**Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)**

**Request for a scientific opinion on**

# Mercury Sphygmomanometers in Healthcare and the Feasibility of Alternatives

## 1. Background

Directive 2007/51/EC[1] (point 3 of entry 19a on mercury) requires that, "*the Commission shall carry out a review of the availability of reliable safer alternatives that are technically and economically feasible for mercury containing sphygmomanometers and other measuring devices in healthcare and in other professional and industrial uses*".

Sale of all mercury containing measuring devices to the general public has been banned under Directive 2007/51/EC with effect from 3 April 2009 due to concerns about the risks posed to human health from discharges of mercury to the environment from broken or discarded measuring devices. However, sphygmomanometers in healthcare were exempted as these devices were regarded by many Member States as essential for the diagnosis of certain life-threatening diseases such as arrhythmia, accelerated hypertension, as well as in gynaecology and obstetrics. The exemption also applies to other measuring devices in healthcare. That position was also in line with the consensus of opinion in the Member State experts of the Commission's Working Group on Medical Devices.

Nevertheless, the European Parliament and the Council decided during the co-decision procedure that the Commission should review the issue by 3 October 2009.

Since March 2008, DG Enterprise has prepared for the review by addressing questionnaires to various stakeholders (Member States, NGOs, scientific organisations and industry) in order to collect relevant information. In addition, the positions of stakeholders on mercury-containing sphygmomanometers (and existence of alternatives) have been recorded in discussions which have taken place during the meetings of the Limitation Working Group which is responsible for the implementation of Directive 76/769/EEC.

Considering the critical importance of the health and safety of patients, DG Enterprise would like to request an opinion of SCENIHR as crucial input for the Commission's review. The Commission needs to ensure a careful examination of the available scientific and clinical evidence, so that any future action, if required, would achieve a good balance between protection of human health from adverse effects of mercury through the environment for the population in general, and protection of the health of patients requiring accurate blood pressure measurement.

[1] Available at: http://ec.europa.eu/enterprise/chemicals/legislation/markrestr/amendments_en.htm

## 2. Terms of reference

SCENIHR is requested to review the provided material and any further documentation available, and to specifically answer the following questions:

(1) Is there sufficient evidence to demonstrate that mercury-free blood pressure measuring devices such as aneroid or electronic instruments are *generally reliable* substitutes for mercury-containing sphygmomanometers?*

(2) Have mercury-free sphygmomanometers been adequately validated over a *wide range* of blood pressures, ages, and clinical conditions to allow for routine use in hospitals and outpatient settings?

(3) Have mercury-free sphygmomanometers been adequately validated for the diagnosis of hypertension in *specific clinical conditions* such as arrhythmia, pre-eclampsia in obstetrics and certain vascular diseases?

(4) Are mercury-based sphygmomanometers essential as reference devices for *validation* of long-term clinical epidemiological studies enrolling patients with hypertension?

(5) Are mercury-based sphygmomanometers essential as reference devices for *calibration* of the mercury-free sphygmomanometers when the latter are used for routine diagnostic purposes?

(6) Is SCENIHR aware of any *adverse effects* for patients' health due to the replacement of mercury-containing sphygmomanometers by mercury-free alternatives?

SCENIHR is also invited to make any additional comments that it considers relevant to patient health in case a future ban on mercury sphygmomanometers would be introduced.

## 3. Deadlines

Considering that the review should be concluded by 8 October 2009, SCENIHR would be invited to deliver a scientific opinion, if possible **by end of September 2009** at the latest.

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* Substitutes cover both liquids to replace mercury in manometers and other measurement techniques based on different technologies, such as electronic devices. The term "*reliable* substitutes" denotes devices that perform (in comparison with the mercury-based sphygmomanometers) to equal or greater accuracy when maintained and used correctly, also taking into account error statistics where known (such as error rates and the magnitude of errors) and the intervals between maintenance and recalibration.