Mr Jean-Claude Juncker
President of the European Commission
200 Rue de la Loi
B – 1049 Bruxelles

CC: Frans Timmermans
First Vice President of the European Commission

Brussels, 12 October 2015

Dear Mr Juncker,

Re: Better Regulation agenda

On behalf of the European Coalition on Homeopathic and Anthroposophic Medicinal Products (ECHAMP), I would like to warmly congratulate the European Commission on its recent adoption of the Better Regulation Agenda.

ECHAMP acts as the voice of the vast majority of the industry for homeopathic and anthroposophic medicinal products in Europe. Our main objective is to enable our members to meet the increasing demand from users and prescribers across the EU for homeopathic and anthroposophic medicinal products; in that respect, we aim to cooperate with the EU institutions as effectively as possible.

It is positive to note that 'Better regulation' was listed as a top priority in the Political Guidelines of this Commission and that with the adoption of this Agenda, this priority is turning into a concrete reality. ECHAMP particularly welcomes the comprehensive nature of the proposed package of reforms, which covers the entire policy cycle. Stimulating openness and transparency in the EU decision-making process, improving the quality of new laws through better impact assessments of draft legislation and amendments and promoting a consistent review of existing EU laws, will ensure that these laws achieve their objectives will support a more effective functioning of the EU as a whole as well as help improve the current image of 'Brussels' as a heavy, slow-functioning and over-bureaucratic policy body.
As EU regulation in the field of homeopathic and anthroposophic medicinal products is not fit for purpose and creates unnecessary administrative burden at Member State level[1], the Better Regulation Package offers possibilities to ensure greater attention for ECHAMP's issues in relation to the current regulatory framework and its implementation. In addition, as most of ECHAMP's members are SME's, the Agenda holds much promise for them as well.

ECHAMP also welcomes the Commission's intentions to better include stakeholders with improving existing policies or assessing new proposals. However, it is unclear how and to what extent stakeholders will be included and how their views will concretely feed into the legislative debate.

[1] recent research by Matrix Insight on the availability of medicines, requested by the Commission, comes to the same conclusions and states 'that the existing legislative framework for homeopathic products may fall short of simplifying procedures and introducing more harmonization across the EU for these products'. it also concludes the current European pharmaceutical acquis could be reviewed to enhance availability of medicinal products'.

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The proposed 'REFIT Platform', bringing together high-level experts from business, civil society, social partners, the Economic and Social Committee, the Committee of Regions and Member States, may be a useful step in the right direction.

There are various reasons why addressing the regulatory and implementation issues facing our specific sector are important:

- *First, a healthy industry generates jobs and contributes to the EU economy*
  It is indeed important to keep our – mainly European based - industry healthy. A regulatory framework which stimulates the industry rather than hinders it will be an important incentive, not only to meet the demand of EU citizens but also the growing demand in the emerging export markets for homeopathic and anthroposophic medicinal products across the world.
- *Second, freedom of choice in healthcare matters to EU citizens*
  Currently, some 100 million EU citizens make use of our products. This is directly related to the fact that today's European citizens feel more responsible for their own health and treatment options. It is an important EU principle for patients should have access to the medicinal products of their choice. This includes innovative medicines as much as traditional herbal and homeopathic medicinal products.
- *Third, our sector aligns with and can contribute to current EU–level priorities*
  Studies and data from the area of health insurance increasingly demonstrate the important economic benefit of integration of homeopathic and anthroposophic treatments in regular and standard healthcare. The products have an overall positive safety record, are available at low cost and can contribute to achieving key EU goals in the frame of health of the citizens.
- There are also clear links with other Commission priorities, such as the current focus on resilient, accessible and sustainable health systems, chronic disease, healthy ageing, patient empowerment, and antibiotic resistance.
- *Fourth, availability of our products needs to be ensured*
  Last but not least, we have been informed that the Commission's report on the availability of medicines, which is awaiting publication, contains a chapter on availability of our products; we have carried out our own research – in cooperation with PWC – which has led us to conclude that it is EU regulation that constitutes a serious bottleneck to sustainable availability.

In view of the above, it is clear that action is needed to guarantee freedom of choice for the millions of users to overcome the shortcomings of enforcement of EU regulation at EU Member State level. In our recent meeting with Health Commissioner Vytenis Andriukaitis, it was agreed that ECHAMP will come forward with a list of concrete issues and barriers which can be addressed at EU level to improve the legislation and the situation of our industry. Needless to say, we will share these concrete points with you, in order to for to consider addressing them, as ECHAMP would like to work together with you and your staff to address our concerns and issues in the most efficient and transparent way.

Many thanks in advance for your attention and interest,

Yours sincerely,

Dr. Gesine Klein
President

Christiaan Mol
General Secretary

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