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## **EDQM experts recommend further research on the safety of inks and tattoos**

The European Directorate for the Quality of Medicines & HealthCare (EDQM) today issued a compendium of the scientific information currently available on the potential toxicity of intradermal inks. This report, which was compiled by the EDQM's Consumer Health Protection Committee and is aimed at risk evaluators and legislators across Europe, highlights potential harmful effects for many of the chemicals present in inks used for tattoos and permanent make-up (PMU).

A comprehensive overview of the challenges involved in the toxicological assessment of intradermal inks is presented, along with an evaluation of the current scientific knowledge on the tattooing process and subsequent dermal tissue response. Although the final chemical formulation of a tattoo ink may be simple, the sheer number of substances available for inks renders the task of market surveillance more complex. In addition, the EDQM experts stress that toxicological assessment of inks requires a different approach to that used for traditional cosmetic products due to their intradermal, rather than dermal, route of exposure. However, the review pointed out that risk assessment approaches for nano or micro-particles in pigments are still under development and that an accurate account of potential health risks deriving specifically from these pigments will only become possible in the future.

Susanne Keitel, Director of the EDQM, explained: "By flagging the shortcomings in present scientific knowledge, our experts sought to cast a light into the specific areas requiring further investigation by risk assessors and also to raise the question as to whether specific test protocols may be needed for tattoo inks. That is, beyond existing standard methods such as the OECD guidelines".

Although the use of tattoos and PMU has become increasingly common across all sections of society, the practice still carries intrinsic risks. Cases of tattoo inks becoming microbiologically contaminated are well documented, and protocols for the toxicological risk assessment of tattoos and PMUs require further development by the international scientific community. With its scientific expertise, the EDQM – the Directorate of the Council of Europe tasked with the protection of public health in Europe – aims to support and guide the work of health authorities and manufacturers concerned with the risk assessment of intradermal ink products.

The publication "Safer tattooing: overview of current knowledge and challenges of toxicological assessment" is the result of the work of the group on Safety of Tattoos and Permanent Make-up of the EDQM's Consumer Health Protection Committee. It supplements the Committee of Ministers' Resolution ResAP (2008) 1 on requirements and criteria for the safety of tattoos and PMU.

The electronic version of the publication can be [downloaded for free online](#); print copies are available for purchase at the [EDQM Store](#) (in English only).

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**Note for the Editor:** Further information is available on the internet site [www.edqm.eu](http://www.edqm.eu)

The EDQM is a leading organisation that protects public health by enabling development, supporting implementation, and monitoring the application of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark worldwide. The European



Pharmacopoeia is legally binding in member states<sup>1</sup>. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

<sup>1</sup>There are thirty-nine members of the [European Pharmacopoeia](#) Commission: *Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Republic of Moldova, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, "the former Yugoslav Republic of Macedonia", Turkey, Ukraine, United Kingdom and the European Union.*

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