Efficacy Evaluation of Cosmetic Products

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• **Increasing Interest** from stakeholders in justification of product claims:

  – **United Kingdom**
    CTPA/ASA Joint Initiative on Advertising Claims

  – **European Union**
    Proposed New EU Cosmetics Regulation
    Article 16 : ‘common criteria’ – Product Claims

  – **Asia**
    e.g. China, Taiwan, Hong Kong, Korea
Current Cosmetics Directive (76/768/EEC)

Article 6.3 - Labelling

Article 7a.1 (g) – Product Information

⇒ will be included in the new Regulation
New recital 40:
The consumer should be protected from misleading claims concerning efficacy and other characteristics of cosmetic products. In particular, Directive 2005/29/EC concerning unfair business-to-consumer commercial practices is applicable. The Commission, in cooperation with Member States, should define common criteria relative to specific claims for cosmetic products.
Article 8.2 (d) – Product Information File

- where justified by the nature or the effect of the cosmetic product, proof of the effect claimed for the cosmetic product

Article 16 – Product claims

- in labelling, putting up for sale and advertising: text, names, trade marks, pictures and figurative or other signs shall not be used to imply that the product has characteristics or functions which it does not have
Article 16 – Product claims (continued) New

- The Commission and Member States shall establish an action plan regarding claims used and fix priorities for determining common criteria justifying the use of a claim
  - list of common criteria for claims which may be used in respect of cosmetic products

- The Commission shall submit to the Parliament and the Council a report regarding the use of claims on the basis of the common criteria (deadline: 3 years after the date of application of the new Regulation).
Article 16 – Product claims (continued)

- The responsible person may refer, on the product packaging or in any document, notice, label, ring or collar accompanying or referring to the cosmetic product, to the fact that no animal tests have been carried out only if the manufacturer and his suppliers have not carried out or commissioned any animal tests on the finished cosmetic product, or its prototype, or any of the ingredients contained in it, or used any ingredients that have been tested on animals by others for the purpose of developing new cosmetic products.
Introduction: not all consumer products are the same

Petrol

- Same limited choice offered by all companies

- Consumers chose brand based on price and convenience of point of sale - not product characteristics

- As a general rule, innovation does not play a major role in driving the market
Introduction: not all consumer products are the same

Cosmetics

- **Diversity** of customers having different and evolving expectations
- Large choice tailored to consumer’s **individuality**
- **Innovation** through new technology and/or by responding to new customer trends & demands can drive the market
- Over 4% **growth** of European market in 2007 (source: Colipa)
Specificity of Cosmetics

- Products need to be differentiated to allow for an informed choice
- Innovation should be encouraged and accurately communicated
- Product characterisation studies should follow robust scientific methodologies
- Communication should be responsible
- Credibility of our industry may be enhanced by the adoption of common responsible positions as set out in industry guidelines:
**Relationship Product Performance & Product Communication**

- **Cosmetic Products**
  - Scientific Characterisation of Performance
  - Efficacy Studies
  - Specific Development Strategies
  - e.g. Organic, Natural

- **Consumers**
  - Communication
  - Other Information e.g. Well being

- **Product Development**
- **Marketing**
Performance Evaluation
Performance evaluation

- **Characterisation and product performance** are obtained via a diverse array of scientific techniques preceding the choice and wording of the claims
  - experimental plan for performance is determined prior to development
- The list of applicable methods is necessarily **open ended** in order to accommodate new products, changing consumer expectations and progress in metrology etc.
- Although standardisation of methodology would be inappropriate for the industry, a **robust and structured approach to the generation of data** is required in order to adequately support product communication relating to efficacy
- Information acquired during tests run according to **several basic experimental approaches** allow for different levels of product communication
In order to take into account:

- The **enormity** of the subject
- **Innovation** and **consumer trends**
- **Technical progress** in evaluation methods

Recommendations on efficacy should outline a general scientific approach which should be applied to all cosmetic products.
Objective

• Definition of a common industry approach:
  – Assist the cosmetics industry to comply with the applicable European regulations for the efficacy of cosmetic products

• Document could be shared with Authorities
Key Points

– **Efficacy** studies generate data on the performance of cosmetic products during product development

– **Claims** communicate product benefits to the consumer (not only those relating to efficacy studies)

– We proposed to use this key concept to defend a renewed guideline approach
The Colipa document responded to the desire in 2001 to publish a consensual document; however:

- The resulting text is too \textit{vague} to be of real use to members

- This vagueness is \textit{not representative} of the seriousness of the industry in this domain

- There is a perceived \textit{confusion} between « efficacy » (performance evaluation) and « claims » (product communication) in the document
2 Documents proposed in order to clarify the difference between the two and to ensure that communication on cosmetic products is not limited to efficacy:

– Colipa Communication Guidelines
– Colipa Efficacy Guidelines
• Guide gives **overview** of established testing methodologies

• Cosmetic Claim substantiation should be an **integral part of product development and design**

• Industry should be **encouraged to research and develop new and improved cosmetic effects for the benefit of all consumers**
Efficacy Evaluation of Cosmetic Products

- Main Methodological approaches
- General Principles for all studies
- Information which should appear on test protocols
- Information which should appear on test reports
- Annexes (Statistics, Bibliography)
• Depending upon use of the cosmetic product in course of development, it is possible to use and design several experimental approaches
Main Methodological Approaches

Evaluation on Human Volunteers

Sensorial Tests
- Auto-Evaluations
  - Use Tests by Consumers
  - Sensorial-Evaluation Tests by Experts
- Evaluation by a Professional Expert
  - Tests under Medical Control
  - Tests under the Control of Other Professionals

Ex Vivo/In Vitro

Instrumental Tests
- Laboratory Instrumental Tests
  - Instrumental Measurements associated with an Evaluation by Professional Experts
General Principles for All Tests

• **Studies** must:
  – Be relevant
  – Be comprised of methods that are reliable and reproducible
  – Follow well-designed and scientifically valid methodology according to good practices

• **Criteria** used for evaluation of product performance should be defined with accuracy and chosen in compliance with the aim of the test
Information Which Should Appear on Test Reports

General Information
- Identification
- Objective of the Test
- Test Schedule
- Methodology
- Statistics
- Results
- Discussion
- Conclusion
- Signatures of the Persons Responsible for Testing
- Summary of the Report

Specific Information
- Evaluation on Human Volunteers
  - Use tests by Consumers
  - Sensorial Evaluation Tests by Experts
  - Evaluation by a professional Expert & Instrumental Tests
- Ex Vivo/ In Vitro Tests
Conclusion

– Common Industry Guidelines for **Product Communication** (claims) and **Product Performance** (efficacy)

would allow Industry to demonstrate both **Responsibility** and **Scientific Robustness**

whilst at the same time permitting continued **Innovation** and a **Responsiveness** to Changing Consumer Needs
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