



Evaluation of Regulatory Requirements Relating to Quality Control of Skin-Lightening Cosmetic Products in Côte D'Ivoire

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Abstract

In many countries around the world, in Africa and specially in Côte d'Ivoire, many women and sometimes men use cosmetic products containing skin-lightening active ingredients. These substances are toxic and cause several public health problems. Their presence in cosmetics is restricted, or even prohibited. Furthermore, regulatory changes set maximum concentrations for certain substances, requiring quantification in various cosmetic products. Our work aims to assess current technical specifications regulations compliance with skin-lightening cosmetic products quality control in Côte d'Ivoire. To carry out this study, we identified the characteristic elements of these specifications as described at national level. Next, we collected and analyzed the national, West African, and international regulations applicable to cosmetic products in Côte d'Ivoire. It appears that specifications established, by organization named "Côte d'Ivoire - Standardization", for skin-lightening cosmetic products were compliant with Ivorian Presidential Decree No. 2015-288 of April 29, 2015. The same specifications were also found in Council Decision No. 07/2010/CM/UEMOA on West African Economic and Monetary Union (UEMOA) cosmetic products registration. This Decision includes references to European Union (EU) regulations relevant annexes regarding prohibited or restricted substances lists, with which common specifications have been identified. While the national specifications comply with international standards, they must be supplemented and fully implemented for a strict analysis of skin-lightening cosmetics in Côte d'Ivoire.

Keywords: Regulation, cosmetics, skin-lightening preparations, specifications, Côte d'Ivoire

INTRODUCTION

At the crossroads of market expectations and technical and regulatory challenges, cosmetic products must meet cosmetics industry ¹ safety and performance requirements; statements listed in a set of legal texts and technical standards. However, the use of cosmetic products can sometimes reveal a genuine public health issue: voluntary skin depigmentation.

This depigmentation practice is found on every continent, with various frequencies, higher in sub-Saharan Africa and Asia. ² The prevalence in 2019, in African countries, was 25% in Bamako, Mali; 67% in Dakar, Senegal; and 53% in Abidjan, Côte d'Ivoire. ³

Recent studies have demonstrated the harmful effects of certain skin-lightening substances in cosmetic products on human health, including the development of bilateral cataracts ⁴, skin complications, steroid addiction, and even kidney failure ⁵. These effects related to skin-lightening cosmetic products are largely due to the use of products prohibited by regulations ⁶.

In Côte d'Ivoire, given the scale of the problem, a Presidential Decree adopted in 2015 banned skin-lightening cosmetic products containing certain substances. ⁷ These products are submitted to quality control at the National Public Health Laboratory (LNSP) based on technical specifications. Therefore, it is important to ensure that the specifications used in Côte

d'Ivoire for analyzing cosmetic products and detecting skin-lightening substances are appropriate and comply with current regulations.

The overall objective of our work was therefore to assess compliance with technical specifications and current regulations used for quality control of skin-lightening cosmetic products in Côte d'Ivoire.

METHODOLOGY

We conducted a descriptive cross-sectional study. The study material consisted in legal texts and technical standards applicable to cosmetic products in Côte d'Ivoire. Legal texts were looked for at the national, Western African, and international levels. Standards were obtained from the Medicines Control Laboratory, Cosmetic Products, and Condoms (LCM) of the National Public Health Laboratory (LNSP) of Côte d'Ivoire, which

is responsible for the quality control of cosmetic products. All the collected documentation was analyzed. The technical standards used for the quality control of skin-lightening cosmetic products and the detection of skin-lightening substances in cosmetics were compared with the relevant regulations in Côte d'Ivoire.

RESULTS

Regulation applicable to cosmetic products in Côte d'Ivoire

In Côte d'Ivoire, cosmetic products are governed by several legal texts at both national and sub-regional levels within the West African Economic and Monetary Union (UEMOA), particularly regarding their approval, quality control, regulation, and prohibited substances in their composition.

Table 1: Texts relating to the regulation of cosmetic products in Côte d'Ivoire

Year	Text	Link with skin-lightening cosmetic products
Sub-regional level		
2010	Decision No. 07/2010/CM/UEMOA adopting guidelines for the registration of cosmetic products in the Member States of West African Economic and Monetary Union (UEMOA) + Annexes to Decision No. 07/2010/CM/UEMOA	<p>Classification, composition of the approval file, labelling rules, conditions for opening and operating factories, procedure for approving cosmetic products, obligation to submit to control any advertising of cosmetics likely to have curative or preventive effects. The cosmetics commission issues an opinion, in particular, on the establishment of lists concerning:</p> <p>Substances that may not be used in the composition of cosmetic products (Annex: list extracted from European Union (EU) Directive No. 1);</p> <p>Substances that may not be used in cosmetic products except under the restrictions and conditions set out in this list (Annex: list extracted from EU Directive No. 1)</p>
National level		
2020	Directive No. 06/2020/CM/UEMOA of 28 September 2020 concerning the status of Pharmaceutical Regulatory Authorities (PRA) of the UEMOA Member States	PRA missions: approval, market supervision before and after placing on the market, quality control, vigilance, control of information and advertising of health products (including cosmetic products)
2022	Regulation No. 01/2022/CM/UEMOA of June 24, 2022, relating to the harmonization of pharmaceutical regulations in the Member States of the UEMOA	Areas of common interest: approval, quality assurance and quality control, procurement, vigilance, advertising, local production, traceability and coding of health products (including cosmetic products)
2015	Presidential Decree No. 2015-288 of April 29, 2015, regulating cosmetic products and personal hygiene products	<p>The manufacture, marketing, and advertising of skin-lightening cosmetic products or hygiene products containing the following is prohibited:</p> <ul style="list-style-type: none"> - Hydroquinone above 2% - Mercury and its derivatives - Corticosteroids (cortisone, hydrocortisone, triamcinolone, clobetasol) - Retinol derivatives, vitamin A

2017	Law No. 2017-541 of August 3, 2017, regulating the pharmaceutical sector	Cosmetic products within other health products for human use (see definition of pharmaceutical product) Application to establishments manufacturing, importing, and distributing cosmetic and personal hygiene products The Ivorian Pharmaceutical Regulatory Authority (AIRP) reviews applications and grants marketing authorizations for pharmaceutical products
2022	Presidential Decree No. 2022-709 of September 14, 2022: Transformation of the National Public Health Laboratory (LNSP)	LNSP is responsible, in particular, for medicines control and other health products (including cosmetics) and for industrial toxicological assessments.

The regulations concerning the approval of cosmetic products in Côte d'Ivoire are found in Decision No. 07/2010/CM/UEMOA, which applies to all Member States of the West African Economic and Monetary Union (UEMOA). Presidential Decree No. 2015-288 of April 29, 2015, regulating cosmetic and personal hygiene products in Côte d'Ivoire, prohibits several substances in skin-lightening cosmetic products, namely mercury and its derivatives, corticosteroids, retinol derivatives, and vitamin A. Regarding hydroquinone, its concentration in cosmetic products is limited to 2%.

Lists of Substances Prohibited or Restricted by Cosmetic Product Regulations

The substances prohibited or restricted by Ivorian Decree No. 2015-288 are also found in other regulatory texts, namely Decision No. 07/2010/CM/UEMOA, and in European Union (EU) regulations, to which the UEMOA Decision refers.

The study also highlighted the specifications used for the control of cosmetic products, which originate from a national institution responsible for developing technical standards called "Côte d'Ivoire - Standardization" (CODINORM). The annexes to these specifications, as well as those of the regulatory texts, contain the lists of skin-lightening substances prohibited or restricted in Côte d'Ivoire. (Table 2)

Table 2: Annexes to regulatory texts and technical standards listing the skin-lightening substances prohibited or restricted in Côte d'Ivoire

Legal texts and technical standards	Prohibited or restricted skin-lightening substances		
	Hydroquinone	Corticosteroids, Mercury derivatives, Retinoic acid and its salts	Retinol and vitamin A
Decision No. 07/2010/CM/UEMOA	Annex VII: Proposed indicative lists extracted from European Union Directive No. 2015/288. List of substances that cosmetic products may not contain except under the restrictions and conditions provided for	Annex VI : Proposed indicative lists extracted from European Union Directive No. 2015/288. - List of substances that may not be used in the composition of cosmetic products	Annex VII
CODINORM Standard NI 362 : 2002	Annex C List of permitted substances subject to restrictions in cosmetic products	Annex A List of substances whose use is prohibited in cosmetic products	Not applicable
Regulation (EC) No 1223/2009 as amended by Regulation (EU) No 2024/996	Annex III List of substances that cosmetic products may not contain, except for the restrictions provided	Annex II List of substances prohibited in cosmetic products	Annex III

The list of skin-lightening substances subject to restrictions under Decision No. 07/2010/CM/UEMOA (Annex VII) is taken from Regulation (EC) No. 1223/2009 (Annex III). In the EU, hydroquinone is among the substances authorized at a maximum concentration of 0.3% for use as a hair colorant, unlike Ivorian Decree No. 2015-288, which limits its concentration to 2% in skin-lightening cosmetic products. Retinol and vitamin A, banned by Ivorian Decree No. 2015-288, were added to the list of authorized substances subject to restriction (Annex III) by Commission Regulation (EU) No. 2024/996 of 3 April 2024 amending Regulation (EC) No. 1223/2009 of the European Parliament and of the Council as regards the use of vitamin A and the substances "Alpha-Arbutin" and "Arbutin" and certain substances with potential endocrine-disrupting properties in cosmetic products.

Analysis of specifications relating to quality control of skin-lightening cosmetics

The CODINORM specifications (NI 362 and 367:2002) for the analysis of skin-lightening cosmetic products allow information collection regarding their labeling and the presence or absence of prohibited or restricted substances. These specifications, used at the National

Public Health Laboratory, cover, in particular, the physicochemical, organoleptic, and bacteriological characteristics, as well as the packaging of cosmetic products. Table 3 presents the CODINORM specifications for the analysis of skin-lightening products, specifically those related to packaging/labeling and the chemical characterization of skin-lightening substances.

Table 3: Content of some specifications used for quality control of skin-lightening cosmetic products

CODINORM Standards NI 362:2002 and NI 367:2002	Required characteristics
Packaging and labeling (NI 367 : 2002)	<p>Packaging Product inertness to packaging materials</p> <p>Labeling</p> <ul style="list-style-type: none"> - The clarifying name - The name or company name and address or registered office of the manufacturer or the person responsible for placing the product on the market - The batch number or reference allowing identification of the production - The weight or volume expressed in legal units of measurement, except for packaging containing less than 5 grams or less than 5 milliliters, for free samples, and for single-dose units - The date until which the product, stored under suitable conditions, continues to perform its original function and is not likely to be harmful to health, clearly indicated by the month and year and announced by the phrase "Best before end" followed either by the date itself or by an indication of where on the label it appears - The statement "Not for use on children under 12 years of age" - The batch number or reference allowing identification of the production - The qualitative statement and quantitative analysis of the substances contained in the product
Chemical characterization (NI 362 : 2002, Annexes A and C)	<ul style="list-style-type: none"> - Maximum permissible concentration <ul style="list-style-type: none"> • Hydroquinone: 2% • Mercury salts: 0.007% (only for eye makeup and makeup remover products) - Skin lightening substances: prohibited and permitted under restrictions - Glucocorticoids: prohibited in cosmetic products

These specifications, described in the CODINORM standards, are also found in Ivorian decree no. 2015-288 and in decision no. 07/2010/CM/UEMOA. All ingredients of the cosmetic product must be listed on its packaging and label. However, there are some differences between the standards used for quality control of cosmetic products and the legal texts applicable to these products.

Differences between legal and technical standards relating to the quality control of skin-lightening cosmetic products in Côte d'Ivoire

The main differences are listed in Table 4.

Table 4: Verification of the conformity of CODINORM specifications with regulatory texts

Required characteristics	Differential elements		
	Decision No. 07/2010/CM/UEMOA	Decree No. 2015-288	CODINORM Standard NI 367: 2002
Packaging Labeling	Product information Special precautions for use	List of excipients with known effects Methods and routes of administration Warning : "Keep out of reach of children"	Warning that must be included on the label and packaging: contains hydroquinone
Chemical characterization	The following skin-lightening substances are prohibited: - Mercury and its derivatives - Retinol derivatives, vitamin A	The following skin-lightening substances are prohibited: - Mercury and its derivatives - Retinol derivatives, vitamin A	

On the label of skin-lightening cosmetic products, which contain hydroquinone, the CODINORM NI 367: 2002 standard requires that the mandatory statement "contains hydroquinone" be included; this is not the case for national and UEMOA community regulations which prohibit the presence of vitamin A and its derivatives in cosmetic products.

DISCUSSION

Evolution of specifications used for the analysis of cosmetic products in Côte d'Ivoire

The Ivorian CODINORM specifications used for skin-lightening cosmetic products quality control highlighted the required characteristics for skin-lightening cosmetics packaging and labeling.⁸ They identified prohibited (glucocorticoids) or restricted (hydroquinone) substances in the composition of skin-lightening cosmetics. The authorized level of mercury salts (0.007%) would limit their presence to trace amounts in makeup and eye makeup remover products.⁹ These specifications require that the presence of hydroquinone be indicated on the label.

This substance, whose toxicity is proved, is included in the list of substances that cosmetic products may not contain except under the restrictions and conditions stipulated.¹⁰ The list of prohibited substances in skin-lightening cosmetic products was expanded to include retinol derivatives and vitamin A by Ivorian Presidential Decree No. 2015-288, in addition to mercury and its derivatives, which are completely prohibited. The ban on glucocorticoids now extends to all corticosteroids which are reserved for medical use, just like vitamin A and its derivatives.

The authorized, restricted, or prohibited skin-lightening substances in cosmetic products in Côte d'Ivoire are listed in Annexes II and III of Regulation (EC) No 1223/2009, as amended by Regulation (EU) No 2024/996¹¹. Decision No 07/2010/CM/UEMOA referring to these annexes through indicative lists extracted from European directives. Indeed, in the

European Union (EU), Council Directive No. 76/768/EEC of 27 July 1976 on the approximation of Member States laws relating to cosmetic products established negative lists, including, in particular, the list of substances that cosmetic products may not contain except under the restrictions and conditions provided for. Decision No. 07/2010/CM/UEMOA refers to this directive, which has undergone several amendments since 1976, leading to its revision and the adoption of Regulation (EC) No. 1223/2009. The reference to Decision No. 07/2010/CM/UEMOA of European directives could be explained by France's pioneering approach to the regulation of cosmetic products, which has had an impact on European regulations in this area.

Indeed, following the Morhange talc case, the French legislature adopted Law No. 75-604 of July 10, 1975, which amended the Public Health Code by dedicating chapters to cosmetic and personal hygiene products.¹² This French case led to the adoption of Directive 76/768/EEC, with the objective of ensuring a high level of public health protection. Regarding retinol and vitamin A, in the EU, they are now included in Annex III, which lists the substances that cosmetic products may not contain, except for the restrictions provided by Commission Regulation (EU) 2024/996 amending Regulation (EC) No 1223/2009.

Since November 1, 2025, cosmetic products containing retinol above 0.05% retinol equivalent (RE) in body lotions and 0.3% RE in other cosmetic products are no longer placed on the Union market, and those already on the market must be withdrawn by May 1, 2027. The cosmetic product label must include the mandatory statement "Contains vitamin A. Consider your daily

intake before use.¹¹ Furthermore, Decision No. 07/2010/CM/UEMOA requires that cosmetic product indication be specified on the label. As for European Regulation (EC) No. 1223/2009, it is the function of the cosmetic product that is required, unless this is clearly apparent in its presentation. According to Ivorian decree n°2015-288, the label of the cosmetic product must also include the list of excipients with known effects, the methods and routes of administration and the statement "Keep out of reach of children"; information generally found on the label of medicines.

This could be explained by the fact that medicines and cosmetics have different purposes, but the same molecules can be used, and therefore cosmetics are required to have a high level of safety, as cosmetics are, in a way, the medicine for healthy skin.¹³ Regarding the chemical characterization of prohibited or restricted skin-lightening substances, the CODINORM NI 362:2002 Standard makes no reference to the analytical methods used for their identification and characterization, even though the choice of a specific method is important.

In France, a study using high-performance liquid chromatography coupled with mass spectrometry made it possible to identify and quantify hydroquinone at higher percentages than those reported in cosmetic products marketed to ethnic skin types.¹⁴

The importance of screening for skin-lightening substances in quality control of all cosmetic products in Côte d'Ivoire

According to current regulations in Côte d'Ivoire, all ingredients in a cosmetic product must be listed on its label, and no ingredient may be kept secret.¹⁵ However, some manufacturers do not comply with these regulations and continue to use prohibited skin-lightening substances without declaring them on cosmetic product labels.

Moreover, in order to remain within international permitted concentration limits, cosmetic manufacturers sometimes list false concentrations of restricted skin-lightening substances on labels.¹⁶ Such practices represent a danger for the populations using these cosmetic products.

Ingredients historically found in skin-lightening cosmetics include hydroquinone, mercury derivatives, and corticosteroids.¹⁷ Therefore, the National Public Health Laboratory (LNSP) systematically tests for the presence of skin-lightening substances such as hydroquinone, with a limit of 2%, in all cosmetic products undergoing quality control, regardless of what is stated on the product label.

In Morocco, the use of hydroquinone as a skin-lightening agent has been prohibited since 2004 due to its adverse effects, including skin irritation, contact allergies, depigmentation, and acne of varying severity. Besides hydroquinone, mercury is a common ingredient in skin-lightening creams and soaps, and can cause acute anuric renal failure due to tubular necrosis, which can occur with high exposure to inorganic mercury.¹⁷

In European Union, hydroquinone has not been used in dermo cosmetic applications since February 2001. Its concentration must be less than 0.3%, and it is used as an oxidative dye for hair coloring. The concentration is set at 4% for formulations available only by prescription.¹⁰

The contribution of cosmetic product regulation in resolving a public health problem

People in Côte d'Ivoire sometimes seek out skin-lightening cosmetic products due to the widespread phenomenon of voluntary depigmentation, as evidenced by cosmetic product advertisements that mostly feature women with light skin tones.

Some specialized women's magazines, which serve as channels for disseminating beauty standards, are increasingly facing competition from websites that promote and sell all kinds of beauty products without any oversight.¹⁶

Despite the ban on advertising skin-lightening cosmetic products containing prohibited or restricted substances, regulations do not define the methods for advertising cosmetic products that do not have a therapeutic or preventive effect.^{15,18} Thus, the main problem with skin-lightening cosmetics is that a significant portion of them operate outside current regulations. The misuse of skin-lightening cosmetics is facilitated by their sale in backrooms or by their artisanal production through the mixing of various uncontrolled products. It is for this reason that Ivorian Decree No. 2015-288 prohibits the artisanal mixing of skin-lightening cosmetic products. In addition, people sometimes resort to using active pharmaceutical ingredients such as corticosteroids, which should not be used in cosmetic products.

These medical products are nevertheless available in several non-pharmaceutical outlets in some African countries.¹⁶ Cosmetic products containing substances banned in Côte d'Ivoire are still on the market despite the ban, hence the need to define the procedures for advertising cosmetic products, even if they fall outside the pharmaceutical monopoly, and to conduct public awareness campaigns about the risks involved in using such products. The development of an efficient cosmetovigilance system could make it possible to identify, among other things, skin-lightening cosmetic products that do not comply with the relevant regulations. Indeed, several cases of side effects have been observed among healthcare professionals without proper reporting to health authorities.

In the EU, Regulation (EC) No 1223/2009 establishes an obligation to report serious side effects of cosmetic products to the competent national health agency. This communication is transmitted to the competent authorities of the other Member States. In France, Law No. 2004-806 of 9 August 2004 established a cosmetovigilance system; a system in which healthcare professionals, manufacturers, and those responsible for placing cosmetic products on the market participate.¹⁹

CONCLUSION

The misuse of skin-lightening cosmetic products leads to a public health risk, which highlights the importance of cosmetic product regulation. This study purpose was to assess the compliance of technical specifications used for skin-lightening cosmetic products quality control in Côte d'Ivoire with current regulations. The CODINORM specifications used for this quality control mentioned above, at National Public Health Laboratory comply with national, sub-regional (West African Economic and Monetary Union), and European Union legal texts. These texts have, however, undergone some changes over time with the addition of new prohibited or restricted substances to the lists. These changes must be taken into account in the specifications used at national level, while also identifying specific analytical methods for detecting prohibited or restricted substances in cosmetic products approved in Côte d'Ivoire. These specifications must be fully implemented for effective quality control of cosmetic products. The contribution of regulation to the control of cosmetic products advertising in West Africa is essential in order to fight efficiently against voluntary skin depigmentation and its disastrous health consequences.

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