Mr Frans Timmermans, First Vice-President of European Commission
Mr Vytenis Andriukaitis, Member of the European Commission
Mrs Elzbieta Bienkowska, Member of the European Commission
European Commission
Rue de la Loi 200
B – 1049 Bruxelles

Brussels, 20 August 2015

Dear Commissioners,

Re: Conference on 50 years of EU pharmaceutical legislation

On behalf of the European Coalition on Homeopathic and Anthroposophic Medicinal Products (ECHAMP), we warmly welcome the planned conference celebrating the fact that EU pharmaceutical legislation has been in place for 50 years.
Indeed, over the past 50 years an impressive body of legislation has been developed around the principle of safeguarding public health, with the progressive harmonisation of requirements for the granting of marketing authorisations and post-marketing monitoring implemented across the entire EU. The timeline, developed by the Commission to show the various milestones as well as general progress, is impressive.

ECHAMP much appreciates the fact that the conference 'will review past achievements while focusing on the present and future role of EU pharmaceutical legislation in protecting the health of citizens in the EU and in the world, and in promoting advances in science, innovation and public health'. While much has been accomplished over recent year, we agree there are still many challenges ahead – particularly for our sector and it is positive to note that the conference wants to bring to surface different perspectives 'in an open and stimulating exchange with representatives from national governments, European institutions, national competent authorities, industry, healthcare professionals, academia and patient groups, with the objective of working towards a shared vision for the future'.

As you may be aware, 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.

Unfortunately, in our day to day work, we consistently note that the current EU legal and regulatory framework for homeopathy and anthroposophic medicine does not work efficiently in practice. It is not fit for purpose and creates an unnecessary and unmanageable administrative burden for Member States' authorities. Apart from posing a severe threat to availability of and access to our products, this ineffectiveness and not being fit for purpose does not benefit patients, doctors and practitioners. Moreover, it threatens the viability of our businesses. **More than twenty years since its adoption, the implementation and enforcement of European medicines legislation for this sector is far from complete**. For your information, we have developed our own timeline with milestones in the area of our specific pharmaceutical area, which you can find in attachment.

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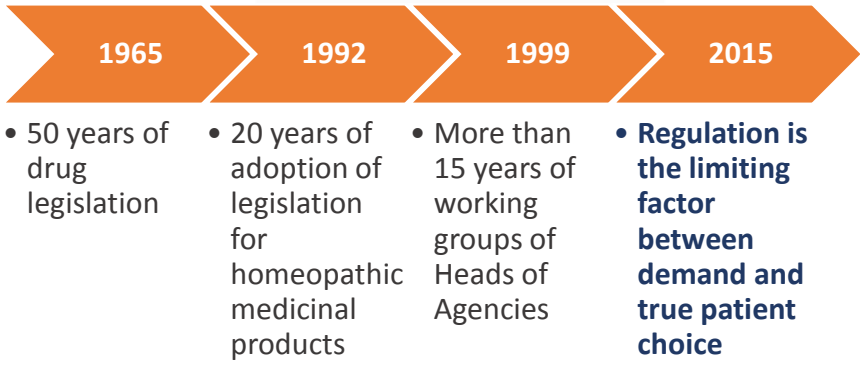

There are various reasons why addressing the issues facing are sector are important:

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, the recent Matrix Insight report, requested by the Commission itself, contains a chapter on availability of our products and basically echoes the findings of our own research, stating that 'incomplete and ineffective implementation in Member States seems to result in relatively few products becoming registered as medicinal products'. It concludes that there is a need to take a closer look at current EU regulation: 'the current European pharmaceutical acquis could be reviewed to enhance availability of medicinal products'.

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In view of the above, we were delighted with the opportunity to meet with Health Commissioner Vytenis Andriukaitis some weeks ago, who requested a clear and actionable set of issues that could be addressed at EU level. We are currently working on this and hope be in a position to share these issues (as well as proposed solutions) with the Commission soon, as it is clear that action is needed to guarantee freedom of choice for the millions of users.

Therefore, we hope that you will be able to address and take account of our concerns and issues during the upcoming conference, as homeopathy and anthroposophic medicine are part and parcel of today's health care delivery; these therapeutic systems clearly – and increasingly - matter to patients and consumers.

We wish you all the best for a successful conference.

Many thanks in advance for your attention and interest,

Yours sincerely,

Dr. Gesine Klein
President

Christiaan Mol
General Secretary

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