

Brussels 27th April 2016

To:

Dr Vytenis Andriukaitis
Commissioner for Health and Food Safety
European Commission

in cc:

Prof Guido Rasi
Director of the European Medicines Agency

Dear Commissioner Andriukaitis,

We are writing you in relation to the latest declarations made by the Director of EMA Prof Guido Rasi on the European newspaper POLITICO (see attached).

Prof Rasi rightfully called for an increased level of harmonisation at the EU level regarding the way we evaluate new drugs. In particular, Prof Rasi spoke in favour of a European approach to the collection of real world data on the effectiveness of new drugs. Several countries are implementing this approach to make sure that only the best and most valuable drugs are in fact reimbursed. We are in favour of the real world data approach, which guarantees both patients' safety and the economic sustainability of the healthcare system. However, we agree with Prof Rasi that Member States should not further fragment the way we assess new drugs, by implementing their own ways to collect and analyse such real world data.

As you know from our previous communications and from our work with the European Parliament in relation to the amendments of the Regulation 726/2004, we strongly believe in the value of harmonisation. The amendments to the Regulation call for the institutionalisation of the EUnetHTA and the creation of a new EU body competent to create relative effectiveness assessments of all new medicines approved by EMA. We hope that the Dutch and Slovakian Presidencies will proceed quickly to the discussion of the Regulation's amendments, so to guarantee the approval of the new regulation in first reading.

Europe needs a strong and clear message in favour of the harmonisation of HTA at the European level. We are conscious of your support for this topic and following Prof Rasi's declaration it would be very helpful if you could consider to take a clear position on the matter once again in favour of further

harmonisation, and therefore in favour of cutting the wastes of time and resources related to the implementation of 28 different HTA approaches in Europe.

Last week, in occasion of the meeting on chronic diseases “Towards the better prevention and management of chronic diseases”, you called for all the European stakeholders to be your partners and help you to defend the case of health vis-à-vis the EU Member States. As you know, ECPC supports your position and we have demonstrated with facts that we believe that a more equitable Europe is possible. To make sure that our voice at national level is heard, we need a strong plan and a clear European path toward harmonisation set in front of us. We need a policy path that each stakeholder can then advocate for at the national level, to increase the leverage needed to make change happen.

We sincerely hope that you and Prof Rasi will work together to lead the European healthcare community towards this revolution.

Kind regards

Francesco De Lorenzo

ECPC President

