15 July 2015
Brussels

Mr Vytenis Andriukaitis
EU Commissioner for Health and Food Safety

Dear Commissioner,

We, undersigning MEPs, thank the European Commission for its evaluation of the availability of medicinal products on the European pharmaceutical market as evidenced by the Commission's engagement of Matrix Insight to provide the Pharmaceutical Committee with a detailed report about the assessment of the way the pharmaceutical market is currently functioning. This enquiry is a convincing indicator of the European Commissions' continuing engagement in improving the performance of this sector.

While we are aware that the Matrix Insight Report is a working document and does not reflect the official position of the European Commission, we nevertheless note that the Report draws the attention to a number of problems, deficiencies and malfunctioning of the EU pharmaceutical market. For instance, the report finds that the size of the market, the interests of the pharmaceutical industry as well as authorization problems in connection with existing legislation hinders the availability of certain medicinal products for patients and citizens. The Report also draws attention to a divergence between European legislation and national interpretations of the way this legislation is implemented by Member States that prevents citizens accessing a full range of pharmaceutical products - particularly those used in the complementary medicine sector.

The Matrix Report also demonstrates a need to improve the operation of the Common Baltic Package Procedure, the Sunset Clause, the interpretation and implementation of certain articles of Directive 2001/83 as well as the regulations governing the availability of herbal, homeopathic and anthroposophic medicinal products - as described in the Case study 6 of the Report. This last matter was also highlighted by the Heads of Medicine Agencies to the DG SANCO in their letter April

8th 2014. Given the demand for such products, consulted stakeholders propose that "further action should be taken to ensure that the process of authorisation of herbal medicinal products and HAMPs (homeopathic and anthroposophic medicinal products) is more consistent, both with the text of the existing provisions and between Member States" (p.111 Matrix Report).

In addition, Matrix Insight consulted some European associations of manufacturers in the CAM field, unfortunately not the health professionals and patients in this sector. The latter group in particular perceives the current situation as decidedly unsatisfactory which was made clear at the recent meeting of the CAM Interest Group in the European Parliament (1 July 2015). Health professionals and patients require a full range of CAM medicines and health professionals prescribing herbal medicinal products require medicinal products with appropriate potency and indications for treatment. Herbals marketed as food supplements are not suitable for this purpose.

We are aware that the Commission has no intention of undertaking a full legislative initiative to modify the existing *Community code relating to medicinal products for human use* to remedy the legal situation of certain medicinal products. However, full and fair implementation of existing legislation throughout the EU will undoubtedly significantly improve the availability of medicinal products to meet the needs of patients, citizens and public health. In the light of this, we urge the Commission to issue a *Communication* addressing the problems highlighted by the Matrix Report concerning the inequitable way that existing pharmaceutical legislation is currently being interpreted. In the interests of citizens throughout the EU, we support the Commission in working in close cooperation with the Member States and their responsible competent authorities as well as all other concerned stakeholders to achieve this end as soon as is practicably possible.

In particular, we would like this Communication to include the answer the following questions:

1. Directive 2004/24/EC introduces the principle, that each Member State shall, when evaluating an application for traditional-use registration, take due account of registrations granted by another Member State. Given the great differences in the uptake of the traditional registration schemes, this principle seems not to work in practice. What steps does the

Commission intend to take to monitor and to encourage the "due account" rule?

2. How can the Commission ensure the general availability on CAM medicinal products throughout the EU thus ensuring a consistent regulatory approach to these products by all Member States?

3. How can the Commission ensure the general availability of herbal medicinal products, and in particular how can the Commission strengthen the coordinating power of the HMPC to ensure a consistent regulatory approach to these products by all Member States?

In the interests of citizens throughout the EU, we support the Commission in working in close cooperation with the Member States and their responsible competent authorities as well as all other concerned stakeholders to achieve this end as soon as is practicably possible.

With kind regards

Sirpa Pietikäinen, MEP
Marian Harkin, MEP
Liisa Jaakonsaari, MEP
Alojz Peterle, MEP
Michèle Rivasi, MEP