IJPSR (2023), Volume 14, Issue 4 (Review Article)

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 19 July 2022; received in revised form, 30 August 2022; Accepted, 28 October 2022; published 01 April 2023

THE CURRENT REGISTRATION REGULATIONS OF COSMETIC PRODUCTS IN "BRICS" COUNTRIES

R. Sathyalakshmi, N. Jaipratap and C. Sowmya *

Department of Pharmaceutical Regulatory Affairs, Faculty of Pharmacy, Sri Ramachandra Institute of Higher Education and Research, Porur, Chennai - 600116, Tamil Nadu, India.

Keywords:

Cosmetics, Regulations, BRICS, Emerging market

Correspondence to Author:
C. Sowmya

Assistant Professor,
Department of Pharmaceutical Regulatory Affairs, Faculty of Pharmacy, Sri Ramachandra Institute of Higher Education and Research, Porur, Chennai - 600116, Tamil Nadu, India.

E-mail: drcsowmya@sriramachandra.edu.in

ABSTRACT: Cosmetic products are produced by the most inventive and technically driven methods to reach more consumers in the developing world. Cosmetic products are also regulated, similar to pharmaceutical products. BRICS countries are emerging markets with a partial regulatory system similar to well-regulated countries. BRICS countries have a registration or notification process for cosmetics based on their classification. A systematic review was carried out. We searched the databases and reviewed assessment agency websites, among other sources. Qualitative studies, official regulations, and systematic reviews aimed to identify a general framework of regulatory activity in BRICS were included. A critical analysis is made of all the aspects that may be useful for any public body that intends to register cosmetics in any of the BRICS countries. BRICS nations are organized to promote, stabilize and consistently regulate cosmetic products among them. The cosmetic regulatory system, registration process, and procedures of South Africa are at their last position, as Russia precedes South Africa. Cosmetic products are very well regulated and the registration process is well-defined in Brazil, China and India among BRICS. The registration process in BRICS countries is appropriate and slightly altered from one another, even though South Africa follows no registration process. BRICS are the world's fastest and largest emerging cosmetic market economies.

INTRODUCTION: Emerging markets are markets that have a few attributes of an already developed market but do not meet its standards completely. These markets might be developed markets or may become developed markets in the future. Both India and China were considered the largest emerging markets along with Brazil and Russia in 2006. The BRICS countries are one of the world's emerging markets. BRICS is an acronym for Brazil, Russia, India, China and South Africa. The term "BRIC" was coined by Goldman Sachs economist Jim O'Neill in 2001.

QUICK RESPONSE CODE

DOI: 10.13040/IJPSR.0975-8232.14(4).1660-67

This article can be accessed online on www.ijpsr.com

DOI link: https://doi.org/10.13040/IJPSR.0975-8232.14(4).1660-67

On December 24th, 2010, South Africa officially became a member nation as China invited them to join officially and other BRIC countries also accepted later. The NDB (New Development Bank) was founded by BRICS and will become a major regional development bank when cosmetics are regulated as equal to pharmaceutical products [1].

The creation of NDB suggests flexibility in governance to develop the BRICS role in global financial institutions. All of the BRICS are set to be essential to future growth.

Rapidly increasing disposable incomes mean consumers are shifting beyond solely purchasing basic products to more sophisticated beauty products. By 2050, these countries will become leading traders of production goods, amenities, and raw materials due to low production costs and labor [2]. The objective of this study is to compare the

cosmetic regulations followed by the BRICS countries; to study the growth of the BRICS countries in the cosmetic sector, and to study the impact of BRICS on the cosmetic industry.

TABLE 1: REGULATION AND REGISTRATION REQUIREMENTS FOR COSMETIC PRODUCT IN BRAZIL

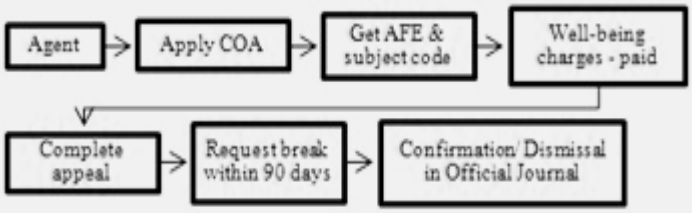
S. no.	Title	Content
1	Regulatory Authority	ANVISA, MOH, GHCOS
2	Classification	Grade I and Grade II
	Grade/class I	Cosmetic Products require Notification
	Grade/class II	Cosmetic Products require Registration
3	Notification process of class I cosmetic product	"Prior Communication" is a warning system. It is a supervising method to manage the goal of commercialising certain items by advising ANVISA. SGAS is also known as ANVISA's electrical stage. A notice will be released on ANVISA's website after the completion of the warning period so that the organisation can market that product.
	Charges	It's between R$ 175.72 and R$ 3,414.32 Brazilian reais
	Timeline	2 months
4	The registration process of class II cosmetic products	To begin the registration process, a request must be presented through the ANVISA electrical stage. Following the solicitation, ANVISA starts the overview of the dossier introduced by the association and also carries out an assessment of the gathering site to ensure its consistency with Incredible Collecting Practices. In the wake of completing the survey and the assessment, ANVISA officially distributes its choice in the Journal, after which the item's commercialization can begin
	Charges	It ranges from R $244.05 to R $4.810,00 in Brazilian reais
	Timeline	90 days
5	Sanitary license and its validity	 Only class II products have sanitary license validity for 5 years from the distribution date in the official Journal
6	Label	The product label must contain: AFE and the process number of the product as generated by ANVISA, which corresponds to a register number. The date of expiry is mentioned in "month and year". The package must contain a leaflet that includes the instruction manual
	Legislation	RDC 07/2015-Chapter II/Annex V/Annex VI. Requirements for the presentation of the Art of Labelling of cosmetics.
7	Legislation for regulation	RDC 07/2015-Technical requirements for the regularisation of personal care products, cosmetics, and perfumes RDC 15/2015-Technical requirements for the regularisation of children's personal care products, cosmetics, and perfumes RDC 237/2018-Updated RDC
8	Timeline	An ANVISA takes 90 days for approval The product under notification has lifetime validity Renewal must be requested 180 days before the expiration date An import licence is valid for 120 days
9	Company operating authorization (AFE)	To manufacture or import Class II cosmetics in Brazil, local companies must have a Company Operating Authorization (AFE) and a License from ANVISA. It contains data such as the company's authorization number and address. Production, manufacturing, distribution, storage, export, and import companies require AFE
10	Registration and notification validity	Registration and notification of cosmetic products have a 5-year validity. The revalidation application should be completed before 6 months of the expiry date, along with the fee for the renewal of registration [3,4]
11	Dossier	Dossiers are prepared for both class I and class II products and contain formulation components for precise amounts, label claims, quality control and stability results, with microbial science tests for confirmation of safety and effectiveness. The producer/merchant ought to have all the data and archives that establish the "Dossier of the cosmetic product", which should be submitted to ANVISA [5]

TABLE 2: REGULATION AND REGISTRATION REQUIREMENTS FOR COSMETIC PRODUCTS IN RUSSIA

S. no.	Title	Content
1	Regulatory Authority	Rospotrebnadzor MOH
2	Classification	Low risk and High risk
	High risk	Pre-market state enrolment confirmation is required for the safety of the products. It takes nearly 90days to complete the State enrolment process as per Customs Union samples
	Low risk	Low-risk products should be tried at an endorsed research facility in the Customs Union. Mostly safe cosmetic products are given by Rospotrebnadzor with an EAC presentation (statement of similarity)
3	General requirements	The new legislation aims to harmonise and align with the necessities of cosmetic products in the Customs Union and the European Legislation. The Technical Regulation is related to the EU Cosmetics Directive 76/768/EEC and the present Cosmetic Regulation 1223/2009/EU. The Local Authorized Representative is responsible for products similar to the Responsible Person in the EU
4	Annexes	The Specialized Guideline records the precluded substances, limited substances, permitted colors/shades, additives, and UV channels with which the item equations should be in line, similar to the EU Guideline, but not by and large the same as the EU Guideline
5	Certificates	The State Registration of Customs Union GOST R Declaration of Conformity
	Objectives of certification	Demonstrates item conformity to Customs' freedom systems, Russian cleanliness, and health requirements
	Timeline	A declaration of conformity can be valid for 5, 6, or 7 years The state registration doesn't have any time limitation
	Documents Required	Application form, Declaration of conformity of the cosmetics to the EU guidelines, ISO certificate (if any), Certificate of Trade, copy of the agreement with the nearby wholesaler/shipment receipt (for the single shipment accreditation) and document signed by an outsider endorsing the security of items. Extra records might be needed during the confirmation system
6	Label	Designation and address of the producer and company with a sign of the country. Brand, if any, can remain in Latin letters Nominal content is given by volume (cm3 or ml) or weight (g) as well as amount, with the exception of 5 ml or 5 g List of elements in the dropping request as indicated by the INCI equation. Conditions, warnings, mark of conformity, leaflets, the expiry date with the EAC confirmatory mark [6]
7	Mark of Conformity (GOST R SIGN)	The GOST-R sign (Mark of Conformity) needs to be given on the cosmetic product, which shows that the product fulfils all the safety regulations and was inspected by a certification authority recognised by Rospotrebnadzor. This results in consumer satisfaction with product quality and safety. The size of the GOST R SIGN should not be less than 4 mm
8	Language	Russian. Only the composition (INCI) and the commercial trademark can be in Latin letters among the necessary markers.
9	Export/Import fees:	Expenses will often include the following items: Analyses and tests on products in accredited laboratories; Audit expenditures, including inspector travel fees and lodging (if applicable); Certificates are issued at no cost. translation services; Overhead expenses[7]

TABLE 3: REGULATION AND REGISTRATION REQUIREMENTS FOR COSMETIC PRODUCTS IN INDIA

S. no.	Title	Content
1	Regulatory Authority	CDSCO BIS
2	Regulation	Classification of Cosmetic Raw Materials and Adjuncts: Part 1 & Part 2. Drug and Cosmetic Act of 1940 and Rules of 1945 (as amended through December 31, 2016). Guidelines on Registration of Import of Cosmetics. Clarification for Import and Registration of Cosmetics
3	Classification	In India, cosmetics are classified based on categories such as skin, hair, scalp, nail, cuticle and oral hygiene

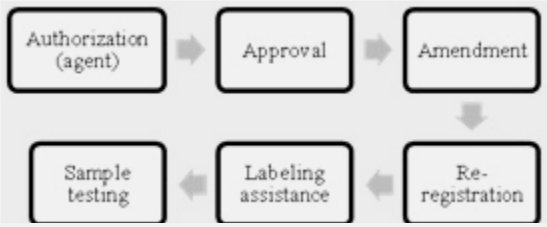
4	Manufacture license	Based on the D&C Act 1940 and rules 1945, the production of cosmetics is regulated under a system of licencing and inspection by each state drug control department. The application for a licence is submitted through the websites of each state in India. Specific procedures differ from state to state
5	Dossiers	It should contain: covering letter, power of lawyer, schedule D (III), list of materials, label, specifications, manufacturing licenses, Certificate of Free Sale, Non Animal Testing Presentation, Declaration for heavy metal and hexachlorophene content, Application form 42, and Fee: TR-6 Challan (In Unique)
6	Registration procedure for producer [8]	
	for importer	
7	Label	It contains the cosmetic name, the name and address of the producer, the manufactured nation's name, direction for use, batch number, manufacturing certificate number, Registration Authentication Number and information according to Part XV of the D and C Rules, 1945
8	Cosmetic ingredients	The BIS Standards are followed for cosmetic products. The BIS classified the raw materials and adjuncts of cosmetics.
	Classification	Class I – GRAS - Generally Recognized As Safe Class II – GNRAS - Generally Not Recognized As Safe
	Restriction	Restriction on assembling/importing restoratives to contain colors, tones, and shades other than those endorsed by BIS. Cosmetics with hexachlorophene are prohibited from manufacturing or importing. Restoratives containing Pb or As compounds are not permitted to be manufactured or imported. The import of cosmetic products is banned for testing on animals [9]

TABLE 4: REGULATION AND REGISTRATION REQUIREMENTS FOR COSMETIC PRODUCTS IN CHINA

S. no.	Title	Content
1	Regulatory Authority	CHSR, CSAR, SAMR, NMPA
2	Regulations - For cosmetic ingredient	Safety and Technical Standards for Cosmetics 2015 (STSC 2015), Inventory of Prohibited Cosmetic Ingredients, Inventory of Existing Cosmetic Ingredients in China by 2021, INCI Chinese Version 2010 Catalogue of Standard Chinese Names of International Cosmetic Ingredients
	For registration and notification	Administrative Measures on Cosmetics Registration and Notification, Provisions for Management of Cosmetic Registration and Notification Dossiers, Provisions for Management of New Cosmetic Ingredient Registration and Notification Dossiers Cosmetic Classification Rules and Catalogues, Technical Guidelines for Cosmetic Safety Assessment, Standards for Cosmetic Efficacy Claim Evaluation
	For manufacture and operation	Practice for Cosmetics Production Licensing
	For labeling and naming	Administrative Provisions on Cosmetics Labeling, GB 5296.3-2008 Instruction for Use of Consumer Products - General Labelling for Cosmetics, Requirements on Naming of Cosmetics
	For testing	Working Rules for Cosmetic Registration and Notification Testing
	For import and export	Administrative Measures on Inspection and Quarantine of Import and Export Cosmetics
3	Classification of Cosmetics	Domestic Cosmetics, Imported Cosmetics
	Classification of New Cosmetic Ingredient (NCI)	High-risk NCI. Low-risk NCI. UV filters, whitening agents, preservatives colours, hair dyes, and freckle removal are present in high-risk NCI. These NCIs require a registration process with NMPA for approval. Other than high-risk NCI, all others fall under low-risk NCI and these NCIs require a notification process for approval

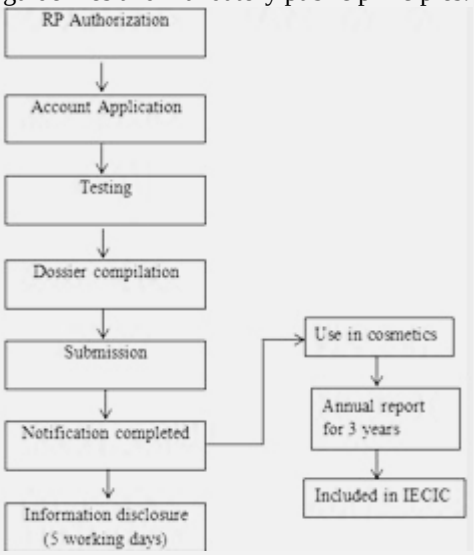
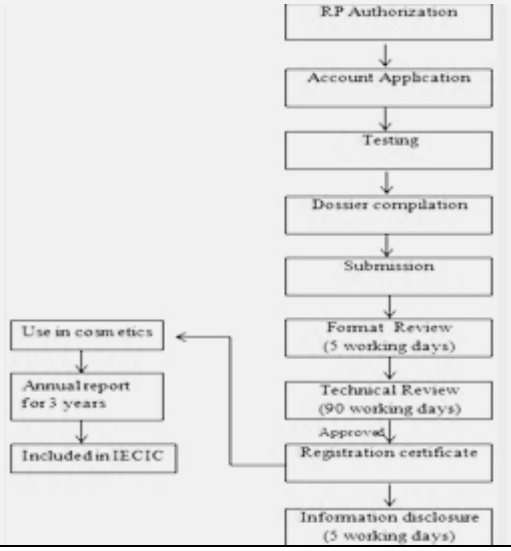
4	Code	Efficacy Claims - 01-26, A*, Application areas – 01-10, B*, Target users – 01-03, C* Dosage forms - 00♦, 01-11 and Application methods – 01, 02. Note: "♦" – forms that are not covered in the specified dosage forms. "*" – Cosmetics with new efficacies other than prescribed category, (The code composed of 5 layers, each layer is represented by a 2 digit number or letters connected by '-')
5	Dossier	It contains the registrant's, notifier's, and local RP's name, address, and contact information; the NCI R & D report; research records on NCI stability, preparation technology, and quality control principles; NCI safety records; and specialised necessities (accessible to the public)
6	Safety Monitoring and Reporting	Registrants and notifiers will build up a security checking framework for the enrolled NCI. During the 3 year notice period, they will report the NCI's utilisation and security information to the NMPA every year and might be needed to direct a security evaluation. If no security issues are discovered within three years, the NCI will be remembered for the IECIC.
7	Safety Re-assessment	The registrant/notifier might present a security evaluation report assuming there is proof appearance that the NCI might have any dangers. If the NCI is found to be dangerous after re-evaluation, it will be prohibited from use in the manufacture of beauty care products or subject to a usage limit
8	Duration and cost	3-6 months for general beauty care products and >10 months for uncommon beauty care products to be registered. The Cost depends on the type of NCI.
9	Labeling	Product designation and licence number, registrant/notifier and production unit designation and address, item chief standard number, net substance, durability, ingredient list, application technique, safety alerts, other substances authorised by laws, authoritative guidelines and mandatory public principles.
10	Notification process for low risk NCI	
11	Registration process for High Risk NCI [10]	

TABLE 5: REGULATION AND REGISTRATION REQUIREMENTS FOR COSMETIC PRODUCT IN SOUTH AFRICA

S. no.	Title	Content
1	Regulatory Authority	SABS, SAHPRA, CTFA, Coschem
2	Regulatory framework	The Department of Health structures cosmetics via the Foodstuff, Cosmetic & Disinfectant Act (Act 54 of 1972) and equal guidelines. This Cosmetic Code is assembled and overseen by the industry, through the CTFA and submitted to the ARB for incorporation into their code. There is an in-market control framework rather than a pre-market control framework.
3	Role of RA - SABS	The SABS qualified the SANAS. Norms Act, 2008 and started up the SABS as the public launch for the improvement and support of standardisation and quality of goods.
	CTFA	To improve reputed regulations and guidelines, Create the ideal financial and administrative working atmosphere by supporting best practise and taking responsibility. Adjust and improve South Africa with worldwide administrative principles. Advance social obligation through the exercises of the Look Great, Feel Better program.
	Coschem	Advance the progression of science and innovation in the beautifying products and toiletries industry. Advance the high moral guidelines of corrective science. Give the means to the dispersal and trade of information appropriate to corrective science. Energize research in surface-level sciences.
4	Application forms	DA185 - Enrolment/Authorizing of Customs and Excise Customers.DA185.4A1 - Enrolment Customer Type 4A1 – Merchant. DA185D - Selection of Specialist.
5	Medical Control Council (MCC)	Any item joined by recuperating or restorative cases should be enrolled at the MCC, and any item joined by thinning or muscle improvement claims should be enlisted at the MCC.
6	Registration	Cosmetic products are not subject to registration, but here they follow an in-market system of control rather than a pre-market system of control. All the formulas that contain alcohol must be registered with the Department of Customs and Excise for duty rebate on alcohol usage, especially for products that are manufactured in South Africa [11]
7	Label	Assertions are “Result of [insert nation of origin]” assuming all components are from that nation, or “Delivered in [insert nation of origin]” if the components utilised are from an unexpected country in comparison to the country where the items were mass-produced. The label should contain the date produced, cassation date, the name and address in South. Africa of the producer, shipper or wholesaler, group number, item weight, and units. Components with the name "Ingredients" toward the beginning of the list, recorded in the dropping request of mass. Names should be in English. [12] The list of components should incorporate the names of any additives or colorants utilized. The additive or colorant's name or number can be utilized, yet the number is discretionary. Dietary tables should show up on the mark, assuming that the item makes a nourishing case. The table should give the supplement amounts per serving, or per holder size. All supplement amounts should be recorded in SI units. There may be no deceptive cases on the names. Items may not contain any prohibited elements, for example, hydroquinone (a skin lightener)

RESULT AND DISCUSSION: As an emerging market, BRICS is currently focusing on regulating cosmetic products to compete with Western markets and grow economically. BRICS countries have to deal with so many regulatory factors since they lag behind in regulations for cosmetic products. BRICS is an acronym that brings five different nations under one roof, but it’s actually challenging to achieve equal growth in the cosmetics market due to different manufacturing processes, climatic zones, labour, financial support, government and supply chain among them. The traditional pharmaceutical and cosmetics markets are small in these five nations. As of now, synthetic and semi-synthetic products have a fastened effect in the cosmetics department, which pushes other parts of traditional cosmetics behind. Even though the growth of BRICS’ cosmetics sales is gentle, it is moving all the way to attain huge economic growth in the cosmetic market. BRICS's aim is to become parallel, economically steady and identical to that of developed countries. Among BRICS countries, the population in China and India is greater, so the use of cosmetics and other beauty products is also greater in these two countries. Thus, cosmetics sales are gradually increasing in China and India. Guidelines and regulations for cosmetics products are not framed as stringent as

pharmaceutical products' regulations. Cosmetic products must be given equal importance and perfect regulations to enter the BRICS pharmaceutical market. The geographical barriers, longitudinal and latitudinal extent of BRICS differ, and it is challenging to frame harmonised regulations and guidelines. The regulators must consider the differences in origin, genetic makeup, size and other factors that challenge them due to the underdeveloped regulatory system. The changes in China and India's population and economy change the country's epidemiological profile. The variation is particularly wide between HIC and LMIC with different regulatory frameworks. The New Development Bank (NDB) is another notable achievement. BRICS is also discussing a framework for BRICS e-commerce cooperation to promote cross-border e-commerce. This new world of e-commerce will bring changes in cosmetic products too [13]. The growth of BRICS is compared to the US and EU markets because of the market size and their promising potential role in the pharmaceutical industry.

The BRICS countries worked hard to improve coordination and establish themselves in a variety of initiatives. They functioned together to stabilize the global financial system through CRA, where countries have decided to offer short-term liquidity support through currency swaps to help with any external contingency. BRICS nations have also banded together to promote, stabilize and consistently regulate cosmetic products [14].

Considering the above information on cosmetic regulatory systems and other beauty product registration processes and procedures, South Africa is in the last position, as Russia precedes South Africa. Cosmetic products are very well regulated, and the registration process is well defined in Brazil, China, and India among BRICS.

CONCLUSION: The purpose of this study was to compare the registration process of cosmetic products and to find out the variances and gaps among the guidelines. The registration process in BRICS countries is appropriate and slightly altered from one another, even though South Africa follows no registration process. BRICS are the world's fastest and largest emerging cosmetic market economies. They are the largest entity on the global stage of cosmetic products. The drawbacks in Brazil, Russia, and China are that the regulations are in their local languages, and the documents required for cosmetics registration should be translated into their local languages, such as Brazilian, Russian and Chinese, respectively. It takes a lot of time to understand the rules and regulations and for the registration of one cosmetic product. To rectify the differences in the guidelines, we need to go for harmonisation of rules, which is also a time-consuming process. But once these guidelines are harmonized, emerging countries like BRICS will benefit even more. We can expect a common guideline worldwide for cosmetic product registration. It can be concluded that the BRICS countries are presenting optimistic growth and direct global investment by creating significant opportunities for cosmetic companies to expand into the world cosmetic economy.

ACKNOWLEDGEMENT: We would like to thank all of the authors of the research publications that we used for the systematic review.

CONFLICT OF INTEREST: None

REFERENCES:

1. Brazil, Russia, India and China (BRIC) [Available from: https://www.investopedia.com/terms/b/bric.asp].
2. The BRICs and beyond: The lure of emerging economies for the beauty industry [Available from: https://www. .com/article/the-brics-and-beyond-the-lure-of-emerging-economies-for-the-beauty-industry]
3. Registration of cosmetics in brazil [Available from: https://globalregulatorypartners.com/wp-content/uploads/Registration-of-Cosmetics-in-Brazil-v2-002.pdf]
4. Brazil Cosmetics Regulations [Available from: https://www.artixio.com/Insights/cosmetic-regulations-in-brazil-anvisa/]
5. Cosmetics Regulation in Brazil [Available from: https://thebrazilbusiness.com/article/cosmetics-regulation-in-brazil]
6. Russia, Kazakhstan & Belarus 2021 [Available from: https://ceway.eu/international-services/russia/]
7. FEDERATION DE RUSSIE Cosmetics Certification Guidelines [Available from: https://www.intertek.es/uploadedFiles/Blocks/Images/IAO/ES/Russia-EG-Exporter%20Guidelines%20for%20Cosmetics-English.pdf]
8. Nagalakshmi S, Vaishnavi S and Pavithra GM: Regulatory Prototype for Cosmetics in India: Asian Journal of Pharmaceutical and Clinical Research 2021; 14: 12-16.
9. India Cosmetic Regulation [Available from: https://cosmetic.chemlinked.com/cosmepedia/india-cosmetic-regulation]

10. China Mainland Cosmetic Regulation[Available from: https://cosmetic.chemlinked.com/cosmepedia/china-mainland-cosmetic-regulation]
11. A One Page Guide to Global Cosmetic Compliance Guidelines [Available from: https://www.iqpc.com/media/1001142/41037.pdf]
12. South African labelling requirements [Available from: https://importexportlicense.co.za/blog/south-african-labelling-requirements/]
13. Shellot Pereira and Jawahar N: The Development and Future of BRICS Countries in the Pharmaceutical Sector. Journal of Pharmaceutical Sciences and Research 2018; 10(6): 1336-1341.
14. Kumari BS, Nagabhushanam MV, Reddy DN, Bonthagarala B and Hanuja GS: Regulatory requirements for registration of generic drugs in "BRICS" countries. International Journal of Pharmaceutical Science and Health Care 2016; 6: 2249-5738.

How to cite this article:
Sathyalakshmi R, Jaipratap N and Sowmya C: The current registration regulations of cosmetic products in "Brics" countries. Int J Pharm Sci & Res 2023; 14(4): 1660-67. doi: 10.13040/IJPSR.0975-8232.14(4).1660-67.