Possible EU Assessment of Human Health or Environmental Risks of Chemicals Used in Pharmaceuticals

Joseph J. Green

December 6, 2016

Several substances used as ingredients for pharmaceuticals and other consumer products will be evaluated for possible regulatory action in the European Union in the next three years.

On 27 October 2016, the European Chemicals Agency (ECHA) announced its proposal under the EU's REACH Regulation to evaluate 117 chemical substances suspected of posing a risk to human health and the environment. Each substance listed on the final Action Plan for 2017-2019 will be evaluated by an assigned Member State which may recommend: a) harmonized classification and labelling for carcinogenic, mutagenic or toxic to reproductions, respiratory sensitizers or other effects; b) identification of the substance as a substance of very high concern; c) restrictions on the use of the substance; or d) actions outside the scope of REACH, such as proposals for EU occupational exposure limits, national measures or voluntary industry actions. These recommendations are submitted to the Commission, potentially prompting regulatory initiatives.

Of the 117 substances proposed for review, 22 are chemicals that were not previously listed. One of these new substances, butan-1-ol (also known as 1-Butanol or n-Butanol), is used in organic chemical synthesis and as a solvent for the extraction of essential oils. According to the draft Action Plan, butan-1-ol is suspected to have reprotoxic properties, and is of further concern due to its widely dispersed use, broad consumer uses, potential for worker exposure, and high tonnage. The substance is tentatively assigned to Hungary for review in 2017.

Other substances used as ingredients in pharmaceuticals on the draft Action Plan include:

- 1-phenylethanol: Used in transesterification to make other chemicals. Suspected of having carcinogenic and mutagenic properties. Scheduled to be evaluated in 2018 by Italy.
- Benzoic acid Titanium dioxide: Used to prevent infection caused by bacteria. It is often used in combination with salicylic acid to treat skin irritation and inflammation. Suspected of being a potential endocrine disruptor. Scheduled for evaluation in 2019 by Italy.
- 1,1'-(isopropylidene)bis[3,5-dibromo-4-(2,3-dibromo-2-methylpropoxy)benzene]: Used as a pharmaceutical intermediate. Suspected of being a potential endocrine disruptor and of having persistent bioaccumulation toxicity and very persistent and very bioaccumulative properties. Scheduled to be evaluated in 2017 by Germany.

The draft Action Plan was submitted on 13 October 2016 to all Member State competent authorities and the ECHA Member State Committee for additional input. ECHA is expected to issue the final Action Plan for 2017-2019 by the end of March 2017. Substances can be added to or removed from the draft Action Plan until such time.

Located in the heart of the European Quarter, the Brussels office of Kelley Drye, together with our Environmental Practice Group, is well positioned to advise and assist clients with any inquiries or concerns regarding the current evaluation process under REACH and/or other EU legislation applicable to cosmetic products. Kelley Drye's Environmental Law Practice Group specializes in providing comprehensive solutions to complex problems. We have decades of experience advising companies and industry trade organizations with respect to chemical management requirements and related compliance and litigation matters.