IDEA
International Dialogue for the Evaluation of Allergens

IDEA Working Group meeting on the
Feasibility of a study to assess the effectiveness of QRA

April 6th, 2016 from 9:00 to 17:00

Martin's Klooster Hotel
Onze Lieve Vrouwstraat 18, 3000 Leuven
Phone: +32 (0) 1 621 31 41
Meeting room: Predikharen room

AGENDA

1. **Opening of the meeting (IR White and Matthias Vey)**
   Tour de table

2. **Anticompetition statement (Matthias Vey)**

3. **Problem definiton and agreement on the objective of the meeting (IR White)**

   3.1 Overview on the prevalence of contact allergy based on clinical data (Jeanne Johansen)

   3.2 What would be the key considerations (including statistics) and principal objectives of a study looking into the effectiveness of the QRA? Specifically:
   Can an empirical study be designed to illustrate that the QRA actually works to minimize/prevent sensitization?
   Can an empirical study be designed to illustrate that the QRA reduces the overall incidence rate of sensitization in the overall population?
   Can an empirical study be designed to illustrate that the QRA reduces the overall incidence rate of sensitization in clinical patients?

   The proposed objectives (to be confirmed) are:
   - To investigate (track progress) of the effectiveness of the QRA (1 and 2) in preventing or minimising sensitisation of consumers to fragrance materials.
   - To provide a tool to enable a rapid response to clinical alerts.

   It is proposed that this is a rolling phased programme and that the focus of the meeting should be on the work to be conducted in the first phase. The aim is to discuss and develop consensus on action plan to address potential remaining issues.

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4. Protocol related discussions and decisions

4.1. Selection of the population group to study
Introduction: Karl Heinz Jöckel

Considerations include: adequate study population, any ethical constraints, whether it should only involve consumers (e.g. exclude those who may be occupationally exposed), focus on fragrance materials for which consumers are able to provide a reasonable estimate of exposure, population size required for statistical significance.
A main issue is how exposure will be assessed. Review of suggested questionnaire.

4.2. Selection of fragrance materials to be studied
Introduction: David Basketter / Graham Ellis

Considerations include: must have been assessed using QRA 1 and/or QRA 2 and have an IFRA Standard assigned, use not particularly regional or country specific, distribution among consumer products well documented (also unlikely to be exposed significantly to other sources), extensive and/or increasing use, reliable and ongoing source of the chosen pure test materials.

Since the objective of the exercise is to critically examine the effectiveness in practice of the QRA the following might also be considered in selecting the test materials:

- Should materials be included where use of QRA 2 would provide very similar AEL conclusions to those of QRA 1 (restricted use) and those where the standard would be very different if aggregate exposure is assessed?
- Should both haptens and pre/prohaptens be included?
- Should different chemical classes be covered?
- Should a new fragrance ingredient on the market be included?

4.3. Selection of clinics and testing protocols
Introduction: Wolfgang Uter

Considerations include: criteria for clinic selection, optimal protocol for each clinic and acceptable variations from this.

4.4. Data collection, validation and processing methodology
Introduction: Ian White

Considerations include establishing a baseline, length of the study (intervals for data collection), how is compliance to be verified, who owns, who has access to, who processes the data as it is generated, what are the criteria for success.

5. Organisational and management considerations

How should the project be organised and managed and what monitoring and reporting mechanisms should be put in place?

6. Summary of key conclusions and agreement on follow-up actions (All)