IPEC EUROPE

European Commission - DG SANTE

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Rue Breydel 4
1040 Brussels
Belgium

Brussels, 9 May 2019

Subject: Notification of the suspension of Titanium Dioxide (E171) as a food additive to Standing Committee of Plants, Animal, Food and Feed (SCOPAFF) on 13 May 2019 by the French Government.

Dear [redacted]

IPEC Europe is writing to reiterate its concerns expressed in the letter dated 1 June 2018 jointly signed by several pharmaceutical associations (enclosed as an annex to this letter) relating to the suspension of the use of Titanium Dioxide (E171) in foodstuffs in France and the possible consequences of this unilateral action in other EU member states.

The French government published an *arrêté* on 17 April 2019 suspending the use of Titanium Dioxide (E171) in foodstuffs for one-year effective 1 January 2020. This decision is based on an inconclusive opinion of ANSES, the French Agency for Food, Environmental and Occupational Health & Safety published on 12 April 2019. This is not aligned with the EFSA opinion published in September 2016 which concluded, and indeed ANSES confirmed, that the available studies and data could not confirm any safety issues with the use of Titanium Dioxide (E171) as food additive and recommended that additional studies should be performed.

In 2018, EFSA made a new call for more safety data on E171 in order to determine an appropriate Acceptable Daily Intake (ADI). The TDMA (Titanium Dioxide Manufacturers Association) and other parties agreed to provide the required data initially by mid-2019 but to mitigate some concerns expressed by ANSES, TDMA accepted to extend the original scope of the study to address potential adverse impacts of E171 on the colon, which extended the completion of these studies to July 2020.

This unilateral decision in France is not based on substantiated safety evidence and will result in distorting the European Single Market as well as undermining the EU risk assessment process led by the European Food Safety Agency (EFSA). Also, it will have damaging consequence on medicines supply and patient safety. Suspending the use of E171 in foods or considering to remove it from the list of permitted food additives could have an immediate and wide-ranging impact on pharmaceutical products, affecting the majority of solid dosage forms marketed in Europe and elsewhere in the world. Due to a long history of safe use over many decades E171 is widely used in medicines and this has made it a critical excipient for pharmaceutical drug products. Only permitted food colours can be used as colourants in pharmaceutical dosage forms in the EU, there are very few alternative materials that confer the same degree of opacity and whiteness to products, and titanium dioxide has extensive global regulatory acceptability. Investigation and identification of suitable alternatives is not a trivial exercise: it would entail a huge effort by the excipient and pharmaceutical industry over a number of

IPEC Europe asbl – International Pharmaceutical Excipients Council Europe
Rue du Luxembourg 16B, 1000 Brussels, Belgium
T:32 (0)2 [redacted] E: [redacted]@ipec-europe.org
VAT number: BE 0501 816 137 – Transparency Register: 341962119314-36

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years because of the extensive use of titanium dioxide and the need to ensure product stability and re-validate manufacturing processes etc. Even if reformulation is an option, it could adversely impact the appearance of the product (identification markings and colour) because it will not be possible to colour match many medicinal products using alternative materials. This could cause patients significant concerns about the identity of their medicines as well as unintended drug shortages through supply issues or even the withdrawal of some products from the market.

Given the seriousness of the situation and the lack of robust scientific evidence to support the suspension of E171, IPEC Europe strongly supports that EFSA finalises its ongoing work programme to complete the risk assessment of E171 before taking any further decision. It is the view of IPEC Europe that the ongoing studies designed to answer the questions identified by EFSA in the re-evaluation of E171 as a food additive will provide the clearest and most appropriate mechanism to address any residual safety concerns pertaining to E171.

Considering the extension of this action in France to other EU member states and the information presented above, IPEC Europe would challenge that there is no legal basis to invoke Article 54 of the EC Regulation 178/2002 of 28 January 2002 which lays down the general principles and requirements of food law, establishing the European Food Safety Authority as the appropriate body to establish procedures in matters of food safety. Therefore, such decisions and actions should not be taken by one-member state in isolation without due reference to the appropriate governing body at the level of the European Union. In conclusion, IPEC Europe would like to request the European Commission / EMA to take all necessary actions to object to the unilateral suspension of Titanium Dioxide (E171) as a permitted listed food additive in France or beyond as it is neither scientifically justified nor is it in the best interest of patient access to medicines of appropriate quality and safety.

IPEC Europe is happy to discuss any matter related to the above at the convenience of the European Commission.

Yours sincerely,

[redacted]

Cc :

[redacted]

[redacted] DG SANTE

E.2. Food processing technologies and novel foods European Commission

Rue de la Loi / Wetstraat 200 1049 Brussels

Initially created in 1992, IPEC Europe is a non-profit European association representing producers, distributors and users of pharmaceutical excipients. IPEC Europe offers a unique forum to exchange good practices and develop harmonised standards for pharmaceutical excipients striving to continuously promote and achieve worldwide acceptance and use of the IPEC developed guidelines as a means of improving and ensuring quality, safety, and functionality of pharmaceutical excipients.

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