control, with the registered office at Šrobárova 48, Prague 10, as an authority competent to decide pursuant to Section 13 (2) a) clause 2 of the Act No. 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts, subsequently amended (hereinafter referred to as the “Act on Pharmaceuticals”), decided

as follows:

Pursuant to Section 76 and Section 63 (1) of the Act on Pharmaceuticals, the State Institute for Drug Control

**issues** to Czech Medical Herbs, s.r.o., with the registered office at Ve Smečkách 1258/6, Nové Město, 110 00 Prague 1, Company Identification No. 016 79 210, based on its request delivered on 4 July 2013,

**permission to distribute the medical products.**

1. The distribution shall be realized from the storage premises at the address: U Továren 256/14, 102 00 Prague 10 (1st room, 2nd floor, building B, with the total area of 34 m²).
2. The qualified person is pursuant to Section 76 (1) b) of the Act on Pharmaceuticals:

RNDr. Eva Matějková.

1. The distribution is permitted within the scope of:
2. Distribution of medical products,
3. Distribution of medical substances and adjuvants to persons entitled to prepare the medical products.
4. Individual distribution places (approved storage premises) and the scope of a distribution activity are specified in Annex 1.
5. The initial inspection, based on which the permission to distribute was issued, was made on 18 December 2013.

The data mentioned in this permission and its annexes corresponds to the document “Compilation of Community Procedures on Inspection and Exchange of Information”, as amended on 2 January 2013.

**Justification**

On 4 July 2013, Czech Medical Herbs, s.r.o., with the registered office at Ve Smečkách 1258/6, Nové Město, 110 00 Prague 1, Company Identification No. 016 79 210, filed an application for permission to distribute the medical products. By filing the application, the administration proceedings under file No. sukls121120/2013 were opened. Within the proceedings and based on the results of an inspection made on site on 18 December 2013, the State Institute for Drug Control (hereinafter referred to as the “Institute”) assessed whether the requirements stipulated by the Act on Pharmaceuticals and its implementing regulations are met in the given case.

After performing such assessment, the Institute states that the requirements are met. In this respect, the Institute decided on the permission to distribute the medical products, as specified in this resolution.

**Instructions on appeal**

It is possible to file an appeal against this decision pursuant to Section 81 et seq. of the Act No. 500/2004 Coll., Administrative Procedure Code, subsequently amended, at the Institute within 15 days after delivery of the decision. The Ministry of the Czech Republic shall decide on the appeal.

Official stamp

PharmDr. Ivan Buzek

Head of Pharmacy and Distribution

Annex 1 – Scope of the permission to distribute medical products (1 page)

Annex 1/1 to the Decision, file No. sukls121120/2013 of 6 January 2014

**SCOPE OF THE PERMISSION TO DISTRIBUTE MEDICAL PRODUCTS**

Name and address of the distribution place:

Czech Medical Herbs, s.r.o., U Továren 256/14, 102 00 Prague 10

**1. MEDICAL PRODUCTS**

**1.1** X with a decision on registration in the EEC country/countries

xx

**1.2** without any decision on registration in EEC and determined for the EEC market \*

**1.3** without any decision on registration in EEC and determined for export

**2. PERMITTED DISTRIBUTION ACTIVITIES**

**2.1** X Purchase/Arrangement

x

**2.2** X Storage

x

**2.3** X Supply

x

**2.4** Export

x

**2.5** Other activities: ---

x

**3. MEDICAL PRODUCTS WITH ADDITIONAL REQUIREMENTS**

**3.1** X Products pursuant to Article 83 Directive 2001/83/ES[[1]](#footnote-1)

x

**3.1.1** X Narcotic and nebo psychotropis drugs

x

**3.1.2** Medical products from blood

x

**3.1.3** Imunological medical products

x

**3.1.4** Radiopharmaceuticals (including radionuclide kits)

x

**3.2** Medical gases

x

**3.3** Cold chain products (requiring the manipulation at low tepmeratures)

x

**3.4** Other products: ---

x

All limitations or explaining notes or stipulation of conditions concerning the scope of the distribution activity: ---

\*Article 5 Directive 2001/83/EC or No. 83 Regulation EC/726/2004

Official stamp

PharmDr. Ivan Buzek

Head of Pharmacy and Distribution

1. Without affecting other permissions that may be required according to the national legislation [↑](#footnote-ref-1)