What do you need to know about cosmetic product claims when selling in the EU?

Tadej Feregotto
CE.way Regulatory Consultants Ltd.
• Why are claims important?
• Legislation overview
• Which claims can or can’t be made?
• When to start thinking about claims
• How to substantiate claims
• Our experience
Why are claims (and their substantiation) important?

• Sales
  – Product differentiation
  – Help consumers choose the best product for their needs
• Increase competition and innovation
• Product classification
• Compliance with the legislation
  – Penalties
• Ethics
• Consumers trust, industry credibility
Claims are somewhat/completely trustworthy

- Natural claims: 41%
- Organic claims: 38%
- Claims backed by science: 38%
- Endorsements by prof. associations: 38%
- Muitl-functional claims: 31%
- Anti-ageing claims: 31%
- Skin whitening claims: 27%
- Endorsements by celebrities: 25%
- Skincare with weight-loss/shaping benefits: 22%

Source: Datamonitor
Consumer Global Survey 2013
Imogen Matthews
What is considered a claim?

• Statements, any text, product names, trade marks, pictures and figurative or other signs that imply implicitly or explicitly the benefits, characteristics or functions of the product
  – On the labels
  – Website
  – At the point of sales
  – Any other marketing material

• “A cosmetic claim is any public information on the content, the nature, the effect, the properties, or the efficacy of the product” (Colipa, 2001)
LEGISLATION OVERVIEW
Regulation 1223/2009

• EU cosmetics regulation
• Applicable across the whole EU and beyond
• Entered into force on 11\textsuperscript{th} July 2013
• Introduces cosmetic product definition, product information file, deals with cosmetic product safety, responsible person, notification... and also with claims
Cosmetic products definition:

“′cosmetic product′ means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours;”
Regulation 1223/2009

• Article 20: “In the labelling, making available on the market and advertising of cosmetic products, text, names, trade marks, pictures and figurative or other signs shall not be used to imply that these products have characteristics or functions which they do not have.”

• RP has to ensure compliance of the product with the Regulation, and this includes product claims

• If RP doesn’t ensure compliance of the product, they may face penalties
Regulation 655/2013

- Additional regulation published in July 2013 dealing exclusively with cosmetic product claims.
- Claims should be **useful, understandable and reliable**, they should enable end users to take informed decisions and to choose the products that best suit their needs and expectations.
- “The main objective of laying down common criteria is to guarantee a **high level of protection for end users, in particular from misleading claims** in relation to cosmetic products.”
Regulation 655/2013

• **6 common criteria:**
  - Legal compliance
  - Truthfulness
  - Evidential support
  - Honesty
  - Fairness
  - Informed decision-making

• “Claims cannot be considered “Legal” unless they are “Truthful”. Truthfulness requires “Evidence”. Evidence is also linked to (and needs to be) “Honest”. Honesty requires “Fairness” which itself provides for “Informed decision making”, and ultimately a satisfied consumer.” (Theresa Callaghan)

• OK, but… which claims can be made, which have to be substantiated, how can they be substantiated, is the proof provided sufficient, how can you use raw material specifications as proof...?
Regulation 655/2013

- Not applicable only to claims made on the label: “This Regulation shall apply to claims in the form of texts, names, trademarks, pictures and figurative or other signs that convey explicitly or implicitly product characteristics or functions in the labelling, the making available on the market and advertising of cosmetic products. It shall apply to any claim, irrespective of the medium or type of marketing tool used, the product functions claimed, and the target audience.”
WHICH CLAIMS CAN OR CAN’T BE MADE?
Which claims can be made for cosmetics?

- Claims that are in line with the definition of cosmetic products
  - Cleaning
  - Perfuming
  - Changing appearance
  - Protecting
  - Keeping in good condition
  - Correcting body odours
- Not achieved by exerting a pharmacological, immunological or metabolic action
- Statements of clear exaggeration which are not to be taken literally by the average end user (hyperbole) or statements of an abstract nature (evidential support) don’t require substantiation
Which claims can’t be made?

• From regulation 655/2013. The obvious:
  – If you claim that the product contains a certain ingredient, this ingredient has to be deliberately present (truthfulness)
  – The claim shouldn’t overstate the product’s proven efficacy (honesty)
  – Claims stating that the product has some specific or unique properties, if these aren’t unique (honesty)
Which claims can’t be made?

• Perhaps not that obvious:
  – Claiming that the product has been approved by a competent authority within the EU (legal compliance)
  – Claims that mean compliance with minimum legal requirements (legal compliance)
    • Not tested on animals
  – Claiming or implying that the finished product has the same properties as its raw materials if it does not (truthfulness)
  – Opinions can’t be shown as verified claims, unless these claims can be verified with other evidence (truthfulness)
Which claims can’t be made?

• Perhaps not that obvious:
  – Claims extrapolating ingredient properties to the finished product without adequate and verifiable evidence (evidential support)
  – Claims denigrating the competitors or ingredients legally used (fairness)
  – Claims creating confusion with a competitor’s product (fairness)
  – Unclear, not understandable or irrelevant claims (informed decision-making)
Which claims can’t be made?

• Claims related to treating or preventing diseases
  – Words or phrases which present a **medicinal intent**
    (not an exhaustive list): cures, heals, treats, restores,
    prevents, clears, protects against disease, helps
    control the symptoms of, traditionally used for
    treatment of, strengthens immune system (HPRA
    guidelines)
  – Brand names should not contain syllables such as –
    med-, -pharm-, or attributes such as “medicinal”
    (Slovenian CA guidelines)
  – **In general any mentioning of illnesses is not allowed**
  – **Acne and itching** are also treated as a disease
Which claims can’t be made?

- Some examples:
  - Enhances the immune system
  - Internal skin care
  - Alleviates skin problems such as dermatitis, eczema...
  - Anti-inflammatory
  - Calming of red and irritated skin
  - Diminishes scars
  - Repairs damaged skin
  - Against pimples and spots
  - Stimulating blood circulation
  - Healing sores on lips
  - Soothes pains of oversensitive teeth
  - Reduces gum-bleeding
  - Antiseptic, disinfecting
  - Treatment of diaper rash
  - Acts against lice and nits
  - Against stiff and cold muscles
  - Solves baldness
  - ...

Tadej Feregotto

In-cosmetics Barcelona 14-16.4.
Sunscreent products

• Special rules for sunscreen products claims
  – Claims to include
    • SPF
    • Efficacy category: low (SPF 6, 10), medium (SPF 15, 20, 25), high (SPF 30, 50), very high (SPF 50+)
  – Prohibited claims
    • 100% protection from UV radiation – sunblock, sunblocker, total protection...
    • No need to re-apply the product under any circumstances – all day prevention...
Which claims can’t be made?

- Other legislation to take into account:
  - Directive on misleading and comparative advertising (2006/114/EC)
Upcoming clarifications

• Claims under discussion:
  – Free from
  – Hypoallergenic
  – Natural, organic, bio
  – Environmental claims
Which claims can or can’t be made?

• What also to keep in mind:
  – Certain things are common across the EU, while certain things differ country by country
  – Social and cultural differences between countries, different expectations, as well as linguistic factors
  – Disagreements between different EU competent authorities – example free from claims; and between claims experts
  – At the end its always up to inspectors and national courts to decide
WHEN TO START THINKING ABOUT CLAIMS?
When to start thinking about claims?

• The sooner the better

• One of the bigger bottlenecks in the process in our experience

• Already when formulating the product start thinking also about **what kind of claims you intend to make for your product, and how are you going to substantiate them** (your formula and raw materials concentrations may be important)

• When choosing raw material suppliers check whether they provide any raw material specs and tests that will help you substantiate your claims (if you intend to substantiate them using raw material specs)
When to start thinking about claims?

• If you will perform any testing to substantiate your claims or do consumer perception tests, also start working on this in time
  – First though find out whether your formula is compliant with the EU regulation
  – And do at least some preliminary testing (stability, challenge) to find out if your product is safe, otherwise you may have to reformulate your product, and would have to do claim substantiation testing again
When to start thinking about claims?

- You can only completely finalize the label once the safety assessments are done.
- But don’t only start thinking about claims and especially their substantiation then.
- Involve a regulatory or claims expert early in the process to avoid any excessive or not sufficient testing, and to avoid thinking about claims that anyway can’t be made for cosmetic products (or even doing testing for them).
HOW TO SUBSTANTIATE CLAIMS?
How to substantiate claims?

• Regulation 655/2013: “Claims for cosmetic products, whether explicit or implicit, shall be supported by adequate and verifiable evidence regardless of the types of evidential support used to substantiate them, including where appropriate expert assessments.”

(evidential support)
How to substantiate claims?

- Depends on the type of claims that you’re making
- Best practice for claim substantiation (regulation 655/2013)
  - Experimental studies
  - Consumer perception tests
  - The use of published information
  - Combination of the above

- Where to perform any testing?
  - Go to a company that performs such studies
  - Do them yourself
    - Study protocol, everything documented
    - Controlled conditions
    - Statistical data analysis
    - Professional equipment
    - Unbiased
    - ...
  - Involve a regulatory consultant or a claims expert to avoid any unnecessary costs
Experimental studies

- In silico (performed on computer or via computer simulation)
- In vitro (studies with cells or biological molecules studied outside their normal biological context)
- Ex-vivo (experimentation or measurement done in or on tissue from an organism in an external environment)
- With instrumental or biochemical methods
- Studies conducted on volunteers
- Investigator evaluations
- Sensory evaluations
- Etc.
Experimental studies

• Studies must be:
  – Reliable
  – Reproducible
  – Follow a well-designed and scientifically valid methodology
  – Achieve scientifically and statistically valid conclusions
  – A study protocol must be prepared
  – Person conducting the study must be properly qualified
Experimental studies

• **Report should include** (same for consumer perception tests):
  – Product identification
  – Study objective
  – Test schedule
  – Test protocol
  – Presentation of results and their interpretation
  – Statistics
  – Signature of the person in charge of the study
Consumer perception tests

• Consumers’ perception of product efficacy and cosmetic properties
• Based on what consumers can observe and feel
• Study protocol must be prepared
• Study must be ethical
Consumer perception tests

• What to keep in mind:
  – **Appropriate number** of test subjects
  – **Representative sample** of test subjects (whom the product in question is targeted at) – strict inclusion/exclusion criteria and clearly defined socio-demographic criteria
  – **Wording of the questionnaire** – clear, unbiased, well balanced scale, no questionable interpretation of the questions intended to substantiate the claims
Published information

- Scientific publications
- Market data
- Information obtained from the raw material suppliers? (not mentioned in 655/2013)
Published information

- Scientific publications on ingredients are acceptable provided that they’re relevant to the product and the claim made.
- If extrapolating (explicitly or implicitly) ingredient properties to the finished product the ingredient must be:
  - Stable in the finished product
  - Its activity must be maintained in the product
  - The concentration of ingredient in the final product should reflect the levels at which the claims have been substantiated – effective concentration
How to substantiate claims?

- Level and type of substantiation depends on the type of the claim.
- Claims where lack of efficacy may cause a safety problem (such as UV protection) require a high level of substantiation.
- Experimental studies are preferred, but sometimes consumer perception tests or the use of published information may be better (again, depends on the claim).
- Not one single prescribed test to substantiate a claim.
- Justification, well-conducted research, product and claim relevant, significant (representative).
- Acceptability of a claim is based on the general presentation of the product, on the weight of evidence of all studies, data and information available depending on the nature of the claim and the prevailing general knowledge of the end users (evidential support).
OUR EXPERIENCE WITH CLAIMS
Our experience with claims

- Claims are one of the most challenging parts (perhaps the most challenging). Why?
  - Legislation is very vague
  - Companies don’t understand the legislation, don’t understand that any claim has to be substantiated and don’t understand the possible implications of non-compliance
  - They’re making claims that are not allowed or claims for which they don’t have sufficient proof
  - Companies are uncooperative
  - It is almost impossible to follow all of the marketing channels where clients can make claims about their products
  - Companies only start thinking about claims at the end of the process, when everything else is already finished
Our experience with claims

• Problems with claims can be generally divided into 3 areas:
  – Making claims that are not allowed on cosmetic products
    • Not tested on animals, medicinal claims, product names (Cure clay mask, Healing skin cream...) etc.
  – Not having (sufficient) proof for their claims
  – Incorrectly interpreting studies results
Our experience with claims

- How do companies want to substantiate their claims?
  - Almost none of the companies want to do any actual testing to prove their claims. Instead they all want to base their proof on raw material specifications
  - Or they want to do questionnaires or some studies by themselves
  - They try everything to avoid spending some money on performing tests that would prove (or not) their claims
Our experience with claims

• Problems that we often encounter when getting proof for the claims made:
  – Very common: claims are made based on the raw materials which the product contains, but the concentration of this ingredient in the product doesn’t match the effective concentration
    • Recommended use level for Vital Hair & Scalp complex mixture 1-5%; in the product in 0.26%
  – Or claims are made based on the raw material specifications, but no document with the effective concentration is provided
Our experience with claims

– Basing claims on some “home made” surveys or consumer testing, which isn’t reliable or representative
  • Hair gel is 100% effective in all weather conditions, allowing your style to last several days. Proof: 5 people walked around the park in various weather conditions and before/after shot was taken
  • A questionnaire was filled in by the consumers, but there were only 10 respondents

– Believing that the claims that they’re making are not “strong” enough, and therefore they don’t have to substantiate them
  • “In my opinion, XX's claims are not strong claims like "The amount of skin moisture is going to increase by using the product for ten days..." It is not necessary to have efficiency tests done”

– Similarly, stating that their claims are too vague to require substantiation
Our experience with claims

– Not believing that certain things are prohibited for cosmetics – usually by referencing other companies (their competitors) who also make such claims
  • 5 free from claim (including free from animal testing): “we really cannot remove the ‘5 Free’ from our bottles. It is our #1 biggest selling point, here and in the EU. It is really just an industry standard and absolutely every competitor has it. If there are any problems we will do it but for now it is just way too important and not one of our competitors is removing this.”

– Asking that we show them exactly where it is written in the Regulation that the claims that we are asking to be removed are prohibited
Summary

• Read the regulation – no matter how vague it is, it does provide some guidance
• If you’re not sure about your claims (if you can make them, how to substantiate them) involve an expert in the field to help you
• Start working on claim substantiation in time
• Differences among EU countries, so check what’s the view of authorities in the countries where you intend to sell
• Checking of claims will probably increase this year, because a report regarding the use of claims on the basis of the common criteria has to be submitted to the EU Commission by July 2016
THANK YOU!