



Evaluation of Analysis Results of Cosmetic Products from National Public Health Laboratory of Ivory Coast before COVID-19

Ambeu-Loko N'ta Christelle Mélissa^{1*}, Yao Adjoa Marcelle², Ouattara Logopho Hyacinthe³, Amin N'Cho Christophe⁴, Bony François Nicaise⁴, Tapé Thierry⁵

¹Laboratory of Constitution and Reaction of Matter, UFR Structural Sciences of Matter and Technology, Felix Houphouet-Boigny University, Abidjan, Ivory Coast, 22 BP 582 Abidjan 22, Ivory Coast

²National Public Health Laboratory of Ivory Coast (LNSP), 18 BP 2403 Abidjan 18, Ivory Coast

³UPR of organic chemistry, Department of Mathematics-Physics-Chemistry, UFR Biological sciences, Peleforo Gon Coulibaly University, Korhogo, Ivory Coast

⁴Laboratory of Pharmaceutical Sciences, Analytical Sciences and Public Health, UFR Biological and Pharmaceutical Sciences, Felix Houphouet-Boigny University, Ivory Coast

⁵CODINORM (Ivory Coast Standardisation), Abidjan, Ivory Coast

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ABSTRACT

Cosmetic products (CP) are an integral part of consumers' daily living. With this in mind, they must always be submitted to regulations and legislation because their use is linked to health and well-being of people. National Public Health Laboratory of Ivory Coast (LNSP) is a well-known laboratory for efficient analysis of drugs, foods and CP. Thus, the general objective of our study, carried out for the first time, was to evaluate the results of 1338 CP quality control in this laboratory, from 2004 to 2018. Our specific objectives were to make a global study of CP analysed and also to evaluate their results. To do this, data collection of CP was done using cosmetic products register of LNSP and also using sheets or certificates of analysis. CP were analysed using test methods from ivorian standards (NI) derived from international standards. The cosmetics were classified into four (4) groups, namely skincare products (868 CP, 65%), hygiene products (280 CP, 21%), hair care products (154 CP, 11%) and perfumery products (36 CP, 3%). From 2004 to 2018, 86% of 1338 analysed CP were in conformity or compliance with ivorian standards compared to 14% which were not in conformity. Among the CP groups, skincare products had the highest compliance rate (66%) and also the highest non-compliance rate (57%). The CP with the highest compliance rate were moisturising milks (17%) and lightening milks had the highest non-compliance rate (28%).

KEYWORDS : Cosmetic products - Compliance - Regulations - Legislation - Standards

1. INTRODUCTION

According to its definition, a cosmetic product (CP) must not harm human health when applied under normal or reasonably foreseeable conditions of use, taking into account particularly, the information on the label and any other information intended for consumers. Manufacturers wishing to market CP are obliged to check that its composition complies with European and national regulations. To this end, there is a positive list of substances that may be used in the composition of cosmetic products, as well as a negative list of prohibited ingredients and a list of substances that may only be used in a certain category of products or in concentrations that may not exceed a certain threshold value [1]. To ensure safety and efficacy, CP are regulated and controlled



world-wide. However, harmonisation of laws dealing with cosmetics is far from being achieved and regulatory frameworks vary greatly between countries making it practically impossible for a global industry to sell the same products on all markets [2]. Indeed, in most countries of western world, there were laws and regulations on cosmetic safety and labelling. In some developing countries such as Ethiopia, cosmetics did not need marketing authorization unlike for medicinal products [3]. In Ivory Coast, the National Public Health Laboratory (LNSP) created in 1956, is a renowned laboratory known for its efficient analysis of drugs, food and CP. Since 2013, the LNSP was accredited to the ISO/IEC17025 standard 2005 version [4], which established the general requirements for competence, impartiality and consistency of laboratory activities. It was applicable to all organisations carrying out laboratory activities, regardless of their workforce. After analysis of CP, this laboratory declared the compliance on non-compliance of CP according to standards before marketing. Thus, the aim of our statistical study was to analyse and evaluate the quality control results of CP analysed at LNSP from 2004 to 2018.

2. MATERIAL AND METHODS

2.1 Material

Data on CP was collected using the CP register at the LNSP's Drug Control Laboratory (LCM) and also analysis sheets or certificates, from 2004 to 2018. These two (02) materials contain several items of information, including the year, registration number, international non-proprietary name and observations made by the quality control department regarding the compliance or non-compliance of the CP analysed.

2.2 Methods

For our statistical study, the CP data were analysed using Microsoft Excel 2016. To analyse the data, the CP were broken down into the groups of CP analysed, the number of CP most analysed within a group, the number of compliant and non-compliant CP according to overall and detailed results. Quality control parameters for the CP were indicated in Table 1. This table also indicated the standards and limit values that must be respected for each CP analysis parameter. A CP was compliant if all its organoleptic, chemical, physical and bacteriological characteristics complied with the criteria or values indicated in the reference standards relating to CP. Otherwise, the CP analysed was non-compliant.

Table 1 : Quality control parameters for cosmetic products (CP)

	Organo leptic charact eristics *	Contr ol tempe rature	p H	Den sity	Alc ohol cont ent (°G L)	Visco sity Broo kfield (Cps ou Pa.s or poise s)	Par ticle size (m m)	Matt er insol uble in etha nol (m/ m)	Tot al fat cont ent (m/ m)	Free alkal i expr essed as NaO H (m/m)	Chlo ride cont ent (m/ m)	Na OH cont ent (g)	Fluo ride cont ent	Hea vy meta ls soug ht**	Hydroq uinone level	IVORI AN REFER ENCE STAND ARDS
Moistur ising milk (a)	Viscous liquid	25 °C	4. 0 - 8. 5	0.8 - 1.2	-	6 000 - 20 000	-	-	-	-	-	-	-	-	-	NI 20.03.0 05
Moistur ising cream (b)	Paste texture	25 °C	4. 0 - 8. 5	0.8 - 1.2	-	50 000 - 250 000	-	-	-	-	-	-	-	-	-	NI 20.03.0 05



Serum (c)	Fluid liquid	25 °C	4.0 - 8.5	0.8 - 1.2	-	50 000 – 250 000	-	-	-	-	-	-	-	-	-	NI 20.03.0 05
beauty Lotion (d)	Fluid liquid	25 °C	-	0.85 - 1.2	< 60°	-	-	-	-	-	-	-	-	-	-	NI 20.03.0 05
Body oil (e)	Viscous liquid	25 °C	≤ 9	0.52 - 1.20	-	6 000 – 250 000	-	-	-	-	-	-	-	-	-	NI 20.03.0 05
Body ointment (f)	Paste texture	40 °C	-	0.8 - 1.2	-	150 – 50 000	-	-	-	-	-	-	-	-	-	NI 20.03.0 05
Scrub (g)	Paste texture	25 °C	4.0 - 8.5	0.8 - 1.2	-	50 000 – 250 000	-	-	-	-	-	-	-	-	-	NI 20.03.0 05
Talc (h)	Fine powder	25 °C	-	0.52 - 0.8	-	-	≤ 0.5	-	-	-	-	-	-	-	-	NI 20.03.0 05
Lightening milk (i)	Viscous liquid	25 °C	≤ 9	0.52 - 1.20	-	6 000 – 250 000	-	-	-	-	-	-	-	-	≤ 2%	NI 20.03.0 06
Lightening cream (j)	Paste texture	25 °C	≤ 9	0.52 - 1.20	-	6 000 – 250 000	-	-	-	-	-	-	-	-	≤ 2%	NI 20.03.0 06
Lightening oil (k)	Viscous liquid	25 °C	≤ 9	0.52 - 1.20	-	6 000 – 250 000	-	-	-	-	-	-	-	-	≤ 2%	NI 20.03.0 06
Lightening lotion (l)	Fluid liquid	25 °C	≤ 9	0.52 - 1.20	< 60°	6 000 – 250 000	-	-	-	-	-	-	-	-	≤ 2%	NI 20.03.0 06
Deodorant (m)	Viscous liquid or cream ou spray	25 °C	-	1	94	-	-	-	-	-	-	-	-	-	-	NI 20.03.0 03
Gel/Toothpaste (n)	Paste, cream or gel, Colour, taste and odour characteristic of the product	25 °C	5 - 10.5	1.25 - 1.55	-	100 000 – 350 000	-	-	-	-	-	-	≤ 0,15 % (m/m), soit 1500 ppm de fluor	≤ 20 mg/k g	-	NI 5501 : 2003



Body gel (o)	Viscous liquid or cream	25 °C	-	-	-	-	-	≤ 17.8	≥ 60 %	≤ 0.15	≤ 1.0	≤ 0.15	-	--	-	NI 04 02 002
Toilet soap (p)	Firm texture with no visible stains	25 °C	-	-	-	-	-	≤ 17.8	≥ 60 %	≤ 0.15	≤ 1.0	≤ 0.15	-	-	-	NI 04 02 002
Hair-relaxing cream (q)	Ointment or cream	25 °C	≤ 1.5	0.8 - 1.2	-	100 - 700	-	-	-	-	-	2 - 2.5	-	-	-	NI 20.03.0 01
Conditioner cream (r)	Ointment or cream	25 °C	≤ 1.5	0.8 - 1.2	-	100 - 700	-	-	-	-	-	2 - 2.5	-	-	-	NI 20.03.0 01
Shampoo (s)	Viscous liquid or cream	25 °C	4 - 8	1.00 - 1.08	-	1500 - 3500	-	-	-	-	-	-	-	-	-	NI 20.03.0 02
Ointment /Balm hair (t)	Paste texture	40 °C	-	0.8 - 1.2	-	150 - 50 000	-	-	-	-	-	-	-	-	-	NI 20.03.0 05
Gel hair (u)	Paste texture	40 °C	-	0.8 - 1.2	-	150 - 50 000	-	-	-	-	-	-	-	-	-	NI 20.03.0 05
Cologne (v)	Fluid liquid	-	-	0.8 - 0.9	40 - 90	-	-	-	-	-	-	-	-	-	-	NI 20.03.0 04
Toilet water(w)	Fluid liquid	-	-	0.8 - 0.9	40 - 90	-	-	-	-	-	-	-	-	-	-	NI 20.03.0 04
Fragrance (x)	Fluid liquid	-	-	0.8 - 0.9	40 - 90	-	-	-	-	-	-	-	-	-	-	NI 20.03.0 04

* The organoleptic characteristics of the CP tested were appearance, texture and odour.

** The heavy metals sought in CP were arsenic, mercury, copper, cadmium and lead (NI 04 02 002) [5].

(a), (b), (d), (f), (h), (t) : products also submitted to reference standards NI 20.03.001 [6] (appendices A, B, C, D and E) and NI 20.03.007 [7].

(i), (j), (k), (l) : reference standard for these products associated with standards NI 20.03.001 (appendices A, B, C, D and E) and NI 20.03.007. In terms of hardness, the products must not attack the skin. In addition, one of the warnings required to protect users was that the products must not be used on children under the age of 12.

(m) : the authorised poisonous substances were zinc sulphophenate (6% calculated as a % of anhydrous matter), methyl chloroform (35%), zinc chloride or zinc sulphate (1% expressed as Zn²⁺) and nitromethane (0.3%) [8].

(n) : reference standard for these products associated with standards NI 20.03.001 (appendices A, B, C, D and E) and NI 20.03.007.



(p) : Laboratory soap samples should be taken and prepared in accordance with NI 04.02.006 [13] [9] and NI 04.02.007 [14] [10]. One of the characteristics of toilet soaps was that they must not be toxic or irritate normal skin.

(q), (r) : the reference standard for these products was NI 20.03.007. The authorised poisonous substances were thioglycolic acid and its salts (8 to 11% ready for use with a pH between 7 and 9.5), thioglycolic acid (8 to 11% ready for use with a pH between 6 and 9.5), potash or caustic soda (2% to 2.5% by weight), zinc chloride or zinc sulphate (0.5% (expressed as salts)). These products must not be aggressive when in contact with the skin under normal conditions of use.

(v), (w), (x) : reference standard for these products associated with standards NI 20.03.001 (appendices A, B, C, D and E) and NI 20.03.007. For these products, the alcoholic strength must not exceed 60 when the preparation was intended for children. As regards chemical characteristics, the authorised poisonous substances were benzyl alcohol and ethanol (with 1% alcohol as a conservator).

(s) : reference standard for these products associated with NI 20.03.001 (appendices A, B, C, D and E) and NI 20.03.007. As chemical characteristics, the authorised poisonous substances were selenium disulphide (1%), phenol and its alkaline salts (1% as phenol), resorcinol (0.5%), quinine and its salts (0.5% calculated as quinine base) and formaldehyde (0.2% expressed as formaldehyde).

Standard NI 20.03.001 (appendices A, B, C, D and E) [6] concerned the lists of substances whose use was prohibited in CP, poisonous substances authorised in CP, authorised substances subject to restriction in CP, preservatives, bactericides and fungicides that may be used in CP, ultraviolet filters used in CP. The bacteriological characteristics required were the absence of total coliforms, faecal coliforms or thermotolerants (NI 03.00.007) [11], yeasts and moulds (ISO 7954:1987) [12], pathogenic staphylococci, *Pseudomonas aeruginosa* (NI 03.00.003) [13] and the presence of mesophilic aerobic germs (103 bacteria/g or ml, NI 03.00.002) [14]. Standard NI 20.03.007 [7] related to the sampling of CP. For quality control of all CP, the LCM of LNSP tested for hydroquinone and heavy metals.

3. RESULTS AND DISCUSSION

3.1 Results

The overall and detailed results of CP analysed are shown, in relation to their compliance or non-compliance with ivoirien standards derived from international standards.

3.1.1 Overall results of cosmetic products

Among 1338 CP analysed at LCM of LNSP, four (4) groups were distinguished [1] and were 868 skincare products (moisturising milks and creams, serums, beauty lotions, oils, ointments, scrubs, talcs or powders, lightening products (milks, creams, oils, lotions)) for 65% ; 280 hygiene products (toilet soaps, shower gels, oral care products such as tooth gels and pastes, deodorants) for 21% ; 154 hair care products (relaxers, detanglers, shampoos, ointments, gels, balms) for 11% and 36 perfumery products for 3% (Figure 1).

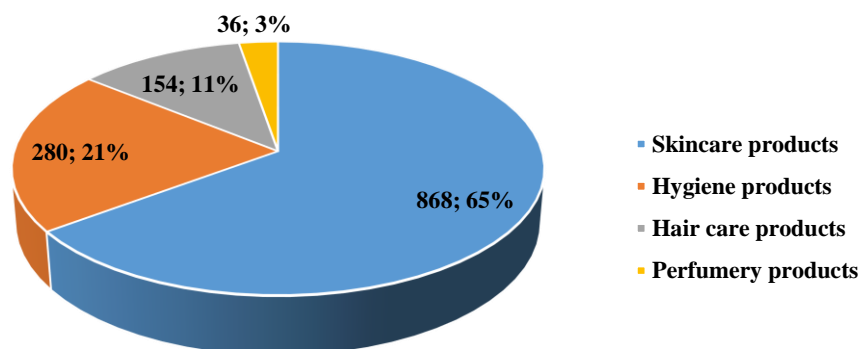


Figure 1 : Distribution of CP groups

So, the most analysed CP group was skincare products. Among skincare products (868 CP), the most analysed CP were lightening products which were lightening milks, creams, oils, lotions and which represented a total of 412 CP for 47%. Moisturising milks and creams were moisturising products and represented a total of 366 CP for 42% (Figure 2).

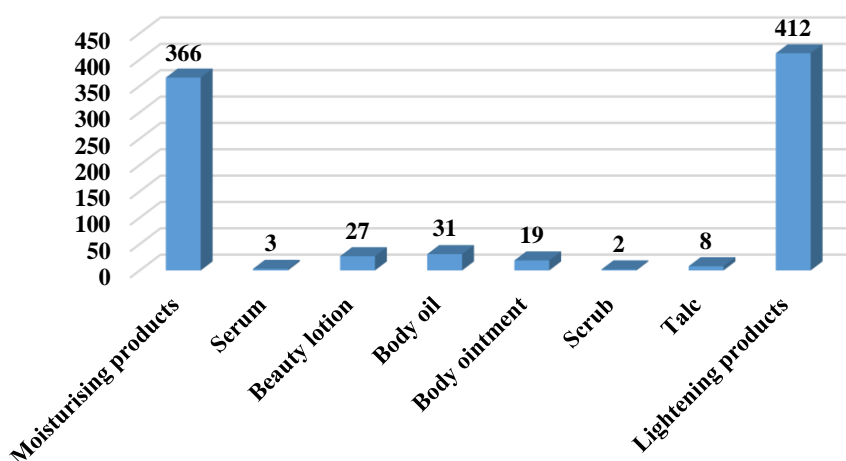


Figure 2 : Distribution of skin care products

Concerning hygiene products (280 CP), the most widely analysed products were toilet soaps, which accounted for 81% of the 227 CP (Figure 3).

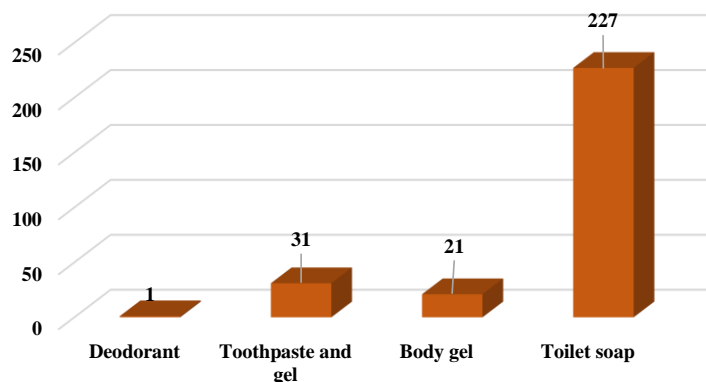


Figure 3 : Distribution of hygiene products

Among 154 hair products, 47% (73 CP) were hair straighteners designed to remove waves (Figure 4). In this figure, other hair products were pomades, gels and balms.

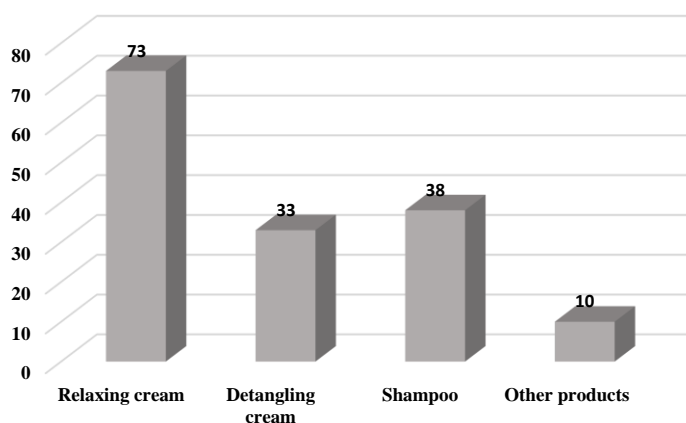


Figure 4 : Distribution of hair products

Perfumery products represented the smallest percentage of CP analysed with 3% for 36 CP (Figure 1).

3.1.2 Overall results of CP quality control

On the one hand, 1146 CP were declared compliant after analysis at LNSP, representing 86% of the analysed CP. On the other hand, 192 CP were declared non-compliant, representing a percentage of 14% (Figure 5). So, 86% of the analysed cosmetics were compliant with ivoirian standards (NI) while 14% were non-compliant during 15 years (from 2004 to 2018).

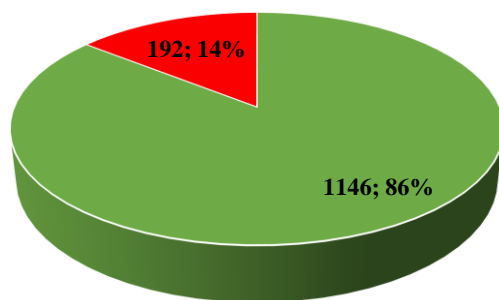


Figure 5 : Distribution of CP according to compliant and non-compliant results

Figure 6 showed the compliance and non-compliance of analysed CP over the years. In 2006, the non-compliance rate (61%) was higher than the compliance rate (39%). But, the compliance percentages of CP had considerably increased especially since 2012. So, we noted important compliance percentages ranged from 89 to 99% since 2012.

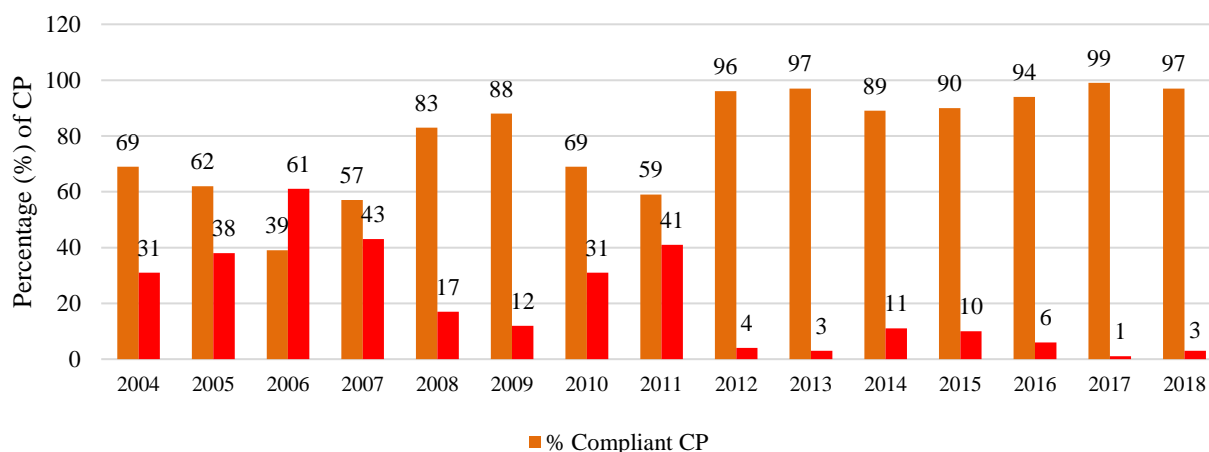


Figure 6 : Evolution of compliant and non-compliant CP rates over the years

3.1.3 Quality control results for CP groups

Among the CP groups, skincare products not only had the highest compliance rate (66%) but also the highest non-compliance rate (57%), Figure 7.

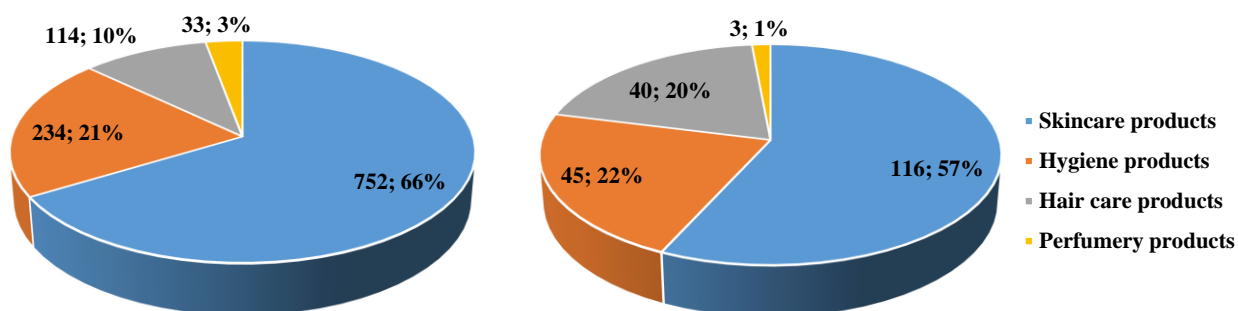


Figure 7 : Percentages of compliance (left) and non-compliance (right) for CP groups

3.1.4 Quality control results for skincare products

Among skincare products, the moisturising products (moisturising milks and creams) had the highest compliance rate (48%). Moreover, the lightening products (lightening milks, creams, oils and lotions) had the highest non-compliance rate (82%, Figure 8).

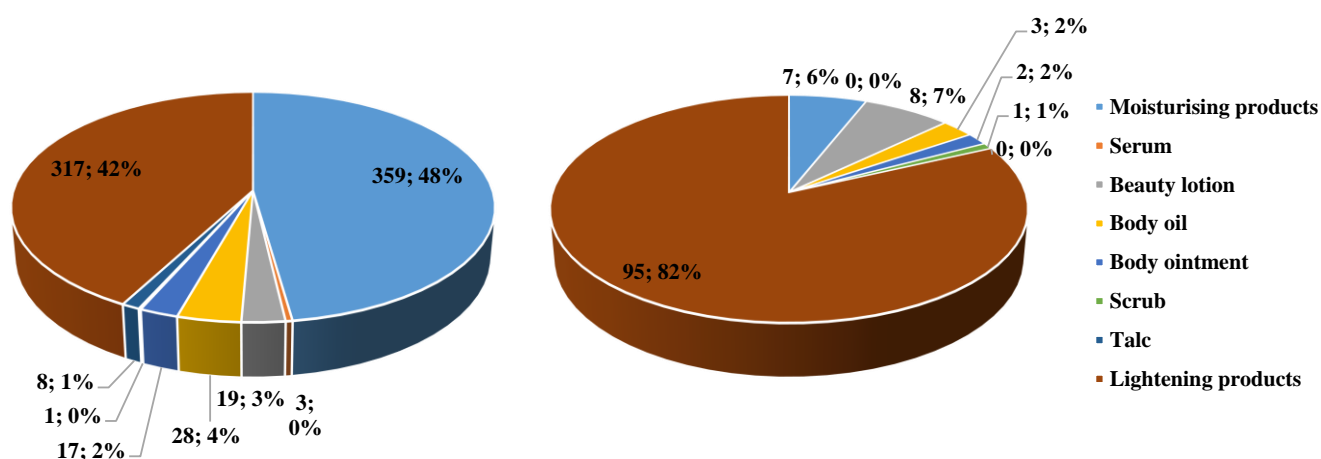


Figure 8 : Percentages of compliance (left) and non-compliance (right) for skincare products

3.1.5 Quality control results for CP type

Twenty four (24) different types of CP were analysed (Table 1). The CP with the highest compliance rate were moisturising milks (17%) and lightening milks had the highest non-compliance rate (28%, Figure 9).

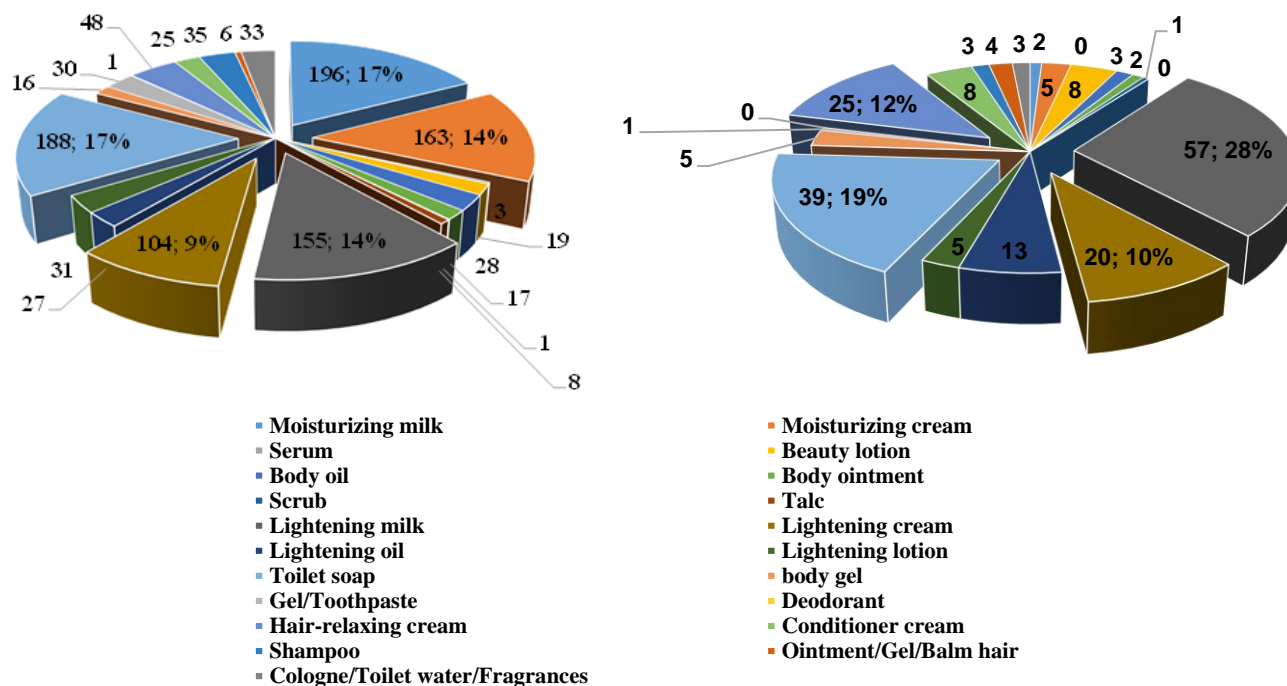


Figure 9 : Percentages of compliance (left) and non-compliance (right) for CP type

3.2 Discussion

The number of analysed CP had increased considerably over the years, especially since 2012 (Figure 6). The increase in the number of analysed CP over the years could be due, on the one hand, to manufacturers becoming more aware of the need to make quality products available on the market. On the other hand, ivoirien decree No. 2016-1152 of 28 December 2016, making ivoirien standards for some products mandatory, particularly cosmetics and personal hygiene products, obliged manufacturers to have CP analysed before marketing authorization. In France for example, awareness was raised by serious public health incidents such as the tragic Morhange talc affair in 1972. This led to the adoption of France's first law on the manufacture, packaging, import and marketing of cosmetic and personal hygiene products on 10 July 1975 [14].

Moreover, the overall percentage of compliance for analysed CP (86% for 1149 CP) is six (6) times higher than that of their non-compliance (14% for 192 CP). The non-compliance rate of 14% caused the circulation of poor quality and counterfeit cosmetics, with harmful consequences for people's health. A CP was compliant if it respected the limit values of Table 1; if it did not, it was non compliant. For example, a lightening milk was compliant if the hydroquinone content was less than or equal to 2% in addition to the other required characteristics [15]. Otherwise, it was non-compliant. Similarly, a toilet soap was non-compliant according to the ivoirien standard NI 04 02 002 if it was contaminated with mould [5]. The overall rate of non-compliance obtained could be due to the lack of qualifications of manufacturers in the field of cosmetic formulation and chemistry : this was the Dunning-Kruger effect. Indeed, some of them are trained in marketing and management and they felt they were qualified in a field of cosmetics that was not theirs [16].

Considering quality control results of CP type, lightening milks had the highest non-compliance rate (28%, Figure 9). Concerning quality control results of CP groups, lightening products revealed the highest non-compliance rate (82%, Figure 8) among skincare products. Their percentage of compliance (42%, Figure 8) was close to that for moisturising products (48%). As in several sub-saharan African countries such as Senegal, Mali and Congo [17], the cosmetic use of depigmenting or lightening products was a frequent practice in Ivory Coast. Unfortunately, there were several disadvantages to misusing lightening products. Prolonged



application of certain pharmacological ingredients in lightening products (hydroquinone, dermocorticoids, mercury) could lead to skin complications (dyschromia, exogenous ochronosis, acne and hypertrichosis, stretch marks, mycosis, pyoderma, erysipelas, scabies, contact dermatitis, etc.) or adverse systemic effects (hypertension, hypercorticism or adrenal insufficiency, mercury nephropathy, etc.) [17]. Generally, the non-compliance of lightening products was related to the high level of hydroquinone they contained. At high concentrations of hydroquinone (4 to 8.7%) especially, uneven pigmentation of the skin with completely discoloured or darker-looking parts were observed, irritating dermatitis, burning or stinging sensations. Hydroquinone used in lightening lotions, for example, were corrosive and caused irreversible depigmentation. It was effective in lightening the skin at a concentration of 2% and was also the concentration at which adverse effects appear [18].

To reduce the non-compliance rate of CP, the AIRP which is a supervisory and management body for the pharmaceutical, parapharmaceutical and medical biology sectors in Ivory Coast, could strengthen its regulatory powers. It had enhanced regulatory powers to protect consumers against counterfeit, fake or falsified pharmaceutical products. It also had the same power to regulate CP. This structure, instituted by law 2017-541 of 3 August 2017, was tasked with guaranteeing the population access to effective pharmaceutical products of proven quality and access to quality CP that were therefore compliant [19]. For example, it could conduct awareness-raising campaigns with manufacturers to ensure that compliant CP was effectively made available to the public. Indeed, a CP placed on the market was not covered by a marketing authorisation and its safety was the responsibility of the manufacturer or its legal representative [1]. Moreover, it could be more supported by the government in monitoring the application of specific standards by passing laws against traffickers regarding the harmfulness and toxicity of non-compliant CP.

In addition, manufacturers must ensure the qualification of people responsible for the manufacture, packaging and quality control of CP [6]. Moreover, manufacturers could be encouraged to adopt the accreditation process in addition to providing proof of the application of specific standards with a conformity certificate and an attestation certificate. The conformity certificate was a document issued by CODINORM (Ivory Coast Standardisation) at the request of the manufacturer, attesting that a batch of CP complied with a reference standard. CODINORM is a non-profit-making ivorian association, recognised as being of public utility and created on 24 September 1992 by the private sector on the authorisation of the Ministers Council on 26 August 1992. It brought together private companies and the ivorian State. To this end, an agreement defining CODINORM's management procedures was signed on 06 January 1995 between the ivorian State and the private sector [20].

Concerning the population, they could also be made aware of the warnings that must appear on the containers, packaging or leaflets of CP. The awareness-raising campaign could provide information on substances whose use was prohibited in CP.

4. CONCLUSION

This study showed that regulations applicable to CP had existed for years in Ivory Coast, as in several other countries. However, there was a lack of control and cosmetovigilance, which were major shortcomings for the safe use of cosmetics. From 2004 to 2018, 1338 CP classified into four (4) groups of CP were analyzed at LNSP. There were 868 skincare products, 280 hygiene products, 154 hair products and 36 perfumery products. Among skincare products, the most analysed CP were lightening products with an analysis percentage of 47%. Like them, toilet soaps representing a percentage of 81% were the most analysed among hygiene products. Furthermore, we assessed overall and detailed compliance and non-compliance rates. Indeed, 86% of all analysed CP were compliant and 14% were non-compliant. We also noted that lightening products revealed the highest non-compliance rate (82%) concerning quality control results of CP groups. Lightening milks had the highest non-compliance rate (28%) for quality control results of CP type. To reduce the CP non-compliance rate, the Ivorian Pharmaceutical Regulatory Authority (AIRP) could increase manufacturers' awareness of compliance with current standards and regulations. As far as manufacturers were concerned, they should respect the working methods (good manufacturing practice, GMP and good laboratory practice, GLP). As for population, they could be made aware of the harmfulness and toxicity of the use of non-compliant CP. Finally, the AIRP could increase manufacturers' awareness of compliance with the standards and regulations. In perspective, another statistical and comparative study could be carried out from the appearance of the coronavirus pandemic to currently.



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