TO: Professor Guido Rasi
Executive Director
European Medicines Agency

Subject: Upholding Good Off-Label Use Practice

Brussels, 8 November 2016

Dear Professor Guido Rasi,

We, the undersigned organisations, supportive of the attached Declaration on Good Off-Label Use, are writing to you as part of our initiative to raise awareness on the subject of good practices for the use of off-label medicinal products in Europe.

We understand that you are due to address the ENVI Committee of the European Parliament on 8 November. Just over a month ago, on the 27th of September 2016, the European Parliament hosted an event entitled "Safeguarding patient safety and quality of care in Europe: Good practice for off-label use of medicines". The event highlighted the importance of setting clear guidelines regarding off-label use, ensuring that the safety of European patients is always put first.

On that occasion, Andrzej Rys, Director of Health Systems and Products in DG Santé, European Commission, noted that the European Commission's study on the use of off-label medicinal products in the European Union will be eventually published by the end of the year. While we look forward to reading its conclusions, we believe a clear approach on the issue is becoming increasingly urgent due to the current trend of promoting the prescription of off-label medicines for reasons beyond the medical need of patients. As you are aware, a number of European Union Member States are imposing prescribing guidelines that effectively promote off-label use for the sole purpose of reducing healthcare spending, thus creating unnecessary and avoidable risks for patients and often placing healthcare professionals in the position of being liable for decisions that they have not taken of their own accord.

It is in this light that we would like to draw your attention to the criteria found within the declaration. The criteria have been independently identified by Professor Marc Dooms, stemming from decades of research and clinical practice. They serve to provide a clear framework on how the use of off-label medicinal products can safely take place across the continent. Such criteria intend to provide a harmonised approach on the matter, while reaffirming that patient safety should always prevail over cost considerations and economic interests.

In this regard, we call on the European Medicines Agency (EMA), as the body created to safeguard the safety of European patients and the guardian of the regulatory framework, to adopt strict guidelines on the use of off-label medicinal products. We reaffirm our willingness to work with EMA on this important issue, seeking to ensure that the medical needs of patients are met, while safeguarding the highest levels of patient safety.

We remain available to discuss with you and your team about this important issue.

Yours Sincerely,
Frédéric Destrebecq
Executive Director
European Brain Council

on behalf of the following organisations:

EBC European Brain Council
EMA European Medical Association
EFNA European Federation of Neurological Associations
European Alliance for Access to Safe Medicines
emsp EUROPEAN MULTIPLE SCLEROSIS PLATFORM