II-4-373

Application of alternative toxicological methods in safety testing of perfumery and cosmetic products in Russia

N. V. Zavyalov and E. L. Skvortsova

The Center of Hygiene & Epidemiology in Moscow, Moscow, Russian Federation

skvorcova_el@mail.ru

In 2010, the Single Customs Union between Russia, Belarus and Kazakhstan was set up. The countries' participants of the Customs Union accepted the basic document "Uniform sanitary-epidemiologic and hygienic requirements to goods subject to sanitary and epidemiological supervision (control)". This document confirms the use of alternative *in vitro* methods for testing medical articles and equipment, personal care products, baby goods, household chemicals, and perfumery and cosmetic products (PCP).

In the practice of PCP control in Russia alternative methods began to be applied widely under the active participation and collaboration of research centers of The Russian Academy of Medical Sciences, Preventive Toxicology Division from the Centre of Hygiene and Epidemiology in Moscow of Rospotrebnadzor, RNIITO Rosmedtekhnologij. The Russian association of manufacturers of PCP, COLIPA, and leading manufacturers of PCP, in particular Unilever & SEAC, supported Russian toxicologists in this direction.

The development of alternative methods for safety testing of PCP in Russia is conducted in a number of directions:

– Revealing correlation between *in vitro* toxicity indicators and different selective effects on the laboratory animals;
– The research of schemes for alternative testing;
– Research of toxicity of different kinds of products on several *in vitro* test objects simultaneously for revealing the most adequate models.

Human skin fibroblasts, cattle sperm cells, luminescent bacteria and the HET-CAM test are used as test models. Three alternative *in vitro* methods have been confirmed for safety testing of PCP in Russia. The method of ultrasound dopplerography on the HET-CAM vessels for irritation testing of PCP is currently at the "statement stage".

II-4-387

Implementation of *in vitro* replacement technologies in regulatory drug testing – an innovation systems perspective

M. Kooijman[1], P. J. K. van Meer[2], E. H. M. Moors[1], M. P. Hekkert[1] and H. Schellekens[2]

[1]Utrecht University, Utrecht, The Netherlands; [2]UIPS, Utrecht University, Utrecht, The Netherlands

m.kooijman@geo.uu.nl

The replacement of *in vivo* methods by *in vitro* methods in regulatory drug testing is rare. The aim of this research is to identify barriers and drivers of the replacement of *in vivo* methods by *in vitro* methods in Europe.

We studied two cases. The first case is the Draize eye test. Since 2009, the *in vivo* test is partly replaced by *in vitro* methods. The second case concerns EPO potency testing. Since the eighties, financial and scientific efforts have been made to replace the *in vivo* EPO potency test with *in vitro* methods; however the efforts failed to deliver expected outcomes. The innovation systems approach is used to identify the drivers and barriers regarding replacement of *in vivo* methods by *in vitro* methods in regulatory drug testing in Europe, such as the presence or absence of legislative pressure, legitimacy, and funding. Combining and comparing the outcomes resulted in an overview of potential barriers and drivers, and an indication of which of these factors are critical for replacement of *in vivo* methods by *in vitro* methods in regulatory drug testing. Policy makers could use these results to formulate policies that enable the replacement of *in vivo* methods by *in vitro* methods in regulatory drug testing.