



Panacea Biotec

Innovation in support of life

TO WHOM IT MAY CONCERN

*Subject: declaration regarding the registration status
of the product PACLIALL in Ukraine and Canada*

Date: June 18, 2024

We, **Panacea Biotec Pharma Ltd.**, company registered under the laws of India, corporate office placed by address: **B-1 Extn./A-27, Mohan Co-operative Industrial Estate, Mathura Road, New Delhi 110044, India**; hereby confirm that we are the developer and owner of the registration dossier for medicinal product Pacliall (INN - Paclitaxel), lyophilizate for suspension for infusion 100 mg in vial. This product has been approved in Ukraine with registration number UA/19949/01/01.

During the registration procedures of the medicinal product Pacliall in Ukraine our company acting as Applicant or Marketing Authorization Holder (hereinafter called - **PANACEA Applicant**)

Our wholly-owned subsidiary company (manufacturing site) **Panacea Biotec Pharma Ltd.**, company registered under the laws of India, placed by address: **Malpur, Baddi, Tehsil Nalagarh, District Solan, Himachal Pradesh, 173 205, India**; during the registration procedures in Ukraine approved as Manufacturer of the finished medicinal product (hereinafter called - **PANACEA Manufacturer**).

A completely similar product in quantitative and qualitative composition; completely similar in scheme and production technology was approved in Canada.

Approved product name in Canada: **PACLITAXEL, Powder for injectable suspension nanoparticle, albumin-bound, 100 mg.**

We declare and guarantee that:

- Pacliall (INN – Paclitaxel; Ukrainian trade name - ПАКЛІАЛІ), lyophilizate for suspension for infusion 100 mg in vial; approved in Ukraine
and

- **PACLITAXEL, Powder for injectable suspension nanoparticle, albumin-bound, 100 mg; approved and marketed in Canada**

are completely similar products in quantitative and qualitative composition; completely similar in scheme and production technology, manufactured by the same manufacturing site PANACEA Manufacturer (details specified above).

A different trade name for the product has been approved due to specific medicinal product naming approaches and regulatory requirements in Canada.

Apotex Inc. a company registered under the laws of Canada, corporate office placed by address: **Toronto, Ontario, M9L 1T9, Canada** is authorized Importer and Distributor in Canada for approved medicinal product **PACLITAXEL, Powder for injectable suspension nanoparticle, albumin-bound, 100 mg.**

Panacea Biotec Pharma Limited

CIN:U24299DL2019PLC347566

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Apotex Inc. does not participate in product manufacturing, packaging, quality control, etc. Apotex Inc. is the exclusive owner of the rights to supply and sell the product of Panacea Biotec Pharma Ltd. in Canada.

Mutual relationship of Panacea Biotec Pharma Ltd. / **PANACEA Applicant** (location: B-1 Extn./A-27, Mohan Co-operative Industrial Estate, Mathura Road, New Delhi 110044, India) and

Panacea Biotec Pharma Ltd. / **PANACEA Manufacturer**, (location: Malpur, Baddi, Tehsil Nalagarh, District Solan, Himachal Pradesh, 173 205, India) and **Apotex Inc.** is a subject of the partnership agreement and technical agreement entered into between them.

For

Panacea Biotec Pharma Ltd. / PANACEA Applicant

Name: Mr. Dinesh Singla

Title: Senior Vice President – Pharma Research & Pharma Regulatory Affairs

address: B-1 Extn./A-27, Mohan Co-operative Industrial Estate, Mathura Road, New Delhi 110044, India

signature



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