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Brussels, 16 August 2022

Dear **Mr. Bikash R. Mahato**,

On behalf of the European Coalition on Homeopathic & Anthroposophic Medicinal Products (ECHAMP), we are writing to share some comments on the draft of the New Drugs, Medical Devices and Cosmetics Bill and to voice some concerns of our Members.

ECHAMP is the European association of companies active in the production and distribution of homeopathic and anthroposophic medicinal products. It serves the common needs of its members (both big and smaller players) and reflects the broad needs of the sector. We have 37 company members from 15 European Union Member States (Full Members) and 4 Extraordinary Partners from Switzerland and UK.

We support the Indian Government's initiative to develop a contemporary legislation. We particularly welcome the way in which the draft legislation reflects India's longstanding pluralistic approach to healthcare. We greatly value the fact that complementary medicine has always been an integral cornerstone in India's health system, making a contribution towards sustainable, effective and cost-effective care.

This revision therefore presents a unique opportunity for India to facilitate innovation for AYUSH medicines, taking a lead as regards the global development of this sector and the further exploitation of its potential.

Our particular interest is homeopathic medicines and we welcome the inclusion of homeopathic medicinal products in the chapter on AYUSH medicines. As manufacturers of homeopathic medicines, some of our members work closely with commercial partners in India, and on their behalf, we also have some important concerns which we would like to share with you.

This draft Bill may inadvertently discriminate against homeopathic products and in doing so severely impact the future viability of this industry as a whole. Firstly, through restrictions of manufacturing techniques to those of the Indian Homeopathic Pharmacopeia (HPI) and secondly through highly increased registration and import fees. We believe it is important that Indian patients should have continued access to homeopathic medicines irrespective of the place of their production.

Furthermore, it is not clear to us whether the recognition of the Indian Homeopathic Pharmacopeia (HPI) and its manufacturing methods is intended to be exclusive and therefore obligatory as regards eligibility for product registration. This would imply that products, manufactured in accordance with other Homeopathic Pharmacopoeias, some of which have been on the Indian market for decades, may no longer be available for the Indian population. Continued recognition of currently recognized homeopathic pharmacopoeias is essential to preserve the existing market and ensure the availability of those products.

With its vast experience and knowledge on Traditional, Complementary and Integrative Medicine (TCIM), India will have an important role to play in achieving the WHO goals on the utilization of TCIM. The retention of a proportional system that continues to recognize all official pharmacopoeias will be an important factor in facilitating these goals. It will also aid innovation and the further global development of the homeopathic sector.

We respectfully ask you to take into consideration the concerns of our Members so as to continue to build on the successful work done by previous AYUSH ministries in the development of the homeopathic sector in your country.

Sincerely yours,



Bernadette Krom
Chair of Pharmaceutical Affairs

Amandine Oset
Public Affairs