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DIRECTORATE-GENERAL
SANTE
Directorate C2 – Public Health, Country Knowledge, Crisis Management
SANTE.C.2 – Country Knowledge and Scientific Committees

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SCIENTIFIC COMMITTEE ON EMERGING AND NEWLY IDENTIFIED HEALTH RISKS (SCENIHR)

PRELIMINARY OPINION ON THE BIOLOGICAL EFFECTS OF ULTRAVIOLET RADIATION RELEVANT TO HEALTH WITH PARTICULAR REFERENCE TO SUNBEDS FOR COSMETIC PURPOSES

SUMMARY RECORD OF THE PUBLIC HEARING HELD ON 12 APRIL 2016

Commission: Philippe Roux, Donata Meroni, Mihaela Haratau (SANTE DDG1.C.2), Victoria Piedrafita (GROW DDG1.C.3), Ana Maria Blass (JUST E.3)

SCENIHR experts:

- Lesley Rushton (WG Chair),
- Jean-Francois Doré (WG Rapporteur),
- Ana Proykova (WG Rapporteur, SCENIHR Vice-Chair),
- Rudiger Greinert (WG member),
- Philippe Hartemann (SCENIHR Chair, WG member)

Participants:

Prof. Mathieu Boniol	International Prevention Research Institute
Mr. Rob Bontje	Sunday's Nederland BV
Dr. Peter Dalum	Danish Cancer Society
Mr. Seven Gilroy	Joint Canadian Tanning Association (JCTA)
Mrs. Lidija Globokar	European Sunlight Association
Dr. William Grant	Sunlight, Nutrition and Health Research Center
Dr. Frank de Gruijl	Leiden University Medical Center
Mr. Frank Harbush	European Sunlight Association a.s.b.l
Prof. Michael Holick	Boston University Medical Center
Mr. Krisztian Imre	LIGHTTECH Kft.
Dr. Marina Khazova	Public Health England, Centre for Radiation Chemical and Environmental Hazards
Mr. Roland Laurent	Swedish Tanning Association
Mr. Joseph Levy	American Suntanning Association
Mr. Gary Lipman	The Sunbed Association UK and Ireland
Mrs. Christina Lorenz	KBL AG
Mr. Henrik Marx	Danish Sunbed Federation
Dr. Lill Tove Nilsen	Norwegian Radiation Protection Authority
Prof. Jörg Reichrath	Dept. of Dermatology, Sarrland University, Germany
Dr. Frank Richarz	IEC TC 61/MT16 and CENELEC TC61
Dr. Mariano Suppa	European Academy of Dermatology and Venerology
Mr. Dignus van de Linde	VDL Hapro bv
Dr. Emilie van Deventer	World Health Organisation
Mr. Huib van Heest	SVZ (Samenwerking Verantwoord Zonnen)
Dr. Daniela Weiskopf	Federal Office for Radiation Protection, Germany
Mr. Alexander Wunsch	Medical Light Consulting
Prof. Mathieu Boniol	International Prevention Research Institute

WELCOME AND OPENING (DG SANTE)

The Chair, Philippe Roux, HoU from the European Commission's DG SANTE, welcomed the 26 participants from a wide range of countries inside and outside of the EU, including the USA and Canada, and briefly explained the role of the SCENIHR Committee as an independent advisory body on scientific matters. The Chair explained that the purpose of the public hearing was to provide oral explanations of the preliminary Opinion and to receive oral scientific contributions. The hearing also provides a platform for stakeholders to have an open discussion with Committee members, he said, and to speak directly with the scientists involved in producing the Opinion. He briefly informed participants about the rules of procedure. The agenda of the hearing was then introduced and participants were reminded that written input for the framework of the public consultation would be accepted until 27th April 2016.

1. PRESENTATION OF THE MANDATE (DG JUST AND DG GROW)

The Commission (COM) (DG JUST) also thanked participants and stressed that the hearing was an important part of the process of reaching a scientifically sound Opinion complementing the public consultation. COM reminded attendees that the current Opinion was an update of the 2006 Scientific Committee on Consumer Products Opinion on the same issue. The European Commission requested the SCENIHR to review recent evidence in order to improve the understanding of risks associated with Ultra Violet Radiation in general and with sunbeds in particular and to provide an updated Opinion.

The Commission (DG GROW) summarised the legal framework surrounding the safety of sunbeds in the EU. COM explained that **Directive 2014/35/EU** would come into effect on 20th April 2016: this directive on the harmonisation of the laws of the Member States relating to making electrical equipment designed for use within certain voltage limits available on the market will continue to set the limit for effective irradiance at 0.3 W/m2 (as per European Standard EN 60335-2-27). COM summarised that the directive was a total harmonised directive and that EU Member States cannot legislate on its scope. However, COM reminded attendees that harmonised standards are voluntary and their implementation presumes conformity with the safety objectives.

COM clarified that the hearing was to focus on the assessment of risks rather than risk management and encouraged participants to ensure that their contributions were relevant to this mandate.

2. PRESENTATION OF THE PRELIMINARY OPINION (SCENIHR)

Phillippe Hartemann (SCENIHR chairman) gave an overview of the three scientific committees in force until April 2016. He emphasised the importance of committee members' independence and assured attendees that care is taken to ensure that members do not have conflicts of interest. The participants were reminded that the committee can only take into account, for its risk assessments, data that are scientifically valid and published on peer-reviewed journals.

Lesley Rushton (SCENIHR member and working group chairwoman) explained the process of writing the Opinion, detailing that the working group wrote the initial draft, which was then discussed in-depth by all SCENIHR members and approved for public consultation.

She presented an outline of the preliminary Opinion, explaining that it was based on the previous 2006 Opinion, but new evidence had been considered in order to determine whether the risk assessment needed to be updated. She briefly went over terms of reference, noting that this Opinion’s mandate did not include the use of sun lamps as

medical devices. She noted that, according to EU surveys of Member States, consumer guidance in tanning studios is not regularly given, the labelling of sunbeds fails to comply at least 20% of the time and there is a violation of the maximum UVA levels of sunbeds which varies between 10 - 90% between Member States.

She re-emphasised that the SCENIHR tries to be as objective as possible when assessing scientific studies, following the specific Memorandum issued in 2012[1]. She pointed out that the SCENIHR is responsible for risk assessment and not for risk management.

In its preliminary Opinion, the SCENIHR concluded that UV acts as an initiator and promoter and is a complete carcinogen. The SCENIHR concluded that there was no need to use sunbeds to increase the body's level of vitamin D, and that it was unable to come up with a safe level recommendation.

In response to a question raised, SANTE stated that the final Opinion will be adopted by the newly created Scientific Committee on Health, Environmental and Emerging Risks, made up of new members announced in March 2016, but assured that continuity in the handover process will be ensured, i.e. most of the members of the working group remain the same.

3. QUESTION AND ANSWER SESSION

All participants but one took the floor in the "Question and Answer" session. The Commission asked that issues raised, along with supporting evidence, be submitted through the public consultation process so that the SCENIHR can examine them in more detail when drafting the final Opinion. Almost all participants presented PowerPoint presentations. A summary of the main points raised orally is provided here below:

- Several participants criticised the design, the methodology and quality of data of numerous studies used to form the Opinion as not being scientifically credible (e.g., Wehner 2012, 2014), and thus not admissible as causal evidence to form a scientific risk assessment. It was claimed that the scientific knowledge surrounding this subject was based on poor quality observational studies that report associations but do not prove causality.
- There was a consensus amongst industry representatives that the scientific evidence used to form the Opinion did not provide a balanced view of the available literature, accentuating studies reporting negative effects, while ignoring those reporting positive ones (e.g. Colantonio 2014), therefore not making full use of the range of literature available. The European Sunlight Association collected 143 studies from the last decade and said that SCENIHR only used 11 studies from this list to draft the preliminary Opinion.
    - As a reply, the SCENIHR representatives reiterated that only studies that are scientifically valid and published on peer-reviewed journals are considered, following the guidelines included in the Memorandum on weight of evidence[1].
- It was also noted by some industry representatives, that the main scientific evidence provided in the preliminary Opinion is based on old data (before 2006), mainly from American and Australian populations and is therefore not relevant for the European population.

[1] Memorandum on the use of the scientific literature for human health risk assessment purposes – weighing of evidence and expression of uncertainty

- The SCENIHR representatives acknowledged that there is an insufficient number of studies on European populations, but explained that this left them with no choice but to use the best data from published, peer-reviewed scientific studies available to date.

- Industry's representatives alleged a lack of consideration for the current context in which sunbeds are being used. Specifically, participants stressed that there is a need to distinguish between sunbeds made pre-1990, 1990-1997, and post 1997, as advancements have been made and implemented in sunbed technology to make them safer.
- Participants from industry also urged for better implementation and enforcement of existing sunbed standards in all EU Member States.
- Moreover, there was a complaint that the SCENIHR Opinion in its current form did not acknowledge efforts made by the sunbed manufacturers to implement European standards and legislation.

    - COM responded that risk management considerations were outside the scope of the Opinion. The mandate was to generate a risk assessment, not to refer to risk management or the implementation of the current legislation in this area.

- Some participants requested that Chapter 9 of the preliminary Opinion, which concludes that no further research is necessary in this field, should be revised (Chapter 9 of the Draft states: "new studies would not be a priority"). Instead, a need for further research was emphasised considering the new radiation limits put into place in 2007, and that melanoma is a long-term cancer, developing years after exposure, sufficient time needs to be given to complete research applicable to the current standards. Additionally, the need for a better measure of actual sunbed use in Europe was proposed.
- Participants stressed the need to put the carcinogenic risks of UVR into a comprehensible context (e.g. in terms of risk compared to red meat, cigarette smoking), because even though the Opinion is meant for use by colleagues in the field rather than for the general public, the public can also freely access the current draft Opinion.

    - COM clarified that the comparable risk is not in the scope of the mandate of the Opinion, which focus on UV radiation emitted from sunbeds.

- WHO's representative mentioned that this Opinion was consistent with WHO's conclusions not to support the use of sunbeds for anyone (sunbeds are classified as carcinogens by WHO/IARC). Annex 1 of the Opinion concerning the literature review could be strengthened and that they would have contributed via public consultation.
- Participants representing universities and research institutes, not representing any private company in the hearing generally supported the Opinion's findings, acknowledging that there is no safe lower level of sunbeds, arguing that results showing otherwise don't consider important confounders.
- The joint representative of the European Academy of Dermatology and Venereology, European Academy of Dermatology and Venereology, European Academy of Dermato-Oncology and EUROMELANOMA supported the conclusion of the Opinion.

- Participants from the industry recommended re-working the Opinion, consulting more external experts in addition to the current ones, e.g. those working in research funded by the industry.

4. CLOSING (DG SANTE)

The Chair thanked participants for their contributions and re-iterated the deadline for the submission of written contributions and supporting evidence through the public consultation process (27 April 2016).

Rules of procedures for contributions to be submitted were mentioned, particularly that the consultation process shall not deal with policy or risk management needs and measures. Only submissions directly referring to the content of the preliminary Opinion and relating to the issues that the report addresses would be considered. Furthermore, only studies and data which are published or accepted for publication in peer-reviewed scientific reports or journals would be taken into consideration. The Scientific Committee will consider all the relevant submissions related to the scope of the public consultation and will decide if and how each of the contributions should be taken into account in the formulation of the final Opinion.

The Chair concluded by thanking the members of the Scientific Committee for their work and expressing his wishes for their continued support going forward.

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

Public Hearing on Biological effects of ultraviolet radiation relevant to health with particular reference to sunbeds for cosmetic purposes

Venue: EUROFORUM - 10, Rue Robert Stumper, L-2557 Luxembourg-Gasperich, LUXEMBOURG

Meeting date: 12 April 2016

12:00 – 16:00

Draft Agenda

1. **WELCOME AND OPENING (DG SANTE) – 10 MINUTES**

2. **PRESENTATION OF THE MANDATE (DG JUST AND DG GROW OFFICIALS)**

3. **PRESENTATION OF THE PRELIMINARY OPINION (SCENIHR REPRESENTATIVES)**

4. **QUESTION AND ANSWER SESSION – UP TO 3 HOURS**

5. **CLOSING (DG SANTE)**