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### SURVEILLANCE OF ADVERSE TATTOO EVENTS

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**Aim:** Surveillance of adverse tattoo events

**Method:** A resolution of the Council of Europe in 2008 has helped to define requirements and criteria for the safety of tattoos and permanent make-up in order to increase the level of consumer health protection for these products.

Nonetheless, vigilance of these products is not specifically addressed by the Resolution. To date some systems for monitoring adverse effect with tattoo products exist:

**Results / Discussion:** At European level, when a serious risk to the health consumers associated with tattoo products is identified, the European Rapex system enables Member States to communicate between each other and with European commission.

At national level in France, the Agency for Medicines and Health Products Safety has created a specific vigilance system related to the adverse effects of tattoos. This vigilance includes reporting of all adverse events (undesirable effect and serious undesirable effect) through a specific notification form. Then an investigation is required by the competent authority, which may lead to corrective actions. Many actors take part to the system: the responsible person, the health professional, the person making tattoos and the consumer. Manufacturers are notably required to report all undesirable effects to the General Directorate for Competition Policy, Consumer Affairs and Fraud Control.

**Conclusion:** In Rapex system, problems identified with tattoo products concern the presence of heavy metal or aromatic amines. In French tattoo vigilance system, clinical adverse effects appeared with tattoos are identified and the controls realized on tattoo inks concern the sterility, the detection of heavy metals and aromatic amines.