Attaining Chinese Cosmetic Compliance with Changing EU Standards in the Post Brexit Era

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Introduction

Regulatory aspects in the challenge of internationalization, in a rapidly changing world.

Never as in this period we witnessed a concertation of international changes that influence, at the same time, the cosmetic panorama. Quarrels and reconciliation between economic superpowers (such as the US-China tariff war), conflicts and internal problems in a country (United Kingdom) that is experiencing the turbulence of divorce from a Union of which it was one of the founders, a period of unknown regulatory scenarios, which will be resolved within a few weeks, as in the case of Brexit. Perspective changes that heavily impact on regulations, therefore also on cosmetic rules: changes that overlap with the normal, previous and robust flow of regulatory and scientific updates that, even in quiet times, involves constant efforts by experts and companies.

I do not think anyone could have imagined that the extension and validity of such an important and influential regulation such as the European one could be uncertain and difficult to foresee two months by a change that, however, will be implemented. If the validity of this law will still be kept (even if temporarly) in UK, or if it will be limited to continental Europe, and in this second case what procedures will be implemented and required to continue the sales and the passage of products across the UK border with the EU.

In addition to the international instabilities, in my opinion we are witnessing an "acceleration" of regulatory developments, due to additional concomitant factors. First of all, we see an evolution in the commercial and advertising channels, so that e-commerce and e-marketing have reached fundamental importance. In the digital field, we can say that we are in a "2" phase of the "web" era, where consumers, businesses and professionals are reached mainly via mobile systems. We are in full "Social Era", and the development of these new channels has undoubtedly produced an expansion of the internationalization activities increasingly extended to smaller companies, compared to the past.

In Europe, the frequency with which binding opinions are expressed (opinions of the SCCS)[1] and the resulting technical adjustments have increased, while the time given to the companies for adapting existing products to the new restrictions is becoming shorter and shorter. Suffice it to say that the European Regulation is updated (albeit only in the technical annexes) several times per year.

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On the other hand, the commercial logics and the strategies of development and expansion must necessarily take into account the regulatory requirements, which, especially if they become complex and variables, can be experienced as a problem, and exactly as limiting factors. The most open minded companies see the rules as opportunities to ride. As well as the most capable entrepreneurs generally experience problems as opportunities and they consider changes positively.

Let's examine the recent and imminent developments to understand how to monitor, forecast (as far as possible) and manage the changes taking place. The goal is not to suffer changes. Be ready for change, and at best to ride changes and grow thanks to them.

Export to China. Conflicting emotions and practical problems.

When I attend a meeting where I see a desperate Regulatory Manager and a joyful Export Manager at the same table, I have no doubts: they intend to export to China.

The legislation in force in China for the registration and approval of cosmetic products is certainly among those that most stress the Regulatory Managers, in front of the enthusiasm of the Export managers, who (rightfully) see extremely interesting potential in the Chinese market. First of all the two regulations (Chinese and European) are based on two diametrically opposite assumptions: the "pre-market approval" (China) and the "post-market survey" (Europe), from which the completely different procedures on many other aspects, with very few points in common (until a few months ago) between the two regulations. The same definition of cosmetics is not exactly referring to the same products under the two laws: according to Chinese legislation, cosmetic products can be applied only on the external surface of the body, therefore products for oral hygiene and products intended for intimate hygiene are excluded. At the same time, breast beauty products in China are considered cosmetics, while other products such as antiacne, whiteners or hairgrowt products are considered there to be cosmetic, which in Europe can only be classified as cosmetics under certain conditions and are not exempt from risks of disputes by the competent authorities.

The differences of course are not limited to the classification, as the registration procedures (involving the approval of State officially accredited laboratories) are among the most distressing of the international scenario, in addition to involving considerable costs and long times. The tests on animals are mandatory and the ingredients must be among those already officially translated and included in the Chinese INCI list, otherwise the procedure requires about further several months of waiting and a considerable investment, to then find the Chinese INCI name freely available for everyone. The latter constitute further elements of discouragement and discontent for the Regulatory Managers of companies. Bad feelings that become "bad news" about the products actually exportable without making changes and about the timing for the actual placing on the market, hence a contribution to the reputation not already very good of the Regulatory Managers, often identified as "herald of bad news" (but in this case I suggest companies to change Regulatory Manager, if he/she is not perceived as a "problem solver" …).

Less noticeable is the distinction in China of cosmetics in two categories, which we also find in many other foreign regulations (although the lists of the two categories do not normally coincide), as in Brazil, Russia and others: "special use" and "non-special use" cosmetics.

Recent evolutions of the Chinese legislation: simplifications and future expectations.

In recent months, some important changes have been made in China, and other further changes have already been planned and announced, and we can define the extent of developments as extremely substantial.

The new Chinese authorities that is put in charge by the Chinese FDA was the China National Medical Products Administration (NMPA), last March, 2018.

First and most impressive: the concept of "Filing" was introduced instead of the "Registration", a great and significant step towards the "Supervised Self-Monitoring" method adopted in Europe, even if limited to cosmetics classified as "non-special" use (for them is kept the old procedure). At the end of the experimentation (December 2018), this modality has been extended to the whole country, with the difference that in the 10 provinces in which the "filing" was initially tested, documentation is filed at the local offices in charge, while in all other Chinese provinces are deposited directly at the NMPA. It is very important to note that the "filing" activities will be carried out by a Responsible Person who will be responsible for the product, and not for the sole conduct of the registration, as in the past. The further changes announced by the Draft of the "Cosmetic Supervision and Administration Regulation" (CSAR) are further promising: The change in the classification of some products, such as products for the treatment of breasts that will be classified as drugs and the declassification of cosmetic deodorants "special use" a "non-special use".

In addition, the procedures for the introduction of new INCI names will be simplified, and in the case of non-critical substances the assignment can be made through a notification.

These are certainly good news, because these changes make the procedure necessary to register products in China certainly less complex, but beyond the practical aspects, clearly improved, it should be noted that the product and test requirements will not change. As well as other aspects that are strongly limiting today, such as the obligation (which remains) to test products on animals.

Persistent incompatibilities: Animal Testing

The real problem of animal testing is not given by legal limitations: even if test on animals are not allowed in Europe, the ban does not involve thirdy part in foreign countries, as in case of Legal/Responsible Person in China that will manage the tests. Then, the only limit for European companies is the impossibility

of using data coming from animals in the European Cosmetic Product Safety Report (and therefore in the PIF). Problem easily solved as European companies and safety assessors have been accustomed for many years to realize Safety Assessment without using animal tests: as we shall see in the next paragraph, one of the most important topics in Europe is given by the alternative methods, the strategies that can replace data from animals and more specifically the most innovative and interesting are given by the approach so called *in silico* (that involves the use of innovative softwares for predicting potential risks derivated by the chimical structure of a substance), which is one of the tools provided by the SCCS (the Scientific Committee for Consumer Safety)[1] to determine the toxicological effects of the ingredients. The real problem inherent in the obligation to test on animals is given by the company "policies" and by the sensitivity of European consumers, who are well informed on the subject, and many of them have spread the (founded) correlation between the distribution in China and he the compulsory animal tests that are requested for that.

After a more thorough verification of the changes underway in the Chinese legislation, we realize that the companies that had the requirements to export to China will continue to do so. Those who were limited or discouraged by the complexity of the procedures will be slightly facilitated, but those who do not have the requisites to export to China (target of customers sensitive to animal cruelty) will continue to not export to China. After all, it is a more formal than substantial change, even though procedural simplifications are always welcome.

Therefore, despite the content of the changes implemented and being implemented in China, the most relevant aspects are: the orientation of the changes, clearly addressed towards a "post-market survey" approach and the very short time with which these changes were implemented. This makes even optimistic about the obstacles that have remained unsolved.

EU and Brexit

At the introduction of the Regulation 1223/2009[2] I was very happy to realize the slides for my University courses and seminars, in which I wrote about the "new European Regulation". I have always wondered when I should have removed the mention "new" in the title, and a few days ago, when I was reviewing the slides of one of my courses I thought that the term "new" is still appropriate, despite five and a half years from the definitive implementation dated July 2013. Personally I think that the Reg. 1223/2009 has not fully expressed its potential, and I believe that many companies, many experts and some Competent Authorities can still improve their familiarity with this regulatory tool that is still innovative today.

Implementations and developments

Keeping the focus on the basic concepts expressed by Reg. 1223/2009, it is necessary to consider that some parts of it are still being implemented. On some issues, such as packaging, the effective implementation of the Regulation assumed in 2013 was the result of an excess of optimism or foresight. Precisely in relation to packaging, the main problem concerns a clear determination of the information that should be shared between the packaging supplier and the Safety Assessor (the European Task Force is working on a guideline for future publication).

In addition to the structural and basic aspects of the Regulation (which are still being refined and consolidated, and this is why I still consider it "new"), the guidelines implemented by the European Commission or the SCCS Committee are constantly being implemented.

Among these, the guideline "The SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation, 10th Revision"[1] (NoG), published in October 2018, is of considerable interest. Also in the previous Revisions, the SCCS NoG guideline has always been a reference document, both for the relevance of the source (the SCCS committee), and for the consistency of the contents, constituting, in fact, a basic guide for both the Safety Assessors both for the Competent Authorities.

In the 10th review several important implementations were introduced, among which the great importance assumed by in silico data and a new definition of Margin of Safety (MoS), for the calculation of which the concept of "Point" was introduced in this "revision of Departure", which extends the MoS estimate also to toxicological data without "threshold effect". Without going into

the details of the topic (which requires much more space even for a brief mention), suffice it to consider that the innovations expressed in the 10th Rev. of the NoG will have a significant impact on the Safety Assessment of new products and those already on the market. In fact, the Safety Assessment must be constantly updated by law, and the consistent implementation of the NoG on the subject undoubtedly requires a review of all the Safety Assessments, after adjusting the assessment methods. It is therefore a great leap in level that will involve, and in a short time, an immense work of revision, calculation assessment and reasoning of all the products currently on the market. Cyclopean and scientifically far from simple work, as well as the implementation of toxicological databases while they are already under improvements given by *in silico* assessments and calculations, (this is certainly not an "informatic" exercise, but scientific, and high-level, act). But despite the relevance (and extent) of these updates, I believe that the greatest source of uncertainty and the most relevant and striking change is undoubtedly given by the consequences of the separation of the UK from the EU, planned for more than two years but subject to a controversial resolution, which will materialize (in a still undetermined way) within a few months.

Brexit: Status and possible scenarios [3].

What will be certain and definitive until March 29th? Probably: nothing. Understanding the possible strategies for the different possible scenarios that can be presented is therefore essential, preventing the consequences of the more drastic (a no deal with a hostile reciprocal attitude) of the possible scenarios, but effectively and without excesses of defeatism.

The worst case scenario would be a "hard" Brexit. On March 29th, 2019, at midnight, Great Britain will no longer be a member of the European Union. And "no deal" in that case will mean sudden mutual inapplicability of the regulations. In the case of the cosmetic product, the most obvious consequence will be the non-recognition of the European Responsible Person in the UK. The common idea is that British authorities will produce a "photocopy" regulation of the European standard. Actually it could be logical to realize a UK law very similar to that made in the EU with the contribution (at the time) of the British experts themselves, at least in a transition phase. Unfortunately, in reality there are some aspects of European legislation that refer to important external structures and commissions. Just think of the restrictions on CMR substances (Carcinogenic, Mutagenic and Reprotoxic), for some of which the use in derogation is allowed only if a favorable opinion has been expressed by the SCCS, which is a committee to which the UK will certainly not be able to refer. Among these substances we can cite one undoubtedly known: Ethanol. Which is carcinogenic by ingestion but being admitted in food use and approved with specific opinion of the SCCS is admissible according to European law. It is not credible that on 29th March alcoholic perfumery products are outlawed in the UK, but whatever solution will be put in place by the British authorities this example gives us an idea of the size of the problem and of the complications not always easy to see at first sight.

In other words, Brexit already entails an important regulatory disruption, whatever the outcome to its effective application of March 29th, "deal" or "no deal": the effects are already manifesting in the need to take action in the worst sense hypothesis, due to the potentially very serious consequences deriving from having underestimated the possibility of a break without agreement. Which is not unlikely. The European post-brexit era will see the birth of a new important extra-European country that will show differences from birth and will require specific operations. Then it will be clear if the British authorities will prefer to evolve their legislation towards a closer to the EU Regulation, which would undoubtedly facilitate both markets, or if they decide to maintain their own strong identity by moving towards a norm away from European requirements. To date it is impossible to know what the direction in which we will see the UK authorities move.

Conclusions: strategies for the new EU-post Brexit / UK / China scenarios

When an European company asks me how to deal with international markets, I recommend first of all implementing and optimizing compliance with European standards, improving the "performance" of the internal regulatory system, the documentations, the toxicological database, the implementation and control system of the CPSR and the interface with the Safety Assessor and production management, internal or, a fortiori, external. In other words: implement your internal system, even before engaging in the study of the requirements of new regulations or in the search for potential distributors. Improve efficiency and rationalize the Regulatory Dept., at first.

For example, the essential tool for European regulatory management is the data base where all information concerning ingredients and formulations is collected and updated. This tool, adopted (consciously or unknowingly) by all companies takes on an even more important role when it is planned to enlarge the markets abroad, as the database itself will be very useful to manage, from the R & D phases, the conformity of the products to the markets to which they will be destined, preventing the use of ingredients not allowed in the target country and allowing to preset the necessary documentation for foreign registrations.

The rules: are limits or opportunities? Three important scenarios were illustrated and commented, important in terms of size and subject to recent and important changes: China, European Union and, in the forthcoming scenario, United Kingdom as a separate nation, due to the more pronounced and "clicked" word in recent months: Brexit. But if we talk about norms and their development (hoping for their harmonization), exactly what are we talking about? Only limits? How can the limitations imposed by growing international changing regulations help to grow the business rather than merely banish restrictions? The apparent conflict between "regulatory" and "marketing", where it seems that the design of new cosmetic products arises from a bloody struggle between the marketing sector, which would have a claim to superlative properties, and the regulatory sector, which seems paid with a "fee-per bad news", how can it evolve into a market that pushes bigger and smaller companies to promote their products in increasingly distant markets?

In fact, the most intelligent interpreters of cosmetic standards, in companies, have long understood that the regulations, created to increase customer safety, are tools that go far beyond the simple "obligation to comply". The flow of scientific information and mandatory requirements, in addition to having to be respected (and therefore their primary function consists in protecting the consumer and the business itself, as a consequence), can also be an intelligent source of opportunities to overcome the strait minimum law and to help the company distinguish itself and transform the criticality into a perception of safety and therefore into a true marketing tool. Those who have had the foresight to coordinate the Regulatory Dept. (updated and internationalized) with the R & D activities in their company has found that the Regulatory aspects (and even more if they are oriented towards the global market) have the possibility of giving a strong and unsuspected impulse to innovation.

Even today, therefore, openness and vision allow some companies to emerge, even in local markets. International challenges and stressful situations such as Brexit require further effort and further growth of companies in this direction. Because success on international markets and survival at the "earthquake" of Brexit, can be strongly helped by an elastic and rational mentality that sees the regulatory aspects as basic and deserving of a futuristic and integrated organization. In the 2.0 world, it will be necessary, in short, to adopt a regulatory management 2.0 as an element of a general "forma mentis" 2.0. The new rules and changes for a curious paradox can not only protect the company, but can also help to compete on international markets.

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