

Retail Therapy:

Regulatory Borderlines: Compliance Challenges in The Beauty and Wellness Industries

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Transcript of Retail Therapy Episode 7:

Nicola	<p>Hello and welcome to Bird & Bird's Retail Therapy podcast – where we explore the trends, changes and legal aspects of the retail & consumer industries.</p> <p>I'm Nicola Conway – I'm a lawyer who specialises in the retail industries, and I'm a consumer who specialises in shopping!</p>
Sana	<p>And I'm Sana Malik, I'm a Trainee Solicitor also at Bird & Bird.</p> <p>In today's episode: We're going to discuss the fascinating intersection where beauty meets science and what that means for both retailers and consumers. We're also going to take a look at some of the legal implications of offering TELA dermatology sciences. That is the triage, diagnosis, monitoring or assessing of skin conditions without the patient or the consumer being physically present via something like a mobile app.</p> <p>We're joined by Pieter Erasmus who is a Senior Associate in Bird & Bird's IP group in London.</p> <p>Pieter would you like to kindly introduce yourself and a little bit about your practice?</p>
Pieter	<p>Yeah sure, thanks very much both. As you've said, I'm part of a London IP group, specialising primarily in commercial and regulatory matters in the life sciences and healthcare industries. I also do quite a lot of general product compliance regulatory work, so this is not always related to advising on pharma products or medical devices but also so-called borderline products. That is where the nature and intended use of a product might make it unclear if it's regulated as, for example, a cosmetic product or a medicine. We see so many fascinating examples</p>

	<p>of these and advise various clients on bringing product and services like these to market. In addition to regulatory and product compliance work across various sectors, my practice also includes commercial and transactional work mainly in these life sciences and healthcare sectors. This includes drafting all sorts of commercial agreements unique to these sectors, as well as supporting corporate deals. I also do IP licensing and other deals in these industries such as research and collaborations and lastly prior to moving to UK and joining the firm over four years ago, I was based at a large firm in Johannesburg doing pretty much the same thing for a number of years.</p>
Sana	<p>Amazing, thank you so much for joining us and just first off, let's dive into what medical regulation or regulated in this context actually means?</p>
Pieter	<p>So let's take a step back here, it's fair to say that all products being placed on the market regulated in some form or another, some areas are more complex than others, for example, as you may imagine pharma products are a little bit more complex than say teacups or greeting cards, but they're all regulated to some extent. It's important that all players in the supply chain of product understand which regulations apply to which products. It really does form the basis of which products are brought to the market in the first place and ensures that such products are compliant. Regulations may dictate, for example, composition, law or manufacturing requirements, how or if products may be promoted or marketed to the public, if any license or permit is required to handle them and so forth. This applies equally to services, it's not just products. It also really depends on the location where the product services are offered and as you might imagine each country may have different rules, so in some sectors like the retail and consumer sector and particularly in the beauty industry, there is often an overlap with medicine or healthcare.</p>
Sana	<p>That's really interesting to hear. Could you give us a couple of examples of pit falls that beauty brands might commonly fall into maybe?</p>
Pieter	<p>Yeah sure, as a regulatory lawyer, I think one of the main pitfalls in this industry is coming to the wrong conclusion as to which regulation regime actually applies to your practise service especially in the case of borderline products but also knowing the limits of the applicable regulatory regime. So, here is an example of a potential borderline product or service, if a product for example is marketed as a cosmetic product and also complies with all necessary cosmetic regulations but say certain medical claims are made or by its very nature has a medicinal function and treats some medical condition, It's probably a medicine and should be regulated as a medicine and not a cosmetic, so marketing a medicine as a cosmetic would also be non-compliance and there's many moving parts and it's always an assessment based on the facts, but complying with the right regulations is fundamental. So our job is also to understand the ultimate intention of the product or service and make recommendations as to how manufacturers may sure that the product or service stays within the territory of example a cosmetic as opposed to a medicine, each of these areas have vastly different requirements and cost implications, so not only might a non-</p>

	<p>compliant product pose health and safety risks to the public, but this would likely attract enforcement action by relevant regulators including recall and bad PR. The exact consequences again really depend on the specific applicable regulations and factual circumstances maybe we can explore some questions such as when does a piece of beauty tech, for example, an infrared face mask become a medical device? When does it treatment, like a skin peel, veer into the medical world? When does the food or nutritional supplement become a medicine? This is a kind of questions we assist clients with on a daily basis. The key question when assessing if a product is potentially a medical product is essentially - does it have a medical purpose? and that is a mantra by which we live when advising clients on these questions. so depending on the product or service the criterion may be different but basically down to the fundamental question. so if the infrared light mask intends to treat medical conditions on the skin, then it's quite like a medical device and at the end of the day it's really about knowing where the boundaries of regulations are and staying within those boundaries.</p>
Nicola	<p>I love that mantra! And apart from being careful about what you create and how you manufacture it. Is it also true to say that once you've created a product it really matters how you market it as well, so for example, how much does it matter what claims you make about something when you're trying to sell it?</p>
Pieter	<p>Yes absolutely, sometimes the question of regulation really depends on the actual composition and underlying function of the product, but it's also sometimes how you market it, for example, if it's quite clearly a cosmetic product but medical claims are made when marketing it, that's a red flag and such claim must be avoided as it's not only potentially misleading, but if it actually does have a physiological effect and treats medical condition this could result in the product having to be registered as a medical product. However, on the flip side of that, downplaying something that's really a medicine but it is manufactured in compliance with cosmetics regulations and marketed with only cosmetics claims that's also red flag, it really is a holistic assessment which includes looking at how products are marketed and users. Apart from the general consumer facing regulations regarding misleading advertising claims, which of course, your both experts on, certain regulated products also have specific restrictions on how they may be marketed. On the one extreme, prescription only medicines may not be advertised at all to the public, while on the other hand, they are specifically prescribed nutritional claims that may be made in respect of certain ingredients forming part of food supplements and going beyond those would pose a real risk of noncompliance.</p>
Nicola	<p>This topic particular is well timed because Pieter, we're currently working together on a piece of advice at the moment that covers how aesthetics and cosmetics clinics can in some cases market the service of giving Botox but you can't promote, market or advertise the actual Botox product because it's a prescription only medicine or as we sometimes refer to it as a POM- a prescription only medicine -POM - so it's a fascinating space to advise in and it's amazing as well to see how and why these businesses are coming up with these marking claims.</p>

Pieter	<p>Absolutely Nicola, this really is a very topical point nowadays. The added nuance here is that while you of course can't advertise prescription only medicine being of the botulinum toxin product, clinics can advertise service of providing a consultation to make the assessment if this is something for you. The advertising standards authority have published guidance on this which is available on the website. It's also further complicated by the fact that there are other cosmetic filler injectable products which are not prescription only medicine which can then be advertised to the general public. It's really very important to ensure that any marketing material doesn't make it unclear to which of these are being advertised.</p>
Sana	<p>And speaking of clinics we've seen quite a lot of buzz around Tela dermatology services which could be for example the platform where a customer can send a photo of their face or other areas affected by potential derma conditions and with the assistance of AI questionnaires or otherwise dermatologist are actually able to assess the potential condition and suggest or prescribe a skin care regimen that might include prescription only medicines in addition to other cosmetic products.</p> <p>Pieter, in your opinion to these pose any regulatory risks in your view?</p>
Pieter	<p>Thanks Sana, yes on a number of levels actually. Firstly, the softer and AI used to triage or even suggest the diagnosis to treating dermatologist might itself be a medical device and a developer of such software will need to have made the assessment whether or not such software has a medical purpose and is accordingly a medical device. If so, this entails compliance with the essential requirements set out and required by the medical device's regulations including and so forth. In other words, the software itself may be subject to specific regulation and it is holistic assessment against the legislation to reach your conclusion on the regulatory status of the software and secondly the provision of dermatology services itself may actually require specific registration with relevant regulator. To the extent there is a diagnosis or treatment of a medical condition, it's quite likely that such service amounts to a regulated activity for which indicates of England at least the Care Quality Commission or CQC, approval must be sought for that healthcare provider prior to that service being offered. Thirdly the individual healthcare professional or dermatologist or advanced nurse practitioner or other professional may be required have certain licenses or permissions in place with the relevant professional body to perform these services and lastly, it's really interesting to see that in some cases we receive virtual waiting rooms where while the customers is waiting for the Tela dermatology session to begin and before the dermatologist joins a session that certain advertisements may be made visible, it's again quite important to assess if those advertisements are permissible and don't for example advertise a prescription only medicine or that any claims made are done within the boundaries of the regulations and industry based practise.</p>
Nicola	<p>Wow, I haven't had the experience of being advertised to while I'm waiting to see my doctor, that's fascinating. Similar to Tela dermatology services but a slightly more nuanced question, if a brand says that something will help you lose weight, whether that's a product</p>

	or an online service or a clinical service is that weight loss claims a medical claim or is that a cosmetic claim?
Pieter	Interesting one Nicola and this is an example of yet another really topical question we're seeing quite often. really, once again it really depends on the intended purpose of the product and is it intended to treat a medical condition? So if it's a food supplement, the type of claim that you can make will be heavily restricted whereas if it's a product that treats medical conditions such as obesity and that's obviously medicine and medicinal claims may in principle be made. Although that being said, these medicines are usually prescription only, which means that this medicine may not be advertised to the public in the first place. Although if these prescription only medicines are marketed to healthcare professionals, the content of claims are also quite restricted and must be aligned with the summary of product characteristics or SNPC which is essentially formal document describing the property and officially approved conditions of use of a medicine. SNPC is the basis of information for healthcare professionals on how to use medicine and safely and effectively.
Nicola	It can be super confusing for consumers as well. We also advise quite a bit on the rules surrounding what you can and cannot claim in your marketing messaging in relation to supplements. We see all the time these huge claims about what a supplement can do for you or change for you, whether it's your skin or your hair or your mood or even your libido, increasingly nowadays were seeing a lot of claims around that, and the claims are just absolutely enormous.
Pieter	Yeah, absolutely. Like in the case of food supplement, you really are quite restricted on what you can claim, and this is largely dependent on which specific claims have already been accepted and included in the relevant regulations. Nutrition is actually quite technical area, and the fundamental principle is that you cannot claim or imply that food can treat, prevent or even cure any disease or medical condition.
Sana	Thank you so much Pieter, thank you for that rundown. That makes so much sense. I know something we worked on together was taking a look at regulations and licenses needed for spas and facialists who actually operate in retail environments. Could you tell us some more about this?
Pieter	Absolutely Sana, that was a really fascinating matter that we were involved in. In the UK, regulations and licensing requirements for spas and facialists operating in the retail environment can really vary significantly depending on either the jurisdiction or the type of services that are being offered. So in the UK, the jurisdiction really plays a very important role, and the licensing conditions and requirements can really depend from, even from borough to borough, and the services can be really kind of niche. I mean you can have different requirements for microneedling, lymphatic drainage massage and so forth. Generally though, these regulations aim to ensure consumer safety, maintain hygiene standards and uphold professional competence. Some notable regulations and licenses may apply include something like a business license and this really does depend on the individual borough or county. Spas and facialists typically need a general business license to

	<p>operate legally within a specific city or municipality. Another kind of category of regulation includes cosmetology or aesthetician licenses. Aestheticians, also known as skincare specialists, sometimes require a cosmetology or aesthetician license to perform facial treatments such as facials, peels and exfoliation. Licensing requirements often include completing a state approved training program and passing a licensing exam. This is in contrast to some jurisdictions where none of this is required. So, it really does depend on where this service has been provided. In addition to that, I think our matter specifically related to massage therapy licenses and we saw that the requirements throughout London and England were vastly different, and it was not a consistent approach that really enforces the importance to kind of look at this on a case-by-case basis. In addition, from a retailing perspective, from a product licensing compliance perspective, if the spa actually sells skincare products and it acts as a retailer, they also need to ensure that the products themselves comply with the regulatory requirements set out under the cosmetics regulations. This just gives a taste of some of the commercial legal ramifications that really coming into play when looking at these.</p>
Nicola	<p>Well there's a lot of food for thought for our brands and retailers here. So, let's let all of that sink in and, in the meantime, let's close with our fun little question. Pieter and then Sana, what something that you purchased or were gifted recently that you love?</p>
Pieter	<p>On the cosmetic side of things, my wife and I were recently in Athens for a long weekend, and we came across the store called the Naxos Apothecary. I'm not sure if anybody of you have heard of that? It's the most beautiful yet uncomplicated space and it's in the same group as the Korres brand of cosmetics which you might have seen before. They are proudly Greek and passionate about using local natural ingredients in the product and this really resonates with me. This is obviously not a paid promotion, but we ended up getting quite a lot of stuff and I really have been enjoying the Korres Greek Yoghurt Probiotic quench Night Cream. As one reaches a certain age, these things become a little bit more important!</p> <p>It has a clean non perfume smell and it's not oily at all and it absorbs quite quickly. Another bonus is that it reminds me of the fantastic local food we had including Greek yoghurt, which really is different out there. Well maybe perhaps this is an example of a borderline product where food meets cosmetics. Well, maybe not!</p>
Sana	<p>That sounds amazing. I love that product. I feel like you've sold that to me, and I will actually be buying that. Kind of similar to yours Pieter, I love the concept of when kind of local ingredients or kind of food products meet beauty products, so I absolutely love the Burt's Bees the original kind of wax lip balm that they sell, it's so natural, it's perfect for sensitive skin and it's got like a slight plumping affect too. What about you, Nicola</p>
Nicola	<p>Which fragrance do you like? Do you just like the original fragrance, or do you like their new ones? They've got one that's coconut and pear.</p>

Sana	I haven't tried the coconut and pear one, no! I've had the pomegranate, rose and the original. But for me it's the original.
Nicola	They've come with a lot of new fragrances recently and they're all really interesting actually, quite unusual ones.
Sana	Have you tried them?
Nicola	Yeah, the coconut and pear one is a winner.
Sana	Oh my gosh, that combination, I'm so intrigued. I am going to try that, that sounds amazing!
Nicola	I'm going off piece here, I don't have a cosmetic product for once. The last thing I purchased was a ballot entry for the 2025 London Marathon which I'm excited about but also very scared because I've never done a marathon but here we go!
Pieter	Well, good luck with that!
Sana	I'm sorry, I'm just in shock!
Nicola	I'm also in shock, believe me! I've been influenced but the thing with the ballot is, I think something like - I'm making statistic up- but I think something like only 50% of the people who enter the ballot get into the marathon anyway, so it's a little bit like a low-risk thing for now, if I actually get through the ballot, then I'll be very scared.
Sana	Have you started training yet?
Nicola	No, no, no, not at all.
Pieter	Well, I think you've got a year now!
Sana	Alright that's the end of our episode – thanks for joining us! If you'd like to join us for more Retail & Consumer discussions, don't forget to subscribe or follow wherever you listen to your podcasts so that you're notified when the next episode goes live. Bye for now!

Thank you

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