From: CAB JUNCKER PRESIDENT
Sent: 14 February 2017 09:10
To: CAB JUNCKER ARCHIVES
Subject: FW: Comitology Reform

Categories: Orange Category

From: maria.curatolo@efpia.eu [mailto:maria.curatolo@efpia.eu] On Behalf Of Eric Cornut

Sent: Tuesday, February 14, 2017 8:49 AM

To: CAB JUNCKER PRESIDENT; CAB TIMMERMANS CONTACT

Cc: Elizabeth Kuiper

Subject: Comitology Reform

Dear President Juncker,

Dear First Vice-President Timmermans,

As your College is discussing the options regarding Comitology Reform again this week, EFPIA, the trade association representing the research-based pharmaceutical industry in Europe, would like to underline the importance of fair and science-based decision-making at EU level.

The process for obtaining market authorisation of innovative products defines the degree of predictability, which business operators require when taking decisions in terms of investment, jobs and growth in and for the EU. Additional uncertainty puts Europe at a competitive disadvantage globally and is also of grave concern to all industries that are subject to product authorisations.

We urge the Commission to guard its independence as prescribed by the EU Treaties and to correctly implement the existing comitology system while discussing the different options. This must be done in full respect for the fundamental principles of EU law, such as non-discrimination, legal certainty and protection of legitimate expectations, the conferral of powers, the right to good administration set out in Article 41 of the European Charter of Fundamental Rights, and the EU's international trade obligations.

In its present form, the comitology process that governs market authorisations, is designed to approve products assessed as safe by Europe's independent safety assessment authorities.

The Commission and its risk assessing agencies should strengthen risk communication to build trust - especially where unfounded concerns persist and avoid fueling any unfounded concerns about new technologies.

In light of the aforementioned concerns and with a view to the foreseen discussion and adoption in the College of Commissioners this week, we call on the Commission to respect the principles for fair and science-based decision-making in accordance with existing law.

We are at your disposal for further information, and hope you will take our concerns into account while adopting your final position.

Yours faithfully,

Eric Cornut Director General EFPIA