European Brain Council

Professor Guido Rasi
Executive Director
European Medicines Agency

Brussels, 30 May 2017

Subject: Roundtable to discuss solutions to regulate off-label use

Dear Professor Guido Rasi,

Following on from your letter of 1 December 2016 (EMA/756658/2016) responding to our concerns on the unregulated use of off-label medicines in Europe, we, the undersigned organisations, supportive of the attached **Declaration on Good Off-Label Use Practice**, are writing to you regarding the publication by the European Commission of the long-awaited study on off-label use of medicinal products in the European Union in February 2017.

As organisations trying to raise awareness about the importance of defining a clear approach to off-label use across Europe, we welcome the publication of the report. While we consider that the study **downplays the limits imposed by the EU regulatory framework and case law**, we welcome the fact that it contributes to shedding light on the drivers behind the increasing use of off-label medicines in Europe, as well as the opportunities and challenges linked to it.

Most importantly, the study presents important evidence regarding the need for a harmonised approach to be adopted across Europe, facilitating access to treatment for patients in need, while ensuring their safety and the respect of the EU regulatory framework.

A number of valuable policy options are presented in the report. In particular, ***the development of general guidelines on off-label use at the EU level****, which describes the legal framework and the relation between the legal framework and professional guidelines,* seems to be the preferred option among stakeholders that contributed to the study. This follows on from the call of the European Parliament in October 2013, which was repeated in May 2015, to the European Medicines Agency (EMA) to develop guidelines on the off-label use of medicines, on the basis of medical need and taking account of patient protection.

The publication of the study offers a unique opportunity to involve all interested stakeholders in the process and work with the EMA and the European Commission to define and **put in place clear and strong European guidelines on the off-label use of medicines**.

In this regard, we are planning to organise a **high-level roundtable on the 10th of July 2017 to discuss potential solutions to regulate off-label use and reflect together on the next steps**. We would like to have the EMA presenting alongside the European Commission and other major stakeholders. We would thus like to check yours and your colleagues' availability to ensure that the EMA will be able to participate and contribute to the discussion.

Key topics for discussion will include the impact of unregulated off-label use on the EU regulatory system and the EMA's role in safeguarding the EU regulatory from national measures promoting economic off-label use.

We would thus invite your staff to liaise with FTI Consulting (Andrea Corazza, Director, andrea.corazza@fticonsulting.com, +32 2 289 09 30), which is supporting us in the organisation of this event, to arrange all the logistics.

We look forward to hearing as to your availability for the roundtable discussion and thank you in advance for your support on this highly important matter.

Yours Sincerely,

Frédéric Destrebecq
Executive Director
European Brain Council

On behalf of

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