The Science of Beauty – part three

Karen Coleman: "And our final panellist before we open it out to the floor is Vanessa Hyde. Vanessa is a quality assurance manager with Shandon Clinical Trials. She is a trained scientist and has a background in basic and clinical sciences including ten years' experience in quality management and clinical trials with emphasis on GCP. She's constantly in touch with leading authorities in her field and responsibility."

Vanessa Hyde: "Good evening ladies and gentlemen. Our last two speakers have touched briefly on the science that goes into products before they actually come to market. I work for a company called Shandon Clinical Trials Ltd. We are based in Cork and we actually perform clinical trials on the end product. Our trials would include trials on cosmetics. We also do pharmaceutical, medicinal product trials.

"Our industry is highly regulated. In Ireland the Irish Medicines Board is the regulatory body which oversees clinical trials. For those who don't know what clinical trials are, that means the testing of products on human subjects to see if they are effective and if they are safe. So as I said before – there's a lot of information on my slides, I'd rather you listened and I'll just use them as a prompt for myself and if anyone would like them I can email them to them afterwards.

"What I'm going to touch on basically is: what are the definitions of a cosmetic product as regards the law in Ireland and the regulations? What are your rights as a consumer? What is a cosmetic? What isn't a cosmetic? These types of things, because I think this will inform you before we have our discussion and give you a contrast to what's gone before. I'll also touch briefly on what a nanosome is, what nanotechnologies are, because those words have been bandied around in the media quite a lot. I'll also talk about functional foods, or super foods, because they also fall into the health and beauty care arena.

"First of all, a definition of a cosmetic: a cosmetic is something that is applied externally, in other words to the skin, the hair, the nails, the teeth, the oral cavity. It's not something that's swallowed or taken internally, that's very important to remember. The second thing is the function of a cosmetic. Legally and as regards the regulations, it's limited to the following things: to reduce body odours, to protect, to keep something in good condition, to change the appearance and clean and perfume. Anything else, it's not a cosmetic. So what is it? It's a medicinal product or else it's a food. I won't mention foods now, we don't have enough time.

"If something is presented as restoring, correcting or modifying a physiological function, or something that changes an immunological function or a metabolic action, then it is by definition a

medicine. This is very important because if something is presented as having those properties, even if it doesn't have those properties, then it is a medicine. So if a cosmetic makes a claim that falls within any of those categories, then it is treated by the regulators as a medicine and would have to get marketing authorisation as a medicinal product. That's why label claims are so important and the wording in cosmetics adverts is a very, very important and sensitive area.

"The regulations in Ireland are governed by four important EU guidelines. The law in Ireland is Statutory Instrument 265, I won't go into it. That's the actual law in Ireland on cosmetics. Then the directive that governs cosmetics in the EU is Directive 768 and that directive was written so that there'd be harmonisation over the EU and that would enable cosmetic products to move from one country to the other, because if each country was complying with the same directive then countries could ensure that if they imported a product, it would be up to the same standards that their own country had for cosmetic regulation. However, the directive is implemented by each individual body in each country. In Ireland, the cosmetic directive is implemented by the Department of Health and Children.

"The objective of this directive is to safeguard public health, but unfortunately it was written in 1976 and as a result, there have been over 48 amendments. It becomes really difficult and complicated to understand because of all these different amendments and there's been a lot of discussion amongst the different countries in the EU. There was a consultation process in March of this year and every country and every member state and interested body was allowed to give comments and as a result, in 2010 there will be a new EU cosmetic directive, incorporating all the amendments and all the comments from the different countries. As I said before, every national competent body is responsible for implementing this directive.

"What's very important to know about cosmetics is that they are regulated once they are on the market, not before. The responsibility lays firmly on the shoulders of the manufacturers or the company that have imported the product. As long as your product has known ingredients, you can put anything onto the market. It's then up to you to ensure that you're not open to claims. So each manufacturer takes very good care to protect themselves from claims by doing safety and tolerability testing beforehand. If a product goes onto the market and there are safety concerns, it will be pulled from the market by the Department of Health or the Irish Medicines Board and there will be fines imposed...

"The scope of the directive on cosmetics, those are the examples, a huge number of products fall into cosmetics, most of them people will presume are cosmetics but there are some things that people don't always think of. Toothpaste is a cosmetic, hair dyes, hair bleaches, after-bath products. A whole lot of products fall into this directive.

"When is a product not a cosmetic? As I mentioned before, if the intended purpose is either therapeutic or prophylactic then it's a medicinal product. If the site of action is different to the site of application, for example something that's applied and rubbed into the skin for joint pain, that can't be a cosmetic because it's actually working at a different level to where it's applied. If it's ingested it can't be a cosmetic, it's either a tablet – it's either a medicinal product or a food.

"OK, nanotechnologies. The word nanosome, or lipsomes, is used quite often in the advertising media referring to products. This basically is referring to very, very, very small structures that can move across small membranes in the body. It's become a - it's a L'Oréal patented product – a nanosome. These are used as a delivery product for controlled release of their active ingredients. The FDA [Food and Drug Administration in the US] are busy looking at this whole area because up until this point there's been no safety data collected on possible effects, safety effects, of the small particle size. However, they're not envisaging any problems because if you look at any drug, any drug will eventually, during its absorption, end up being very small and they're not expecting the safety profile to be any different for the very small particles that are used. They're used in sunscreens as well.

"Cosmeceutical. Now this is an amalgamation of the words 'pharmaceutical' and 'cosmetic'. It's used quite often by manufacturers to support their claims, to make their products sound as if it's, you know, subconsciously it reads that it will have pharmaceutical properties. This word has no legal basis. In law the FDA doesn't accept it. The Irish Medicines Board doesn't accept it. But there is a huge area of borderline products. What's a cosmetic and what's a medicine? And each member state of the EU gets to look at the product on a case by case basis. Some countries will err on the side of 'It is functioning as a medicine therefore it should go as a medicine,' whereas other EU countries say 'No, that's more like a cosmetic'. It's a huge area because as Raniero mentioned, the whole science of beauty is becoming more and more complicated and as a result products are actually having medicinal properties as regards the definition. However, no-one wants to make medicinal claims because then they have to regulated, which means clinical trials: a lot of money has to be pre-authorised; if it's an American product it has to be approved by the FDA before it goes to market, otherwise here it will be the Irish Medicines Board or whatever other EU member state you were in. The word itself doesn't actually have any legal basis.

"Advertising, as was mentioned, the authority in Ireland is the Advertising Standards Authority and that's a self-regulating body looking at making sure that any adverts are ethical, they tell the truth, they're honest, they don't make any anti-competitive statements and are generally a good business. It's a self-regulating industry and it works very well, especially in the cosmetics area.

“Labelling of products and the Consumer Protection Act. These are linked. A new Consumer Protection Act came into being earlier this year and [among areas that it covered] was that cosmetic manufacturers had to include certain details on their products and these include that they had to have the contact details of the manufacturer. Unbelievably this wasn’t always on all products but now a consumer has to be able to have a point of contact for their products, like with medicinal products.

“Also, they need to include the composition of their product, all the details from the highest concentration of the ingredient down to the lowest. There was an issue with manufacturers not wanting to give away 'state secrets', however, they’re going to have to give the specific amount, they can give a range for example: this particular ingredient is available in this product from 0.01 per cent to, you know, they can give a range; they don’t have to give the specifics if they don’t want to give away the actual composition of the product. The FDA in America are slightly different in that on application manufacturers can get permission to leave off certain secret ingredients if they feel that if they bring those ingredients to the fore, the competitors will steal their composition.

“I just want to mention something briefly about functional foods because that’s also a beauty issue. This is a Japanese concept. In the 1980s healthcare was costing so much in Japan they were looking for a way to reduce costs and in doing so they were looking at foods as a way of decreasing the risk of disease and promoting health. The type of foods we’re talking about are probiotic yogurts, margarines for lowering cholesterol, there are a lot of new ones coming out, super foods, for example blueberries, cranberry juice, all of those are mentioned in the media at the moment. However, EU legislation prevents any foodstuff being labelled as preventing disease, so if there is any medicinal claim on a foodstuff it then moves into the arena of being a medicinal product. Foods are governed in Ireland by the Food Safety Authority of Ireland and they regulate all label claims.

“There are various helpful websites which actually have a lot of frequently answered questions on them: the Department of Health and Children; the Food Safety Authority of Ireland; the Irish Medicines Board will just say that they don’t regulate cosmetics but then explain what a medicinal product is and they’ll link you to the Department of Health; Colipa is the European federation of perfumes, toiletries and cosmetics, I don’t know where the word Colipa comes from, but they are very, very helpful on that website to tell you exactly what your rights are, what the regulations are in Europe, what has to be on a label.

“And just in closing, one thing that I’d like to say about labels; unfortunately labels have to mention ingredients in the chemical name, which to most people, even to myself as a scientist, if somebody puts their hand up and says ‘What’s…?’ and they mention some ingredient, unless I work with that

ingredient, I won't know. So I think if people are really interested in what is in their makeup, you can buy a Dictionary of Cosmetic Ingredients in Eason's or Waterstone's, and it's a very thick book and it will tell you straight away what's an emollient, what's surfactant, what's sodium lauryl sulphate which you see in nearly every hand cream. It will tell you what those are in simple terms straight away because a lot of the same ingredients are used again and again so you'll know straight away if you learn what the eight basic ingredients are. Compare the ingredients on two bottles, look at the prices, and look at label claims. Label claims have to be supported by clinical research. We can make an informed decision that way. Thanks very much."

Coleman: "So I was just going to put one or two questions to the panellists before we open it out to your own questions. One thing that struck me that was interesting about your presentation, Vanessa, is that cosmetic regulation is not required until the product is on the market so, I suppose, there is this huge issue about safety and the safety of a product, especially when chemicals are used in the product. Raniero de Stasio, maybe you could answer this question, say from L'Oréal's products: how do you know, how do I know, if I put L'Oréal moisturiser on my face, you know, foundation or whatever, that I'm not poisoning myself by doing so?"

Raniero de Stasio: "Well, very simply, as Vanessa said very eloquently, it's our responsibility to make sure that every single ingredient and the product as a whole do not harm anybody. You've shown us article one of the [unclear] that says what a cosmetic is. Article two says, basically, in very simple layman's terms, cosmetics shall cause no harm. And if they do, our managing director will go to jail, as simple as that."

Coleman: "But how do we know that? It may be years before we know, for example, that a product potentially could be poisonous. What level of testing do you carry out to ensure that your products, under no circumstances, will damage the person who's going to buy them and use them?"

De Stasio: "Every single ingredient is either tested or there are tests on file, data in the literature, data available, to ensure absolutely, beyond doubt, that the product will not harm anyone. Under conditions of use, of course. If people, for example, drink or eat it or do something that is not foreseeable…The products have to be safe under normal conditions of use and foreseeable conditions of use. So, for example, if I know that a particular kind of consumer will use a rinse-off conditioner and leave it in their hair for hours, maybe permanently, then I should actually test it for safety as a leave-in product. We do do those tests when we know that products are prone to be used in a slightly different way from what we recommend."

Coleman: "And maybe just for you, Chris Gummer, the skin, I believe, is the largest organ in the body and it absorbs, it's an absorbent organ on our body; what happens, for example, with the likes of tanning lotions? Because I know as a journalist, a broadcaster, it's something that would come up on my show. Because effectively it looks like you're colouring your skin, again how do we know that these tanning lotions are safe for us?"

Chris Gummer: "As Raniero said, we've tested the ingredients so we know a lot about the chemistry behind the ingredients. The other thing is, the skin is the largest organ on the body, but its sole function in life is to keep everything out. One of our big problems is actually trying to get stuff into the skin, to make it do what we want it to do. So there's this constant dilemma between the formulators, who are trying to deliver ingredients, and between the skin, which is trying to keep everything out. That's its sole function in life really, to keep all your bits in and all of the world outside. And most of our products actually work in a very, very superficial capacity in the skin. We're talking about less than 1mm into the skin. So we're not driving it very deep. And even your tanning lotions are working in the very superficial layers of the skin. So, as I said, it's a constant dilemma, you're trying to push stuff in, the skin's trying to push stuff out and stop it going in. And the only time that you really notice that things are going into your skin to any great degree is after about an hour and a half in the bath and it's absorbed a lot of water. It takes being immersed in hot water for that length of time, and even then, within a few hours you're back to normal and you've pushed it all out again."

Coleman: "What about the tanning lotions? I mean, L'Oréal has a variety of products like tanning lotions."

De Stasio: "As Chris said, tanning lotions affect the very superficial layer of the skin. They will change the colour – most of the cells on the very superficial layers are actually dead. The ones that you are colouring are the ones that are dead and they're going to be shed anyway because the skin actually grows from the inside out and you shed literally thousands, hundreds of thousands of cells, every day as part of the normal exfoliation process, which we can accelerate with exfoliators. That's why the scrubs and the exfoliators are very popular. Even when you have a natural tan, you lose it very quickly the more you scrub your skin, the more showers you take, just because the natural process is to get rid of those cells."

Coleman: "But are you actually putting a dye on your skin?"

De Stasio: "No, it's actually not a dye. It's a chemical called DHA, dihydroxyacetone, which has been known for decades. I'm not sure when it was discovered. And it does a very similar reaction

– I know it sounds like a joke – but it's a very similar reaction to your toast, when you toast your toast in the morning. Toast goes from white to brown. It's called melanin reaction. And that's what happens to the skin, to the protein in the skin. Very, very safe. It's as safe as eating a slice of toast."