ECHAMP Response:
'External Study Report on the Availability of Medicinal Products for Human Use,' by Matrix Insight

ECHAMP warmly welcomes the publication, 'External Study Report on the Availability of Medicinal Products for Human Use,' by Matrix Insight, released on the website of the Pharmaceutical Committee of the European Commission on 24 November 2014.

This new report is a positive indication of the Commission's interest in the availability of medicines and its commitment to addressing one of the important principles of the EU's pharmaceutical legislation, that patients should have access to the medicinal products of their choice. It gives specific attention to the situation regarding the availability of homeopathic and anthroposophic medicinal products, which shows clear recognition of the special issues facing our industry.

The Matrix Insight report takes account of and echoes many of the findings of ECHAMP's own report, 'The Availability of Homeopathic and Anthroposophic Medicinal Products in the EU,' carried out in cooperation with PwC and launched in the European Parliament in 2013.

- **EU regulation is a barrier to availability**

The new report states that there is a divergence in national procedures and approach to homeopathic and anthroposophic products (HAMPs), and that 'purely regulatory problem drivers can mainly be linked to unavailability of...HAMPs'.

It also underlines that although simplified registration procedures are viewed as 'broadly appropriate,' 'incomplete and ineffective implementation in Member States seems to result in relatively few products becoming registered as medicinal products'.

This echoes ECHAMP's research, which shows how EU regulation constitutes a serious bottleneck to sustainable availability of our products, and that the implementation and enforcement of European medicines legislation for our sector has been slow and is very incomplete, despite it having been in place for over twenty years. This means that availability of registered/authorised homeopathic and anthroposophic medicinal products in the EU is insufficient and the demand cannot always be met.

- **Lack of a coherent legal framework is an important driver of availability problems**

The report includes a specific case study on homeopathic and anthroposophic medicinal products, referring to them as 'another type of product where there are potential availability problems' and stating that 'the lack of a coherent legal framework across the EU that would allow for products to be authorised (both new products and those already on the market) is also seen as an important driver of availability problems'.

In addition, the case study:

- **Underlines** that, although 'HAMPs constitute less than one percent of the EU pharmaceutical market, sales of such products remain significant and warrant an exploration of the availability issues associated with these product groups'.

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- **Reports** on the 'inconsistent application of Article 16.2 of the Directive' and that 'as a result in only a selection of Member States where it has been adopted have products been registered through this procedure'.
- **Quotes** ECHAMP´s finding that direct availability of anthroposophic medicinal products is generally worse than direct availability of homeopathic products.
- **Repeats** ECHAMP's conclusion that the existing regulatory procedures contribute to unavailability problems, as they are either ineffective or incorrectly applied.
- **Concludes** that the findings 'suggest that the existing legislative framework for homeopathic products may fall short of simplifying procedures and introducing more harmonization across the EU for these products'.
- **Also concludes** that 'the implementation of existing EU provisions concerning these products could be further improved, ensuring that the process of authorisation of HAMPs is more consistent, both with the text of the existing provisions and between Member States'.

- **Need to review the EU pharmaceutical 'acquis'**

While the Matrix Insight report notes that 'in general, availability in the Member States is not particularly problematic, with the products surveyed generally being available when ordered in advance', this statement does not take account of the findings by PwC in ECHAMP´s report, that many of the available HAMPs still do not carry a registration number. This underlines Matrix Insight´s overall conclusion 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'. ECHAMP also supports the recommendation to work to improve the national implementation of simplified procedures for HAMPs.

- **ECHAMP calls for further exploration to improve the situation of HAMPs**

ECHAMP warmly endorses the statements in this report and welcomes the fact that 'its outputs are expected to inform policy options for the Commission to consider in order to address the issue of unavailability, notably in terms of better application of the current legislative framework.'

Currently, over 100 million EU citizens make use of our products. Homeopathy and anthroposophic medicine are increasingly asked for by citizens with a significant to high demand in at least two thirds of EU Member States. However the regulatory environment, including assessment capacity and policy at national level, is not proportionate to the large range of stocks and multiple finished medicinal products produced from these stocks, which are used in homeopathic and anthroposophic therapy. In many Member States the number of registered products poorly reflects the high numbers of homeopathic prescribers.

Divergent implementation, interpretation and enforcement policy in the Member States make it extremely difficult for companies to operate across Europe. Action is needed to overcome the shortcomings of enforcement of EU regulation at EU Member State level and to guarantee freedom of choice for the millions of users of these products.

For further information:
External Study Report on the Availability of Medicinal Products for Human Use:
http://ec.europa.eu/health/files/committee/73meeting/73plus/study_report.pdf
The Availability of Homeopathic and Anthroposophic Medicinal Products in the EU, ECHAMP 2012:
http://www.echamp.eu/publications/special-reports/availability-report.html

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