

Transcript of The Official Recording - The Science and Regulations Behind Cosmetic Claims_ A Comprehensive Guide



Presented by



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Founder of CosmetiChroma

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Welcome everybody to this live training session. Today we will be looking at the science and regulations behind cosmetic claims.

AGENDA



- Introduction: What is a Claim?
- Types of Claims
- Claims Evidence & Substantiation
- Protocols and Test Reports for Claims Testing
- Consumer Panel in Claims Studies
- Legislation on Claims and Advertising
- Case Studies

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About Me

This slide just shows a little bit about me and in fact you will see that I have about 20 years of cosmetic industry experience.



About Karen LV MANN PhD

With two decades of immersion in the **cosmetics industry** in the **UK** (Burberry, WBA), **Paris** (L'Oréal) and **Milan** (Dolce&Gabbana, Intercos) Karen's journey has evolved into founding **CosmetiChroma (CC)**, a beacon for scientific & technical training and consultancy in the global beauty sector.

 **CosmetiChroma** was created for cosmetic industry professionals looking to master cosmetics development and global launches with confidence by transforming technical, scientific and regulatory obstacles into successes.

 Karen's prior roles in Italy included **Global Head of Quality & Regulatory at DOLCE&GABBANA** and **Global Director of Regulatory Affairs at Intercos**.

 She has worked with all Global markets in particular the EU, US, Asia especially China, Middle East and Africa.

 Whilst at The University of Bristol, UK Karen obtained a PhD in Inorganic Chemistry with 15 publications in international journals (<https://www.linkedin.com/in/karenlvmann/>).

 On a personal level, Karen has lived in 7 countries, so you could say that flexibility and adaptability has become essential. Her mother tongue is English and speaks 2 additional languages fluently: Italian and French.

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I started my career with L'Oreal and then I moved over to Paris where I work with them with them until 2011.

I then moved back to the UK and worked for Walgreens Boots Alliance as well as Burberry, I then decided to move to Italy to obtain a job at Intercos as Global Director of Regulatory Affairs.

I then expanded my responsibilities at Dolce & Gabbana, where I was also in charge of Quality.

Recently, literally last July, I set up my own business called CosmetiChroma, and essentially I set this company up in order to help you navigate the cosmetic industry, in particular the scientific and technical aspects, which can be quite complex, especially when you're developing and trying to sell products.

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I have infact worked with all global markets and with particular expertise with the EU, the US, Asia, especially China, but also the Middle East and Africa.

I went to University at Bristol in the UK and obtained PhD in inorganic chemistry. I also obtained 15 publications in international journals. You can view all of these on my LinkedIn profile.

On a personal level, I've actually lived in seven different countries and I have also lived in many different places within the UK. My mother tongue is therefore English, but I equally speak 2 additional languages, which is Italian and French.

Agenda

Let's now dive in and have a look at what we will be discussing today. Essentially, we will start with the introduction on what exactly is a claim. Then we shall move on and look at the different types of claims. We will then look at the claims evidence and substantiation, followed by the protocols and test reports which are needed for claims testing. We shall look at the consumer panel in claims studies and then we will finish with the legislation on claims and advertising. And finally, we will look at a couple of case studies.

Introduction: What is a claim?

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The English Cambridge Dictionary describes the claim as a statement that something is true or is a fact.

Furthermore, the European cosmetic regulations stipulates that in the product information file you need to have proof of the effect of a particular cosmetic product. In other words, this means the performance.

Furthermore, Cosmetics Europe, which is the European Cosmetic Industry Trade Association, defines cosmetic claims as statements that describe the characteristics and functions of a cosmetic product - that was done in May 2019.

Cosmetic product claims are actually generally information used for marketing purposes and depending on the claim, this can obtain competitive advantage.

They can claim things on the content of the product, the type of product, how the product performs, or the effect, the properties as well as the efficacy of the products. But bear in mind that claims are not only text, they can also be names or trademarks, pictures and other signs which may appear on products in the advertising.

Before and after images

This slide shows that you can actually use before and after images and this will be classified as a claim and also so will graphs. What you need to be careful of is the European regulations on Article 20 - they actually say that labelling, advertising, text names, trademarks, pictures or other signs shall not be used to imply characteristics that the product does not actually have. You therefore have to have proof that the product will have the performance that you are stipulating in your claim.

Exercise

Here's an interesting exercise with a shampoo:

Introduction: What is a Claim?



EXERCISE
Identify the Claims



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We see that there are a number of claims on the front of this bottle. You can see first of all “thick and full” and you can also see some claims relating to ingredients: “biotin” and also, “collagen” which is within the skin.

Then you also have a logo which says “salon quality” as well as “pH balanced” and “gentle formula”. These are all claims which actually need to be backed up.

It then goes on to say that the statement of identity is a shampoo - statement of identity is actually what the product is, and it indicates to the consumer what exactly they need to do with it. The average consumer understands that a shampoo is used to clean the hair.

They then go on in the advertising with a statement to say “an exclusive blend with vitamin B7 biotin, collagen and hydrolyzed wheat protein which helps to infuse the nutrients into every strand of the hair and creates the appearance of thicker, fuller, healthier looking hair”.

They then go on to finish with “sulphate-free surfactants”.

There's a huge amount of claims on the front of this bottle.

When we look at the logo, we need to be very careful what we mean by “salon quality”. We need to actually be very clear on that so that we can explain it to the authorities in case they question us.

Equally, “pH balance”. Does that mean that it's pH-7? Which is the middle of the pH range such as water? Or does it mean it's balance for the actual hair?

Equally, “gentle formulation”. Do you have a consumer study to say that the consumers consider this to be a gentle formula?

Equally, what about “thick and full”? How are you going to claim that? We will look at this in a second.

And equally, “vitamin B7 biotin, collagen, hydrolyzed wheat protein”. These also all need to be present in the list of ingredients, but also an efficacious amounts as they are claimed to be causing the performance of the product that you have. Equally, you need to show that these ingredients do infuse the nutrients into every strand of the hair and how on Earth are you going to show that?

It's a complicated pack with a complicated claims.

“Sulphate-free” surfactants also need to be proven. You need to demonstrate that any surfactant that you're using is indeed sulphate-free.

We will now look at, during this training exactly what types of studies one could use to actually substantiate the claims that are stated on this bottle.

The other thing is where can claims be placed exactly?

Well, claims can be placed in a number of different areas and direct mail was used a lot in the past, but I think this is used much less than before.

I would say that social media, online, probably radio and also TV, are the most common. I think also they are used in press and obviously the point of sale.

Equally on the pack you will find claims as we saw with the shampoo bottle. Many claims can be placed on the primary packaging which has direct contact with the product or formula OR the secondary packaging which is not in direct contact with the formulation.

And yes, cinema can be used for the advertising.

What is the purpose of a claim exactly?

The purpose of a claim really is to communicate messages about a product to potential buyers. They should really answer the questions of the mind of the buyer of: why, what and how.

Why?: So why should I buy this particular product? What is the unique selling point of this product compared to another product on the shelf reporting to do the same function?

What?: how can this product be a benefit for me? What is it going to do to add to my life?

How? How will I know the product has worked?

Clearly, when we look again at the example of the shampoo. The role of a shampoo is actually to clean the hair, which is actually an active ingredient of surfactant. So therefore you should feel that your hair is clean, but all shampoos will do this function. However, with the additional claims, the add-ons and the benefits are you seeing those benefits?

History of claims

Let's have a look at the history of claims and restart back to the 1950s and the 1960s. You will see this delightful advert from Jade and the claims are rather interesting and probably quite shocking to you now, because we won't see these kind of things anymore in the industry. But what they said was "immediately after application the actives penetrate in depth into the tissue, clean and sanitise the skin from the inside and the outside".

The claims are therefore pretty bold and really exaggerated. And at that time during the 50s, 60s, I would say that there was a very limited regulatory oversight of brands making claims and they would use these to maximum effect to try to outdo other brands who are their competitors. They will equally make promises of miraculous results like "instant wrinkle remover" or "dramatic skin lightening".

I show you another example. This actually is an example from the 70s, the early 70s. And here they say with cream 21, they say contains "3 vitamins which protects regenerates the skin, making it more resistant and stimulates blood circulation". This is indeed very bold.

However, in the 1980s and the late 70s, we actually saw the introduction of the EU Cosmetic Products Directive and this started to increase consumer awareness by shifting it to more realistic and substantiated claims. Also, there was more focus on safety and efficacy and also they wanted to see claims backed by scientific evidence.

So, in this particular example of the noxzema cream, you can see that they talk about "clear, healthy skin by deeply cleansing pores and removing dirt and oil" and you can see that you would then start to need to substantiate these types of claims.

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In 2009, we saw the introduction of the EU Cosmetic Products Regulations 1223/2009. The difference between a directive and a regulation is a directive in the EU still needs to be transposed into each individual Member State legislation. However, a regulation does not need to be transposed and must be applied “as is” within each of the Member States.

Furthermore, in the EU there was an introduction in 2013 of the EU common criteria, which sets out six common criteria for claims, and we should look at this shortly.

So you could say that present day claims are highly regulated, more transparent and they should be more clear, understandable and substantiated.

There are further legislations coming and we will discuss this shortly as well.

Now, let's look at the types of claims

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There are about 8 different types of claims. The first one deals with performance and the next one deals with ingredients themselves, and we saw this in the previous example of the shampoo, but then we can have ingredients related to the formulation. Then we can have sensory and aesthetic, comparison, environmental, perception and puffery claims.

Let's now look at each one of these in turn.

In general

In general, when you're thinking about the EU regulations I mentioned about the common criteria, which is a specific EU regulation 655/ 2013 and it states that information that is shared to the consumer through claims must be useful, understandable and reliable.

Equally, the information must enable consumers to make informed decisions and choose products that best suit their needs and expectations.

Within the European Cosmetic Regulations 1223/ 2009, you will actually see the definition of a cosmetic product here and it states that any substance or mixture intended to be placed in contact with the external parts of the human body with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in the condition or correcting body odours.

It's very important that when you're making a claim in the EU that you stay within the boundaries of the cosmetic legislation.

Many companies do try to push their claims closer and closer to borderlines, and borderlines means a product that is in between a cosmetic regulation and a medicinal regulation or other. And they do this in order to achieve competitive advantage. However, the key point that a cosmetic stays a cosmetic by respecting the European cosmetic definition. In other words, your cosmetic product must perform those functions of cleaning perfuming, etc. If it does not, it may well fall into a different directive and therefore the regulations that we're discussing will no longer be applicable.

Let's look at performance claims

What does the effect mean when we're talking about the product information file that we saw earlier? Well, in fact, the effect means that a cosmetic product has an effect or I suppose an action on the cosmetic functions which we saw earlier. It's basically how the product will perform and how effective it is.

Equally, you can focus on claims that talk about the length of time that it will perform this efficacy: how it actually does so and actually what it does so for example, "long lasting", "reduces appearance of fine lines up to X

percent” and “UVA protection”

It's important to realise that when you're actually doing studies to back up your claims, the results are obtained must be across the entire tested panel. And they must be statistically valid.

This is quite a complex area of cosmetic claims, which we will only touch upon today.

Ingredients

Other types of claims focus on the ingredients that in the product, and we saw this earlier with the shampoo. So for example, you just state that it contains a particular ingredient such as vitamin C, ceramides and so on. And it's fine but if you want to make performance claims. or further claims you must support the particular benefits that the ingredient actually has. So for example, claims related to an ingredient benefit or how having this ingredient imparts benefits to the final product, need to be backed up.

So for example with hyaluronic acid known to help skin stay moisturised, you would therefore need public information or scientific information which demonstrates that hyaluronic acid is known to moisturise the skin.

And the other point is a claim extrapolating ingredient properties to the final product, you must show that how the ingredient data relevant to the actual ingredient properties are extrapolated to the finished product. And therefore they must be in functional doses.

Sometimes claims or about for example, contains vitamin C you can have very low levels.

However, when you are extrapolating performance claims of an ingredient to the finished product, you must make sure that that particular ingredient has an effect so it's different from just stating that it contains an ingredient. This is very important, and sometimes it isn't always easy to prove that there is an extrapolation to the finished product.

Ingredients/ Formulation

Now we have ingredients and formulation. So what do I mean by this? Well, this really is about the activity of certain ingredients present in the formulation, such as, we know the vitamin C is an antioxidant, we also know that ceramides help repair the skin barrier.

Equally, camomile bleaches the hair and soothes the skin, and phytosterols increase skin firmness. So this actually is known of those particular ingredients have those particular properties.

But equally, you might have claims related to the formulation which enable the consumer to make an informed choice, for example “formulated with a certain percentage of natural ingredients”.

Equally, claims related to the lifestyle choices, personal values and beliefs such as vegan, halal or organic claims.

And equally certification to various bodies can strengthen the validity of such claims, including the use of logos.

But for example, organic, vegan or cruelty free and so on, there are various

different types of logos one can use. And it depends. Which body and which logo you are going to use depends on your choice within the marketing for that particular product. And if you have a certified organisation, generally speaking, you have to apply to that organisation and fulfil all the criteria that they ask you for in order to receive their logo that you can put on the artwork.

Here's information about storytelling related to ingredient claims. So for example, the first one about the “seven day facelift with the lifting molecule AVC 10”. Equally, we have ceramide claim and it says in French: “new innovation in phytocosmetics extracts of ginkgo and echinacea are combined in a vital equation for the skin's beauty.

Then we also have Neutrogena visibly young anti-age night cream and here they talk about it contains active copper. And they say that it states: “to visibly reduce wrinkles and make your skin firmer and younger looking”, and they actually demonstrate the study they say in clinical study: “100% of women saw a visible improvement”. Clinical study means that a dermatologist, was involved in that particular study.

Sensory and aesthetic claims

Sensory claims. It's really our focus on olfactive, textile and visual. Olfactive being the smell. So, for example, “fragranced with Lavender”. Tactile is the application, the texture, the touch: easy smooth application for example, and the visual could be a 2-phased eye makeup remover.

Then we have **aesthetic**

We have the appearance, what the packaging is and also the format for the products, the formulation. So for example maybe the format is a mousse.

Also the appearance, it comes out as a mousse.

Flip-top cap for ease of use, packaging and format: stick for no touch.

Comparison claims

Comparisons are as they, as it sounds, a comparison to previous formulations you've already launched on the market or also to competitor products. New improved formula "voted number one by Which magazine", these kind of things.

However, it is important that you are also subject to another legislation in Europe called the Misleading and Comparison Advertising Directive and they focus on the fairness criteria of the EU regulations protecting the competitor interests, so basically you cannot denigrate a competitor with your claims.

If any testing is carried out to substantiate your claim, as I mentioned before, this must be included in the PIF file in the product information file, which is the European cosmetic regulations. And you must ensure that you include any batch codes equally, if it's relating to a competitor.

Environmental claims

Environmental claims are seeing a big shift in Europe at the moment, but they do and must adhere to the current EU cosmetic product regulation, the same as any other claim, and in fact, the EU cosmetic regulations is pretty sound in the terms of the fact that you have the common criteria and you also have commercial practises directives which cannot denigrate your competition.

So recently we have seen that the European Commission has proposed a new EU Green Claims Directive. And the key points of this in addition to the

regulations that we've already seen, there will be an independent verification will be needed to actually audit the fact that you're saying that those tests back up that environmental claim. You will need an accredited auditor to say yes and they will issue some kind of certificate of conformity.

The reason why the European Union decided to tackle this was because of greenwashing and we're talking about all sectors - it's not just the cosmetic sector. And they did some various studies, 2020 and 2018, where they actually found that a lot of claims were misleading. I do believe that cosmetic industry in Europe is pretty well regulated for the claims, but I think for environmental claims this goes one step further and for the cosmetic industry, there will be more focus on the claim substantiation, ensuring that in fact you are as green as you say you are.

Perception claims

This in fact is related to how a consumer perceives a product and needs to be supported by consumer testing. So in other words, consumer testing is where you get a panel of consumers and they need to evaluate various factors of a cosmetic product using a survey and it's their own personal perception that's important. That could be related to all the types of sensorial, tactile olfactive, etc, types of claims we saw earlier or also a performance attribute that is claimed.

So for example, as I mentioned, with performance, "skin hydration improved after one application", this will be a statement in the survey and the panel, the people within the test, will need to say "yes or no" or they can also give a score or whatever it is that the company wishes to have a response from the consumer on.

Puffery claims

Puffery claims are a little bit as they sound, and these are claims of clear exaggeration, but they're not to be taken literally by the consumer. For example, "Red Bull gives you wings". The average well-informed consumer will know that Red Bull does not give you wings.

And claims already known that do not need further substantiation. For example "putting a body about on your skin helps genes slide on easier".

Safety & Technology claims

Then we also have other types of claims. We have safety claims and we have technology claims.

Regarding safety, there's "hypoallergenic", "non-irritating", "safe for the eye area" or "ophthalmologic" and "dermatologically tested".

There are also technology claims such as "patented", "sustainably developed", "penetration technology", "microcurrent technology", "nobel prize inspired". These kind of claims.

Hypoallergenic

Now a word on a "hypoallergenic"

If it cosmetic product claims to be hypoallergenic, the presence of known allergens or allergen precursors, so precursors to an allergen must be totally avoided, and in particular the legislation talks about these.

If the EU Scientific Committee has identified an ingredient as a sensitiser when assessing the safety of cosmetic ingredients, then they should be

avoided in hypoallergenic products.

Just a comment about SCCS. It's the Scientific Committee for Consumer Safety and the European Commission asks this body for advice on particular ingredients. They will then give back their feedback and the European Commission decides whether to go ahead and make a legislation or not for that particular ingredient. There are other official Risk Assessment Committee's and equally, any ingredient classified as as a skin sensitizer must not be added.

Also, we know about CMRs: category 1, category 1A or 1B - complicated topic again which can be seen in some of my other courses on Regulatory.

Equally, any ingredients that have been identified by the company on a basis of the assessment of consumer complaints and equally generally recognised as sensitisers in scientific literature or for which relevant data on their sensitising potential are missing.

So what we can say is hypoallergenic does not guarantee a complete absence of risk of an allergic reaction and the product must not give the impression that it does. However, if you are allergic to particular ingredients, it's really advised that you actually go for a skin allergy test for cosmetic ingredients that you suspect of being problematic for you, so like a skin, skin allergy test. And the doctor will put a small amount of those particular ingredients on your skin, and you should see a reaction very quickly if there is an allergic reaction.

Example

Here is an example of a Clarins product and they talk about restorative total eye concentrate. So for the first time an eye product that targets the

entire eye zone area from temple to temple. So basically, they're not just talking about the product acts under the eyes, they're talking about a product that actually targets the entire area from here. They say that it reduces the appearance of crows feet and frown lines between the eyebrows, and this can be demonstrated either by instrumental tests or it could also be attested by consumer study. Here we see in the study they've said: "71% of users notice a reduction in the appearance of wrinkles". So actually in this case they've used the consumer study.

They then talk about the presence of various ingredients like isoflavones, dermaxyl, parsley and shea butter, etcetera, which lifts and replenishes and de-puffs the entire eye area. They would need to have evidence of this, probably through the consumer study.

And lastly, we've got puffiness and dark circles are noticeably reduced. Again, this would need to be proven through the consumer study.

Now we've looked at the different types of claims we can now look at claims evidence, and substantiation.

Claims Evidence & Substantiation

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Levels and types of evidence

So essentially there are levels and types of evidence for claims.

Claims Evidence & Substantiation



Levels and Types of Evidence for Claims

Levels	Types
• Widely acknowledged • Needs Evidence • Evidence from <u>Significant Advances in Science</u>	A. Publications B. <u>in Silico</u> C. <u>in Vitro</u> D. <u>ex Vivo</u> E. <u>in Vivo</u>

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Under levels, there are three factors widely acknowledged: needs evidence and evidence from significant advances in science. The different types of evidence would be: publications in silico, in vitro, ex vivo and in vivo. We shall look at each of these in turn.

Levels

So starting with the levels.

Widely acknowledged. What does this mean? But for example, consumers know that EDT eau de toilet or eau de parfum are fragrances, with eau de toilet being the less strong of the two. In other words, EDPs, eau de parfum, are much more concentrated in terms of the amount of fragrance in the product.

As we mentioned before, consumers know what a shampoo does. They know it will clean the hair and they also know that lipsticks will cover the lips.

Consumers might know that hyaluronic acid is used for moisturisation in skincare or that beeswax is not vegan, so these are things which potentially the consumers have acknowledged and recognised.

There are also a level of evidence which **needs more evidence**. And for example, a particular formulation requires evidence of the claim and this would be “long lasting” etcetera, generally performance claims.

But equally, the duration of the benefit: “25% increase in skin hydration”, “18 hours wear” all of these need to be proven.

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Also product type not normally associated with that claim. For example a hydrating powder.

Generally a powder is used to absorb oil from the skin, so it's unusual to see a powder that's hydrating.

Also, guidelines or legislation which actually require additional testing by law, such as SPF testing, waterproof and so on.

And equally marketing target groups, gender neutral skin or hair types, ethnicities. We will look at this a little bit later when we discuss the consumer panel.

And then there's also evidence from **significant advances in science**. Such as a new type of ingredient action that wasn't discovered before, a new benefit that is seen from a particular product, a new sensory product that has come up maybe out of the consumer studies. And also new ways of measuring product effects. The advantage of having new ways of this means that you can actually prove a greater range of claims, a broader range of claims, and this is why it claims evaluation and claims studies are actually quite significant for some companies.

Types

Let's look at the types.

Publications.

Well as it sounds, these are material from published books and legal texts. They could also be publications and scientific studies or monographs in the USA. For example, in the USA, SPF products are considered OTC drugs and

therefore they have a monograph for SPF product with the type of actives and the percentage, percentages of ingredients that are allowed for them, as well as labelling constraints and many others.

In Silico

The second one is in silico, and this is basically consumer modelling.

In Vitro

In vitro is when you have cell tissue models or living components of an organism and the objective is a biological mechanism or mode of action.

Ex Vivo

Then we have ex vivo, which is actually organ culture. So for example, the tresses of human hair or skin samples, which may have been taken from surgery. And the objective of these is performance.

In Vivo

And then we have in vivo and this basically is on live people during a consumer studies. For example, meeting the sensory aspects of the product or the performance claims that the company wishes to use.

There are three types of in vivo tests.

- You can have the in-use test with self evaluation by a consumer, which is very subjective.

- You can have a sensory tests with self evaluation by trained expert panels and this is where you're moving a little bit further on from the subjective to the objective.

- And then finally you have controlled clinical testing which is highly objective with strong reproducibility. In other words, you're using machines which actually will measure the performance of the product on the individual.

Order of Pertinence

So, the order of pertinence, in terms of the different types of testing is in silico with a highly theoretical simulation, which is computer modelling. This actually would be the least reliable out of all the testing.

Then we go to the other extreme of the in vivo, which really is your ideal and the gold standard.

So as we looked at in tubo, for example, is isolated molecules that you take and you actually examine them and see how they perform like enzymes or dpsh. And then with in vitro, you actually have a monolayer cell culture, which has been grown, for example in Agar Jelly and these are generally single cells.

Then we have three types of ex vivo one are the explants but of course, for the explants you have to consider that whilst it is closer to reality, there aren't any nerves or blood vessels and you also have skin models which have the same issue and of course are incomplete.

Therefore your ideal is to always try to conduct testing where possible on live, human volunteers.

In Vitro End-Points

When we're thinking about in vitro and as mentioned before, these are the mono layer cell structures and the single cells. You basically have some endpoints that are you, you are looking for and there are many types of different tests that you can, you can do and many endpoints that you can look for. For example, you might want to be looking at how collagen is

affected or elastin, etcetera when you're looking at anti-age studies. So you would interact these cells with your finished product to see what the before and after would be.

Then there can also be a pigmentation studies like melanocytes and you're going to insert your products together with those cell cultures to see how the melanin is affected. Again, enzyme activity like tyronase.

You also have swimming studies like glycerol production triglyceride content.

And energising studies, for example or not, the study itself is not energising well, it could be, depending on the type of study, but it's really is focusing on the ATP, which is adenosine triphosphate, which is basically the Kreb cycle which generates energy within the human body when it's broken down into ADP, adenosine diphosphate plus a tri-phosphate, which releases energy.

In Vitro Testing

And then looking at in vitro testing, so, in vitro testing, you're looking at the the human hair for example, is that you have hundreds of possible protocols and you can look at the cellular metabolism, enzymes activity, antioxidant properties, anti-inflammatory properties and DNA or genetic analysis. The problem with the testing is that there is no standard harmonisation across the board so you'll have different companies testing. For example for anti-oxidant properties, but they'll use a different protocol, so therefore it's difficult to see whether in fact the test is viable or not. And then there's also the difficulty of extrapolating these results to the in vivo, so to the live case, so to the human being, which actually will use your cosmetic product.

Ex Vivo Testing

When we think about ex vivo testing. So this is basically, human tresses, or skin cells, and you can take these a number of ways. With the tresses for the hair you get human volunteers who are willing to give part with their hair and for the skin you can actually put a piece of tape stripped to someone's skin and then pull that off, which will peel off the epithelial, some of the epithelial cells of the skin.

You could also pluck some hair from the follicle and you could also have some 3D skin pieces or biopsies, which could have been taken from plastic surgery or so on. And you can also have reconstituted 3D skin models as you can see on the right.

So basically ex-vivo or 3D models of the human skin or excised human skin or animal skin and again there are a great number of possible protocols, endpoints and markers but there are no standard protocols. There is ISO - the International Standards Organisation, and of course they've issued testing related to SPF, waterproof and some micro testing. But there are a huge range of tests that could be done to prove efficacy claims or performance claims that it really becomes impossible to standardise.

And you may not have any minimum of maximum levels, but the benefit of ex vivo is it's closer to in vivo and you can have a better extrapolation to in vivo.

Now in vivo testing, as I mentioned before, is on the actual person and it's actually, the product is applied directly onto the skin and it is a full organism, so this can be a little bit ethical when you're thinking about animal testing and it is banned by the European legislation. And you also have to be careful with the human volunteers as well and we'll look at the

panel in a second.

You can have two types of in vivo testing.

One is invasive and the other is non-invasive. Now invasive is very rare and would generally be used in medical situations as there's a possible risk for the volunteer because you're taking biopsies from them and there are specific laws in the EU and so on that you have to consider.

Most of the tests in the European Union are non-invasive and they are consumer testing which is no or low risk for the volunteer. The methods are increasing in number and the methods can be very simple to very complicated.

Instrumental Tests

This slide illustrates the types of protocols and tests that can be done in terms of instrumental. So for example, if you want to measure hydration and trans-epidermal water loss, you can use a corneometer or a tewameter. These will then give you a very objective, precise measurement within the tolerances of the machine, and it would tell you before and after and you compare the difference with imagery and so on, and also numerical values.

Sebum production. You can use a sibutape before and after or an actual sebumeter, which can measure the level of sebum on the skin.

There's also **wrinkle reduction**, so you could use fast optical in vivo topometry of the human skin and a 3D mapping. In fact, I've actually seen this machine and it's really amazing. It's like a ball and you put your face in there and you can really see your skin as it is under the surface. It's amazing.

Slimming and anti-cellulite. You could use ecography kind of what they use in hospitals with the ultrasound.

Firmness. There's a machine called cutometer and aeroflexmeter.

Microcirculation. So looking at how the blood is moving around, that's laser doppler flow meter. They actually use a dwhen you're measuring blood flow within the heart.

Cutaneous fatigue would be NMR, which is nuclear magnetic resonance spectroscopy, quite a complicated technique.

Skin colour. A chromometer or mexameter.

Skin absorption. FTIR - fourier transform infrared spectroscopy.

And **keratolysis, desquamation, cell cohesion** there's a DSQUAM® skin sampling and analysis technique.

I've put three dots there because there are thousands. There are many, many different types, protocols and tests and machines that can be used. The more that can be developed by your company and the more that's available to you, to you to use the more bold your claims can be, so long as it stays within the boundaries of cosmetic regulation.

Protocols and Test Reports for Claims Testing

Now let's look at protocols and test reports for claims testing.

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Repeatable, Predictable, Reliable, Robust

So we need to ensure that when you do the write-up of your claims test, you need to make sure that those particular tests are **repeatable, predictable, reliable and robust**. Because sometimes with authorities globally, they will look at the test reports and they will try to repeat them in their labs.

Now there is an argument between what type of protocol they're using and what protocol you're using and if they contest the product licence when you're trying to place your products on the market. If they find a result out of spec, it's possibly because of the protocol and that is why the protocol needs to be based on harmonised international standards as much as possible.

Equally, the report itself needs to be clear, needs to be written step by step.

Good document practices need to be followed which is quality. You need to have credibility with the report, so therefore it needs to be well written and equally these protocols and test reports, particularly the test reports, will go into the product information file which the EU authorities can look at at any time during an inspection.

And then also you have claims advertising. So for example with the US and particularly with the UK, you actually need to submit a dossier before you're actually allowed to advertise because they want to check that your claims are generally, following the right guidelines.

So basically your objective is to ensure that the test reports are approved by the authorities for registrations, going to market, pre-ad clearance and also in the case of challenge, you can use them to support your arguments.

So when we're looking at repeatable, predictable, reliable, robust tests, they must be able to be consistently repeated with similar results on that exact same protocol on those tests and the same panel and with good quality by any evaluator.

Step-by-Step

Step-by-step, we are really thinking about what's actually in the test report and how it's laid out. We want to make sure that the sponsor or the, the testing house is indicated, your organisation, what is the objective of the study, what product has been tested and how long the test will go on

for and what type of test it is. Some tests are very quick and other tests can take quite a long time depending on what you're trying to prove and what the claim is.

The panel type is important, that needs to be specified. What controls they used so for example before and after. The actual test methods, so how you go about doing the test and how is the test relevant to the study objective? In other words, a new to be coherence. The test that you're using, and what you're actually looking to validate for the claim. The results from the test, how the results are interpreted, the discussion of the results and conclusions.

These are in a way, standard ways of writing tests in a scientific report and scientific studies. These are a standard protocol up to a point. We certainly do write all this with an introduction and background as well.

Equally, we need precise measurements of product quantities, probably need to know the margin of error, times and methods of application – so how the product was applied – equipment used or the reagents, environmental conditions so on and so forth.

Good Document Practices

And then very important is **good document practices**, because if your test report is not signed and dated, it will not be valid and therefore your registration with the authorities to get your product onto the market will be refused, so you need to be very clear that you follow those and that you also have the person conducting the test, any relevant signatures, dates, the validity and sample numbers and references and so on and so forth.

Credibility

Then we have credibility so any claims substantiation must be credible with a claim it needs to substantiate including relevant panels. So, if you're making a claim like "sensitive", "suitable for sensitive skin", you need to have a panel which has sensitive skin.

If you're claiming a particular gender so for example, "gender neutral", you need to show that it is applicable for all kinds of genders.

And overall weight of evidence based on all sources of evidence. So for example, you can't have 50% of the test results supporting your claim and the other 50 doesn't support your claim. This would therefore make the claim invalid.

Product Information File

And product information file we've seen this before that you need to put the claim studies into the product information file.

Claims Advertising

And also for claims advertising. As I mentioned before, you do need claims dossier particularly for the UK, possibly for the US.

Consumer Panel in Claims Studies

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Now let's look at the consumer panel, because this is pretty important with your claim studies. If you, if you don't get the consumer panel right, it will invalidate your claim. So it's imperative to consider inclusion and exclusion criteria for the panel as well as the number of people you will be doing the testing on.

There are also fundamental differences in biological systems which lead to variability such as **biological** and **demographics**. Let's have a look at these.

Biological - 3 types **ethnicity, skin types and age**.

[KM: correction – 5 types including chronobiology and circadian rhythms, gender

Ethnicity

Ethnicity can vary across different ethnic groups. For example, you will get more redening of people's skin who have fair skin than those who have darker skins. People of darker skins will have drier hair generally.

Skin Types

And equally, when you're looking at skin types, you have combination, dry, oily, sensitive, acne prone and so on.

Age

And also age. So as you change your needs change because your skin needs different things so when products cease to meet your expectations, you will therefore buy different types of products as, as you go along your life. So particularly when you're, you're changing a different age, suddenly your skin needs a different, different things. And then you've also got the actual age versus the perceived age.

Chronobiology and circadian rhythm

So this is linked to cronobiology and circadian rhythms. You have the cycles, particularly with the female cycles, you have hair loss patterns, 24 hour cycles and so on. And you also have circadian rhythms like water loss, hydration, cellular renewal, etcetera.

Gender

And then you also have the gender so male, female, transgender, gender neutral and so on.

Demographics

Demographics. So we need to think about **location, lifestyle** and **attitudinal**.

Location

So when we think about location, it could be a hot dry, tropical, humid, cold climate. You could also be in the countryside, in the town, the city where there's lots of pollution, or you could work inside an office all day, or you could work outside, work inside, and so on.

Lifestyle

Lifestyle. How much are you exposed to the sun? How much are people smoking? What is their diet like? What is their sleep like?

Attitudinal

Attitudinal. This is linked to the expectations of the particular consumers and how subjective they are.

Legislation on Claims and Advertising

Now, legislation on claims and advertising.

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So the UK and the US, as I mentioned before, they are the strictest in terms of claims globally. And actually, the US also requires pre-advertising clearance and there is a legislation being developed for online - social media, for example.

EU Legislation

Now when we think about the EU legislation, we've already looked at this.

So we have the EU regulations 655/2013 on the common criteria and we also have just as a reminder, the EU cosmetic legislation and in particular the proof of effect is the effect on the functions. So, for example, the cleaning, perfume and so on.

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Now, when we're looking at the common criteria, this is a self-regulation in the European Union and it is targeted towards an averagely informed consumer.

There are six factors and criteria. First one is legal compliance. Then we have truthfulness, evidential support, honesty, fairness and informed decision making.

For legal compliance, you cannot claim something which is already not permitted, for example "free from arsenic". It is clear that you can't intentionally put a heavy metal into your product and therefore saying "free from" all the banned ingredients on the EU cosmetic legislation ingredient list, it's already not allowed, so you're not gaining any competitive advantage by saying that.

Truthfulness. So whatever claim must be true, "is recommended by plastic surgeons" for example, you must have proof of this - written, documented proof and signed.

Evidential support. We've talked a lot about this.

Honesty, we also talked about this during the consumer panels. You must make sure that the target group is the right group for your claim.

Fairness, you cannot denigrate your competition. We saw this previously.

And you need to help the consumer make a decision about whether or not to buy your product, for example, "enhances palatal health".

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Then we actually also have another - it's not a legislation as such, but it's a technical document and it is one of these things that it is advisable to follow because these are industry guidelines. We have "free from" and we have "hypoallergenic".

So, for example, the story of parabens. It's a long story, but essentially parabens mostly are safe, some are not, some are. And unfortunately, there were some small companies who started saying "free from parabens" on all their artwork, and it therefore means that the consumer thinks parabens are the bad guy. And the problem is is that parabens are very effective of reducing mould and bacteria and so on and protect the consumer. Obviously not using a banned paraben or, or using them in the right amounts according to the legislation would be OK but it's not OK to say that to denigrate an ingredient which could potentially be safe to use.

And "free from allergenic or sensitising" ingredients, this is isn't really honest, because any ingredient can cause sensitisation. It's a little bit like water, for example. Everything is safe OR everything is unsafe, but it depends on the quantities. If you're drink 60 gallons of water, well, I think that would be virtually impossible. But you know what I'm saying? If you drink like 60 litres of water in one go you're actually going to kill yourself, so water is of course safe if you drink it in the right amounts and it's free from pollutants and bacteria, viruses and so on. So it's it is a bit of a misleading statement because any ingredient can cause sensitisation or harm in high amounts. So now we have the claims "suitable for sensitive skin".

EU Legislation: Borderlines

Just an important point about borderlines. Now when we're thinking about cosmetic products and medical products or drugs, in the EU, there's only one regulatory status which is allowed, which is either / or. So either a cosmetic or a medicine. You don't want your cosmetic product to be

classified as a medicine, because then you have to follow a completely different legislation and this will mean much greater extended development time. Cosmetics are about 18 months or less. A medicine 10 years.

You need a different testing requirements, different factory requirements, different artwork requirements, you're restricted on the amount of, actions that you can use and so on. So you need to stay within the boundary of the cosmetic also to keep your costs down.

But basically in the USA you can be a cosmetic and a product or a medicine at the same time but in EU you cannot.

And equally a cosmetic product cannot be a food product, a medicinal device or a biocide. at the same time because all these products come under different regulations. There are some exceptions. So for example a cosmetic can be a toy at the same time. So for example might make up for a child and you would have the toy legislation and then you would have the cosmetic legislation. Clothes can be a cosmetic support, like at shirt containing anti-UV or as a French would call it a cosmétotextile so you would need to consider the cosmetic legislation and textile legislation. So these are exceptions.

Example

So here is just another example of a product, L'Oréal product and you can see that they've actually put a graph when you had to show the before and after and the reduction of micro- relief and wrinkle depth.

USA Legislation

The US legislation is a bit different, but fairly similar to the EU. 21 CFR is the main legislation used for cosmetic products and a particular point relating to claims is that cosmetic products are deemed misbranded if they're labelling as false misleading. What they basically mean is that if you are guilty of misbranding or misleading the consumer then there could be a legal court case involved in that.

Equally, any structural changes that you make which are not cosmetics, that's a medicinal action, which makes it a drug. Over the counter products in the US are SPF products, oral care, antiperspirants, acne. Each of those has a monograph. In the monograph they stipulate the, they have a positive list of actives that you're allowed to use and the maximum percentages and you also have other constraints in terms of testing and manufacturing facilities and also labelling and so on.

And also there's a Section 5a where they say claims and adverse events must be truthful, cannot be deceptive or unfair, and must be evidence based.

There's also a national advertising division. As I mentioned before, the US is really strict on the legislation and again that they are basically saying the same thing about honesty.

Now we have two different organisations in the US that are involved with claims and one is the Federal Trade Commission and they regulate advertising and the FDA oversees the labelling of the claims, i.e. the packaging.

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Again, you'll see similar messages about truthfulness and substantiation, so this is the FTC for advertising and overlap with FDA. So for example, if a cosmetic product makes therapeutic claims, eg treating or preventing disease, it may be classified as a drug and subject to FDA regulations, which would be the drug legislation.

So examples of acceptable claims would include, similar to the EU, cleansing, enhancing the beauty, promoting attractiveness and altering the appearance.

So the other point that the Federal Trade Commission talks about is the unfair practices. So the fact that you cannot mislead or deceive the consumers, you cannot harm the competition or create an unfair advantage in the marketplace and equally, they will enforce it and they will equally publish results on a website. So it is quite expensive to get it wrong and therefore you have to be quite careful with claims to make sure that the wording does not change the status of your products. Equally the same with false advertising. So essentially it was very similar to the EU regulations.

And for the substantiation, as I mentioned before, the FTC want to have a dossier before advertising. The type of claims, as I mentioned before, you have objective claims and subjective claims. And I mean by that is whether it's instrumental or subjective.

And subjective is obviously up to the perception of the person, the panel and the objective claims are much more rigorous so you will actually have clinical studies or the instrumental.

The nature of the product can decide at the level of some substantiation, so how complicated the product is probably a skin care product is, is more

complicated for sure than a shampoo. Ingredients used and the intended use of the product. Equally, we talked about claims substantiation: what a reasonable consumer would expect based on the claim, could you inadvertently mislead the consumer based on the claim? And equally, is it consistent with all the other claims about the products so you need to have the consistency in the marketing across the board.

Here is the definition of a cosmetic products by the US and you can see is fairly similar to the one in the EU, but the general spirit is similar, the wording might be slightly different, but it is more or less saying pretty much the same thing.

USA Legislation: Borderlines

And borderlines again. So you can move your product into an OTC category, for example like a SPF, anti-acne, antiperspirant. And it's, a cosmetic can be classed as a drug also if it claims that it can look after reduce treat or prevent an illness. That the product claims it can change the structure or the functioning of the human body. Or it contains an ingredient destined for medical use.

Even if a cosmetic containing of pharmaceutical active ingredient does not claim a therapeutic action, it can be considered a drug. And what do I mean by this? I mean that if you put an SPF active into your product, but don't claim it, it will still be considered a drug, even though there's not a claim on the product because the active is present in the dose that makes it a drug.

So you can see here that if you have an anti-dandruff shampoo, it has two statuses because as a cosmetic status because it cleans the hair which is an action on the function as seen in the definition and it also has a

therapeutic action because it takes care of the dandruff. So therefore it has 2 statuses and it is therefore subject to both regulations.

Example

This is just an example.

Korea and Japan Legislation

Korea and Japan are much more complicated. Korea have a three types of categories of, of cosmetics and of particular importance is the functional cosmetics, which has sunscreens whitening, anti wrinkle. The claims are highly regulated and you need full registration by the Korean FDA.

In Japan, they're called quasi drugs and these are products which has SPF, whitening, anti-acne, anti-dandruff, hand sanitizers and again full registration is required.

Rest of World Legislation

In terms of the rest of the world, we have ASEAN and other markets they follow or some of those countries follow the EU model but particularly with ASEAN, they have a bit more of a deviation from the EU regs due to halal and various other, various other factors.

In China, there is an evaluation of the efficacy of the claims. Now if you test all your products in the European market for certain claims, the Chinese will expect to re-test all of those claims locally in an accredited Chinese laboratory.

Case Studies

So finally we have some case studies.

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ASA Ruling on Sisley Product

It was an ASA ruling in September of 2018. I think that data's wrong. I think that was 2018. An advertisement in a UK magazine was challenged.

So, for example, Sisley innovates a new slimming formula. And they say that "...discovery of plant extract significantly reduces fatty deposits by stimulating energy consumption in the same way as exercise and led to the development of Cellulite pro". They then say that: "they combine this powerful extract with a high concentration of other slimming active ingredients, and by doing so, it achieves these results", "decreases the accumulation of fatty deposits, reduces appearance of cellulite, diminishes orange peel aspect, refirms the body contour, improve skin quality, fluid and refining cream with draining properties. Studies conducted in vitro."

And equally further to this, I see the date is 2008 in fact.

So in fact the ASA so the Advertising Standards Authority in the UK, they said “no” to all of the claims and the company was forced to withdraw the advertisement. They said that: “the in vitro reduction of new fat storage does not simulate a reduction of existing fat in vivo. There was no evidence for this particular ingredient to show a change in some metabolism like exercise.” In the clinical study they found a lot of errors. Not placebo. And so there was no placebo involved and you always have to have one. There was no statistical significance between treated and untreated. No weight loss was observed and the user assessment insufficient to claim slimming. And drainage due to massage.

So basically, the company had to withdraw the advertisement.

ASA Ruling on Clarins Product

Here’s a counter example, and this was actually from Clarins, they had a similar product that was fighting Cellulite. “Secret to a perfectly streamlined body leaves an instant feeling of lightness and well-being and application. Patented formula with eight plants extracts helps to streamline hips and thighs and reduces the appearance of cellulite and ensures smoother, more toned skin with high definition results”.

So in this example, it was approved.

And you can see the claims are lighter, but essentially it's similar type of product.

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So this now comes to the end of our section. I hope you enjoyed it. We had a look at many types of aspects of claims, but essentially these are the foundation of knowledge that you would require.

We looked at exactly what is a claim, the different types of claims, the types of evidence and the levels of evidence that you can use for substantiation.

We also saw good practices for protocols and test reports.

In terms of legislation, we saw that the UK and the US are the most strict in terms of advertising and they require a claims dossier prior to being able to advertise your cosmetic product on these markets. Furthermore, we saw legislation on the EU again as well as the US and we went into more detail for the US.

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We also saw legislation on ASEAN and other global markets such as Japan and Korea, as well as other markets such as China.

We finished off with case studies, two case studies, in fact.

The first showed the non-adherence of the guidelines was the second example showed adherence of the guidelines and now it can make such a big difference if you ensure that your testing is correct and that aligns with the claims that you wish to make.

Closing Remarks



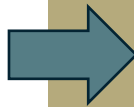
Well, this now brings us to the end of our live training session and thank you very much for attending. And please feel free to e-mail me with any questions that you may have at karen@cosmetichroma.com.

And I hope to see you in our next live training and/or webinar. Thank you.

Take care. Bye.

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