State of play skintest

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COIFFURE EU - Miet Verhamme





Current status of skin testing

<u>2011 (April)</u>: The cosmetics industry should submit a new concept for the test, addressing the need for a better harmonized and standardized method. The new concept shall aim at answering questions raised by the <u>SCCP in 2007</u>

Latest evolution:

- A sub-group called 'skin allergens' has been created for Europe.
- The cosmetics industry is working on an improved harmonization of the allergy test for consumers.
- The new protocol must guarantee 'sensitivity' and 'specificity'. Safety must also be guaranteed.
- The report on this project will be available by the end of 2017.

Current state of play?





Meetings 'Cosmetic Forum' Ueapme

<u>1st meeting Cosmetic Forum (Ueapme) 14 January 2016</u> representatives of SME cosmetics companies + WG Coiffure EU Conclusions of the discussion:

- Cosmetic industry: rather convinced about our points of view
- Main concern: PPD, at present: no alternative
- Short term: Cosmetic Forum (Ueapme) with Cosmetic Europe

<u>2nd meeting Cosmetic Forum (Ueapme) 31 March 2016</u> Cosmetic Europe (Mr. Florian Schellauf) + COSMED + WG Coiffure EU





Situating research Cosmetic Europe

Principal Investigator: Professor Pieter-Jan Coenraads (Netherlands) Investigators: 5 Study centers

- Professor Diepgen/Professor Weisshaar (Germany, Heidelberg)
- Professor Aberer (Austria, Graz)
- Professor Cristaudo (Italy, Rome)
- Dr Holden (UK, Sheffield)

Monitor: Professor Blömeke

Kick-off meeting with all investigators and monitor: 15 October 2013 in Trier Delay of the study in relation to constraints in connection with the European Directive 2001/20/EC on clinical trials

The first results are expected by the end of 2017





Subjects tested in the 5 centers

		Number of PPD-positive subjects		
		Having	Having	
		entered the	finished the	Drop-outs
Study centers	Launch	study	tests	
Groningen	18 July 2014	8	5	1
Heidelberg	17 November 2014	4	2	1
Sheffield	17 February 2015	2	0	0
Graz	17 March 2015	8	1	0
Rome	20 April 2015	1	0	0
Total		23	8	2

Explanation Cosmetic Europe

The group of scientists expressed 2 concerns about the skin test:

- The harmonization of the different protocols, which vary even among companies (different protocols are tested)
- The skin test may cause an allergy (searching for data)





Problems in general

The study:

- Difficult to find enough test persons
- A training for the interpretation of the test
- Avoid unnecessary exposure to the test
- Before launching the study, it was submitted for approval to the ethical commission of every country. They had to wait very long for an answer.





Concentration of exposure

Cosmetic Europe:

- the concentration of exposure is estimated
- experts QRA (Frankfurt) are proponent of the test (cfr the recommendations)
- each type of reaction is a signal. If the test causes a small reaction, the hair dyeing product may not be used.
- doesn't understand the following dilemma:

 Hairdressers choose not to carry out the test, when they know their customers can leave their salon with a serious allergy or irritation
- the test is better than nothing at all
- the 'manufacturer' is responsible for the test





Carry out the test 48h in advance

Cosmetic Europe: 'You cannot mislead nature by shortening the time. But it is much easier to carry out the test at home'

Result of the meeting:

- the test can cause a reaction even a week after carrying out the test (need for a more personal approach)
- difference in use between consumers and hairdressers (reaches the allergy threshold much faster)
- it also depends on the pH-value of the skin test product
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Problems with the skintest

- research showed that 30% of the results were false-positive.
- psychological effect on the customer (as people know the test could cause a reaction, they wait until they feel something)
- according to the national Austrian law, hairdressers are prohibited to carry out the test
- inhabitants of the southern countries perspire faster and more. Perspiring can lead to a distorted opinion about the skin test
- the use of medicines (anti-histamine) can also reduce redness





Replacing the skin test by questionnaires

Cosmetic Europe: not in favour of the questionnaires, because:

- questionnaires depend on the knowledge of customers, which is not very reliable
- in the UK a pilot project is already launched. Experience showed that the test cannot simply be replaced by questionnaires
- when using questionnaires, the responsibility is shifted to the customer. If the customer lies, you don't have any prove against the customer
- if necessary, the questionnaires can be filled out after the test was carried out





Why do we not develop less harmful products?

Then we don't have to carry out a test. Reference to a less sensitizing product from Wella

Cosmetic Europe:

it is a long-term process. It will take several years before starting to develop such products





Does the research take into account the basic points of departure of scientific research?

Such as: a sufficient number of participants, blind research, information about reproducibility, information about side effects ...

Cosmetic Europe: Yes





Conclusions

- Cosmetic Europe proposes to examine if the hairdressing sector and the cosmetic sector can write a common document about the responsibility
- Cosmetic Europe will transfer the request to replace the skin test by questionnaires to its adherents
- Cosmetic Europe is not against the fact that Coiffure EU is present at the European working groups. Coiffure EU (Ueapme) was already present at the last meeting of the working group on cosmetics
- Cosmetic Europe asks us to collect court cases and other concrete problems that occur in salons





Thank you for your attention!

Coiffure EU

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