RUMA®
Marker-System

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Statement of no objection

Regarding the marker procedure which is applied for the identification of urines, marker polyethylen glycole (Macrogol) is used. The individual markers differ in the number of repeating units and thereby also in molecular weight and chain length.

Macrogol is used in the manufacturing of almost all drug groups, e.g. in the production of many antitussives (effervescent tablets) which are also approved for children. Furthermore, they are present in tablets and coated tablets such as garlic tablets, antihypertonics, sedatives, relaxants, pain relievers and many more. They are used as solublizers for fat-soluble substances, also externally on the skin as antidote in case of poisonous substances, as well as, on a trial basis, internally in case of tablet bolus formation.

Although the markers are used in various medical products, they themselves do not fall within the definition of pharmaceuticals of the German Medicines Act and are therefore not subject to approval. In order to be a pharmaceutical in terms of the Medicines Act (Arzneimittelgesetz, AMG), in accordance with § 2 para.1 No 1-5 the marker would have to fulfil one of the functions set forth therein.

In the present case, a classification as diagnostics would come into consideration. According to § 2 para. 1 No 2 AMG diagnostic substances are substances which reveal the nature, the state or the function of the body or of the mental condition. However, this refers exclusively to substances which, in their own capacity, serve the purpose of identification of physical detriment or mental conditions.

However, the markers themselves are not diagnostics since they only serve the purpose of marking the urine provided by the test person as their urine. Only if the function would be fulfilled that the provided urine was prepared for a later test and that this test was not possible without taking the substance, the definition of diagnostics would apply. This, however, does not apply in the present case.

Neither is the marker substance subject to the German Act on Medical Devices (Medizinproduktegesetz, MPG). This would require § 3 para. 1 MPG where the marker would be defined as a substance or a formulation of substances which are intended by the manufacturer to serve the purpose of detection or treatment of illnesses in humans by way of their function.

However, in the present case the marker neither serves the purpose of detection of an illness nor the execution of a test which would not be possible without intake of the substance. The marker only serves the purpose to mark the urine provided by the test subject as their urine.

The district government of Cologne also adopted this legal opinion in their letter of June 26th, 2002, certifying with said letter that the marker substance is neither subject to the definition of the German Medicines Act (AMG) nor the German Act on Medical Devices (MPG). Insofar an approval is not required, the markers can safely be applied and ingested.

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