Application to add broad-spectrum sunscreen to the World Health Organization Model List of Essential Medicines and Model List of Essential Medicines for children

Submitted by:

THE UN INDEPENDENT EXPERT ON THE ENJOYMENT OF RIGHTS BY PERSONS WITH ALBINISM
Secretariat – hrc-ie-albinism@un.org

Together with

THE GLOBAL ALBINISM ALLIANCE
Antoine Gliksohn – agliksohn@albinismalliance.org

With the support of

THE INTERNATIONAL ALLIANCE OF DERMATOLOGY PATIENT ORGANIZATIONS (GLOBALSKIN)
Jennifer Austin – jennifer.austin@globalskin.org

THE PIERRE FABRE FOUNDATION
Christophe Przybylski – christophe.przybylski@fondationpierrefabre.org

BEYOND SUNCARE
Mafalda Soto – mafalda@beyondsuncare.org

STANDING VOICE
Harry Freeland – harry@standingvoice.org

THE INTERNATIONAL LEAGUE OF DERMATOLOGICAL SOCIETIES – ILDS
Liz Hollenberg – lhollenberg@ilds.org

Submission date: December 16th, 2022
A. SUMMARY STATEMENT OF THE PROPOSAL FOR INCLUSION, CHANGE OR DELETION

This submission is made in support of the inclusion of broad-spectrum sunscreen on the core Lists of Essential Medicines (EML) and Essential Medicines for children (EMLc) for persons with albinism.

Due to a deficiency of melanin pigment, persons affected by this rare congenital condition are highly vulnerable to ultraviolet (UV) radiations. In the lack of efficient prevention measures, they are exposed to chronic effects of UV radiation on their skin and, ultimately, are at high risk of developing skin cancers.

The use of broad-spectrum sunscreen in persons with albinism significantly reduces morbidity and mortality due to these occupational skin diseases. Access to these products is often very limited in countries where they are needed the most (i.e., in countries with high incidence of solar radiation), which are often countries with low socioeconomic status.

Broad-spectrum sunscreens are the only preventative treatment available to protect parts of the skin that remain exposed to the sun. The strength and safety of these over-the-counter medical products are regulated by national regulatory agencies.

B. CONSULTATION WITH WHO TECHNICAL DEPARTMENTS

Prior to submitting the application and during the drafting process, the applicants held discussion with the focal point for human rights at the WHO, in order to share information on the mandate of the Independent Expert and the human rights value of adding sunscreen to the EML and EMLc.

C. OTHER ORGANIZATION(S) CONSULTED AND/OR SUPPORTING THE SUBMISSION

In preparing this submission, the applicants (the UN Independent Expert on the enjoyment of rights by persons with albinism and the Global Albinism Alliance) consulted the following organizations:

- International Alliance of Dermatology Patient Organizations (GlobalSkin)
- International League of Dermatological Societies (ILDS)
- Beyond Suncare
- The Pierre Fabre Foundation
- Standing Voice
All these organizations have signed on as supporting organizations.

D. KEY INFORMATION FOR THE PROPOSED MEDICINE(S)

1. INN and ATC Code

The international non-proprietary name is not applicable for sunscreen because it is an over-the-counter product designed to prevent skin damage that could result in cancer.

ATC Code: D02BA – Protectives against UV-radiation for topical use

2. Dosage form(s) and strength(s) of the proposed medicine(s)

This application is submitted for the proposed “product/medicine” (broad-spectrum sunscreen) in all topical dosage forms authorized by regulatory agencies (see §K.1): cream, lotion, stick, gel, oil, butter, paste, ointment and spray. This excludes other forms, such as wipes, towelettes, body washes, shampoos, and powder.

The recommended strength is a sun protection factor (SPF) of 50+. Furthermore, to ensure effective protection, the sunscreen must be broad-spectrum, i.e., it must filter both UVB and UVA radiations.[59] More specifically, the UVA protection value should keep a precise correlation with the UVB protection value mentioned on the label, in compliance with the standards of the regulatory agencies referenced in §K.1 below. The minimum UVA protection should be at least 1/3 of the UVB (e.g., a SPF 50 product in the UVB range shall have a UVA protection factor of at least 17).[1]

Lastly, a sunscreen with these characteristics, but that is not aesthetically pleasing (e.g. one that is oily and leaves white residue on the skin) is unlikely to be used by those with albinism and will, therefore, not achieve its purpose. In other words, the sunscreen must be acceptable to the population to whom it is targeted, as compliance is a key factor for good UV protection.

3. Indication(s)

Sunscreen is proposed not for treatment, but for prevention of the following diseases in the target population.

International Classification of Diseases, 11th Revision (ICD-11)
14 Diseases of the skin
Malignant neoplasms involving the skin
> In situ neoplasms of skin
> Malignant neoplasms of skin
Skin disorders provoked by external factors
Dermatoses provoked by light or UV radiation
> Chronic effects of ultraviolet radiation on the skin

E. PROPOSAL FOR AN INDIVIDUAL MEDICINE OR REPRESENTATIVE OF A PHARMACOLOGICAL CLASS / THERAPEUTIC GROUP

This application is not for an individual sun screening agent. Rather, general specifications for a topical sunscreen in multiple possible dosage forms are proposed with a minimum strength (see above paragraph).

The proposal aligns with the preventative value of over-the-counter medicines and medical devices such as condoms and fluoride included on the EML and EMLc.

F. INFORMATION SUPPORTING THE PUBLIC HEALTH RELEVANCE

1. Target Population

This application is submitted specifically for persons with albinism, whose condition results in greatly increased risk of the harmful effects of ultraviolet radiation on unprotected skin.

Albinism is a rare, non-contagious, genetic congenital condition characterised by decreased or absent pigmentation (i.e., lack of melanin pigment) in the hair, skin and/or eyes. Melanin is the pigment that gives skin its color and protects it from sun damage. Studies have shown that the lack of melanin pigment in persons with albinism increases their vulnerability to UV radiation, their exposure to the chronic effects of ultraviolet radiation on the skin and ultimately their susceptibility to skin cancer.[2,3,4]

Albinism occurs worldwide regardless of ethnicity or gender. The incidence of albinism in Western societies has been documented to range from 1:14,000 to 1:17,000. In African countries it is said to lie between 1:1,500 and 1:15,000.[5] However, these statistics have been shown to be underestimated in some cases. For example, The Republic of Malawi’s 2018 population census places the total population of persons with albinism at 134,636.[6, p39] With a total population of 17,563,749 in the country,[6, p5] that places the incidence of albinism in the country at 1:130. There are also studies from Northern Ireland and the Netherlands which have shown that the actual prevalence in these countries are 1:4,500 [7] and 1:12,000 [8] respectively, rather than the estimated 1:14,000 to 1:17,000 for European countries. A high incidence of albinism ranging from 1:28 to 1:6,500 has also been reported among indigenous communities in the Americas.[9, p12]
It is to be noted that, while this application is submitted for persons with albinism as only target population, it is emphasized that the use of sunscreen would greatly benefit populations with other rare skin conditions such as xeroderma pigmentosum (XP), pigmentary disorders and other conditions causing high UV-sensitivity.

2. Epidemiological Information on Disease Burden

Oculocutaneous albinism is an inherited condition that causes a complete absence of or decreased melanin biosynthesis in melanocytes. Due to the reduced or absent melanin in the skin, patients with albinism are highly susceptible to the harmful effects of UV radiation and are at increased risk of acute and chronic actinic damage to their skin (in particular solar elastosis, actinic keratosis and skin cancers).[2,4,10] Chronic exposure to high doses of UV radiation are associated with accumulation of DNA changes, immunosuppression, and ultimately with development of cutaneous carcinomas. DNA changes and immunosuppression happen at a much higher pace in the skin of persons with albinism due to melanin deficiency.[2]

Exposure of people with albinism to the sun without sun protection is a cause of premature death from skin cancer, in addition to causing high morbidity and a drop in quality of life due to premature skin photoaging, multiple skin lesions and large anesthetic scars following malignant skin lesions surgical excision. People with albinism in Africa, for example, are reportedly 1,000 times more likely to develop squamous cell carcinoma (SCC) than the general population.[11] Other studies show that persons with albinism predominantly develop skin cancers by the time they are 20 and do not commonly live beyond the age of 30 years.[12,13] What distinguishes persons with albinism in such places from those in the Global North are higher UV radiations, the lack of a culture of the use of sunscreen, the relatively high cost of sunscreen (particularly broad-spectrum sunscreen), the financial barriers to purchasing sunscreen, and limited to very limited access to sunscreen. The use of sunscreen, however, is essential for all persons with albinism regardless of geographic location, and, therefore, even regions with relatively low incidence of UV radiations, such as Europe.[14]

Studies have clearly documented the highly deleterious effects of sun exposure in patients with albinism in sunny climates including the Federal Republic of Brazil and Sub-Saharan Africa.[2,15] Precise statistics concerning the increased morbidity experienced by persons with albinism due to skin cancer are not known. However, one study suggests that Africans with albinism have as much as a 1,000 times greater risk of developing skin cancer than the general population.[16] Another study carried out in the United Republic of Tanzania indicated that half the population of persons with albinism, “will develop advanced skin cancer between 20 and 30 years of age”.[10 p11] Further studies have shown that, without
sunscreen, children with albinism can develop chronic skin damage from as young as 12 months.[17]

3. Public Health Relevance

While sunscreen use is recommended for everyone, the public health relevance for persons with albinism to protect their skin from UV radiation is an imperative, especially in sunny climates such as Sub-Saharan Africa.[2,17-19] Further, the public health relevance of the essential medical nature of sunscreen for persons with albinism can be considered in a human rights context, in the context of governmental action and legislation and in the non-governmental context. It is important to note that the development of skin cancer in persons with albinism seems to be correlated to their occupation.[20] Premature photoaging as well as skin cancer in people with albinism, therefore, fall under the category of “occupational skin diseases” and is predominantly a consequence of people’s efforts to access education and work.

The public health relevance has also been noted by the WHO, as evidenced by the history of sunscreen listing on the EML:

1989: p-aminobenzoic acid and benzophenones with SPF15 were added. The WHO Technical Report Series #796 [21, p48] notes “... since ultraviolet damage to the skin from solar radiation contributes to basal cell carcinoma and other skin tumours, particularly in patients with xeroderma pigmentosum. Sun-blocking agents with a sun protection factor of 15 or higher are effective in preventing these diseases.”

1991: Zinc oxide is added “because it is cheap and effective”, with Technical Report Series #825 noting that “sun-blocking agents are included because of their importance in preventing UV-induced skin cancers in people whose occupations expose them to sun for long periods of time.”[22, p51]

1995: p-aminobenzoic acid (PABA) is removed “since other UV-blocking agents are more effective”.[23, p61]

1997: The benzophenones and zinc oxide are replaced by a broad-spectrum topical sun protection agent with activity against ultraviolet A and ultraviolet B. The agent consists of 3% octyl methoxycinnamate, 2% titanium dioxide and 2 % butyl methoxydibenzoylmethane formulated in an arylate polymer or an oily base.[24, p64]

In 2005, sun protection agents were removed from the EML with consideration of a review received from the International Society of Drug Bulletins.[25] The
corresponding report of the WHO Expert Committee reports only the following [26, p25]:

“During its meeting in 2003, the Committee recommended that sun protection agents be reviewed for possible fast-track deletion at the meeting in 2005. A review was received from the ISDB.

Despite this removal, the Committee noted that the use of topical sun protection agents (sunscreen products) containing substances that protect the skin against ultraviolet radiation (UVA and UVB) prevents squamous cell skin cancer in susceptible people.[27]

The Committee also noted the high public health relevance of this item for the prevention of skin cancer but appeared to justify its removal on the basis that sunscreens are normally not provided by public facilities and that provision through such sources was not needed.”

The sections below set out the continued public health relevance of sunscreen and how the situation has changed since 2005 to justify the re-addition of broad-spectrum sunscreen to the EML.


The UN Human Rights Committee has stated that, “The obligation of States parties to respect and ensure the right to life extends to reasonably foreseeable threats and life-threatening situations that can result in loss of life. States parties may be in violation of article 6 even if such threats and situations do not result in loss of life.”[28, §7] In her report on the protection of persons with albinism, the UN Independent Expert on the enjoyment of rights by persons with albinism (UN IE), indicated that, “the failure of a State to prevent any intentional or otherwise foreseeable and preventable life-terminating harm or injury [such as skin cancer in persons with albinism] can constitute a violation of the right to life.”[29, §54] The UN IE has further demonstrated the public health relevance of sunscreen for people with albinism in numerous observations and recommendations contained in reports of the mandate.[29-32]

Access to sunscreen by persons with albinism constitutes a right in terms of Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), which enshrines the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, as well as Article 25 of the Convention of the Rights of Persons with Disabilities, particularly Article 25(b) which requires states to, “Provide those health services needed by persons with disabilities specifically because of their disabilities”. In this regard, it must be noted that the UN Committee on the Rights of Persons with Disabilities [33, §7.4][34,
§7.5] and the UN IE have recognized, not only the visual impairment of persons with albinism, but also the lack of melanin as a disability.[30, §17-25][35, §14]

Providing access to sunscreen for persons with albinism further aligns with the UN Sustainable Development Goal of good health and well-being (SDG-3). In a December 2017 report, the UN IE points out the intersection of ICESCR and SDG-3 by calling attention to the “leave no one behind” principle of the UN SDG and the fact that sunscreen is absent from many countries’ essential medications list.[30, §63 and 64] Sunscreen however is included on the essential medicines list in some countries such as South Africa.[36, p5.31 and 5.32]

5. Public Health Relevance – Governmental and Legislative Context

Government programs and existing laws support the public health imperative relative to sunscreen as an essential medicine for persons with albinism. Brazil is an example, with several relevant programs. The city of Maceió, Brazil enacted Law No. 6605 which provides for the distribution of sunscreen free of charge to persons with albinism.[37, §19] The Brazilian municipality of Salvador has been distributing sunscreen free of charge to persons with albinism since 2006.[37, §42] And at a national level in Brazil, Article 3 of Bill No. 7762/2014 provides that persons with albinism have the right to access dermatological care, including sunscreen and essential medicines. If adopted, the bill would significantly benefit persons with albinism nationwide by establishing that sunscreen is an essential medicine for persons with albinism.[38]

Other countries have similar, relevant initiatives. The Republic of Uganda provides tax exemptions on imported products such as sunscreen to enable organizations to import donated sunscreen duty-free.[39, p28] In other countries, including Tanzania and Malawi, the authorities have partnered with organizations such as Beyond Suncare, the Pierre Fabre Foundation and Standing Voice to enable the production of low-cost sunscreen which persons with albinism can access for free. [39, p30] The Republic of Kenya and Malawi also provide an annual budget for programming including empowerment of persons with albinism to, for example, understand measures they can take to prevent skin cancer and where they can access relevant health services. [39, p5,6][40, §23,30,41]

At the continental level, the Executive Council of the African Union (AU) adopted a Plan of Action on Ending Attacks and Discrimination against People with Albinism (Plan of Action 2021-2031) in July 2019. Section 4.3 (a) of the implementation matrix for the Plan of Action 2021-2031 calls on State members of the AU to, "Ensure access to health support, services and health goods such as visual aids and sunscreen for all persons with albinism particularly in rural areas and with emphasis on skin cancer prevention and treatment as well as specialist services for low vision and dermatological care."[41, p37] National actions plans
for persons with albinism in Malawi, the Republic of Mozambique, the Togolese Republic and Uganda include provisions for dermatological care for persons with albinism, including access to sunscreen. Draft national action plans for Tanzania and South Africa also contain such provisions.

6. Public Health Relevance – NGO Context

Some non-governmental organizations have recognized the public health imperative for persons with albinism by creating programs to meet the critical need for sun protection. Three such NGOs serving people with albinism in various countries in Africa, and whose programs include local production of sunscreen, are Beyond Suncare,[42] Standing Voice[43] and the Pierre Fabre Foundation,[44].

The above international standards, laws, policies, and practices of governments, as well as activities by NGOs evidence an increased recognition of the need for the provision of sunscreen, particularly for persons with albinism. They further evidence an increased practice of the provision of sunscreen including by public facilities.

G. TREATMENT DETAILS

In order to reach the protection level indicated by the sun protection factor, sunscreen products have to be applied on the skin in quantities similar to those used for testing, i.e., 2 mg/cm².[45] The WHO as well as several governmental agencies generally recommend sunscreen to be applied 15 to 30 minutes before sun exposure and every 2 hours for all exposed parts of the body when exposed to the sun. Application should be repeated after swimming or bathing.[46-52]

Several experts have proposed more practical indications. One is the “teaspoon rule”, which applies to a certain number of dosage forms such as cream, lotion and ointment. For the whole body of one average adult person the recommended dosage (2 mg/cm²) corresponds to approximately 35 ml or 9 teaspoons of sunscreen: one teaspoon each to left arm/forearm, right arm/forearm, and face + scalp + neck, and two teaspoons each to the torso, right thigh/leg, and left thigh/leg.[53]

H. REVIEW OF BENEFITS SUMMARY OF EVIDENCE OF COMPARATIVE EFFECTIVENESS

It is well established that the engagement of sun-protective behaviors early in life is key to reduce the risk of skin cancer and the chronic effects of ultraviolet radiation on the skin for the general population.[49] On this basis, wearing sun-protective clothing, broad-brimmed hat and sunglasses, as well as avoiding the
sun / seeking shade whenever practical is recommended by health authorities in many countries.[49] However, the topical application of broad-spectrum sunscreens is also recommended as a safe adjunct measure in protecting human skin from UV radiation when the above mentioned measures cannot be applied (i.e. on parts of the skin that remain exposed to the sun), or are insufficient. Indeed, it is well established that sunscreens protect against the damaging effects of UV radiation on the skin and that the proper use of sunscreen significantly reduces the risk of skin cancer.[54] In the context of persons with albinism, sunscreen use is considered part of healthy sun protection practices.[55, p21]

Extensive research has shown the benefits of using sunscreen in reducing the incidence of skin cancer in all groups of people including in persons with albinism. “Use of sunscreen has been shown to reduce the incidence of both melanoma and non-melanoma skin cancers.”[54] Another study concluded that regular use of sunscreen can have prolonged benefits in preventing SCCs of the skin.[56] A 2022 study concluded that sunscreen use was associated with a lower prevalence of skin cancer.[57] With respect to the target population, a study concluded that “Exposure to sun without protection is a risk factor for the occurrence of cancerous lesions in persons with albinism” based on observations that “The average age of persons with albinism with cancer was 34.6 years and 65.1 years for individuals [without albinism]…”[19]

Finally, a recent study including recommendations from an international expert panel shows that while an SPF of 30 might be effective in the general population for darker skin phototypes, “broad-spectrum sunscreen with SPF50+ and a balanced protection against UVA (UVB/UVA protection ratio as close to 1 as possible) is recommended for the prevention or treatment of pigmentary disorders”. This study further shows that “The latitude of where the individual lives should also be taken in consideration” (e.g. higher SPF for populations living closer to the Equator).[45]

I. REVIEW OF HARMS AND TOXICITY SUMMARY OF EVIDENCE OF COMPARATIVE SAFETY

Concerns about the toxicity of UV filters, increased risk of melanoma and reduced vitamin D synthesis related to the use of sunscreen have been raised. The management of sunscreens must therefore balance their essential protective effect against the potential toxicity of the UV filters for humans (and for the environment). In relation to this, regulatory agencies set the standards in terms of UV filters safety (see §K.1 below).

Regarding the alleged potential increased risk of melanoma for sunscreen users, Lodén et al. provide the following information: “… the suggested association
between melanoma and sunscreen use has been explained by failure to control for confounding factors, such as the sun exposure dose. It was also recently reported that regular use of sunscreen in Australia appeared to actually reduce the incidence of new primary melanomas and also protect from invasive melanoma.”[58]

The correlation between sunscreen use and vitamin D deficiency has also been disproved by studies. This is summarized in a review article published in 2022: “Theoretically, sunscreens that inhibit erythema should also inhibit vitamin D synthesis, which would be a possible adverse effect of sunscreen use, with public health implications. However, in practice, sunscreens can be used to prevent sunburns and still allow vitamin D synthesis.”, and further “The use of sunscreen for daily and recreational photoprotection does not compromise vitamin D synthesis, even when applied under ideal conditions”.[59]

That same review of sunscreen concepts and controversies published in 2022 mentions the following. “Currently, there is a growing public concern about the harmful effects of chemicals in sunscreens. The most common adverse effect of using sunscreens is the risk of photoallergy, particularly with benzophenone class organic UV filters, which are considered allergenic UV filters. […] however, the clinical relevance of these findings remains uncertain.” Regarding mineral filters, the authors mention that “although controversy has recently arisen regarding the systemic absorption of micronized particles from these inorganic filters, studies have not shown potential damage and reinforce the role of these active substances in protecting the skin against adverse effects induced by UV radiation, including DNA damage and skin cancer.”[59]

In their article on “The efficacy and safety of sunscreen use for the prevention of skin cancer” published in 2021, Sander et al. conclude that “Emerging evidence suggests that some chemical sunscreen ingredients are systemically absorbed, but the clinical importance of this remains unclear; further research is required to establish whether this results in harm.” They also highlight the fact that “Ultraviolet filters found within chemical sunscreens may be harmful to the environment.”[54]

In reaction to this concern, regulatory agencies, such as the United States of America Food and Drug Administration (U.S. FDA), are taking action by updating, when necessary, the conditions, such as active ingredients, uses (indications), doses, labeling, and testing, under which over-the-counter sunscreen agents are “generally recognized as safe and effective”.[60]

In recent years, concerns have been raised with regard to the potential toxicity of sunscreens in spray dosage form. Here again, national regulatory agencies are addressing this concern by updating their regulations. As an example, the U.S. FDA in its proposed order OTC000008 published in September 2021 identifies “two primary safety concerns specific to spray sunscreen dosage forms: (1) the
potential risk of respiratory harm from inhaling sunscreen ingredients and (2) the potential flammability risk when consumers are exposed to flame or heat before spray solvents have completely dried." This administration is subsequently proposing the following regulation update:“we believe that both potential risks can be acceptably mitigated by proposed formulation limitations, labeling requirements, and adequate testing, and thus propose to establish these as additional conditions in the monograph to ensure that sunscreen products in a spray dosage form would be GRASE” (generally recognized as safe and effective).[60, p58]

Lastly, it is important to note, as Lodén et al. state, “The use of UV filters is regulated by the responsible authorities and the filters appear on an approved or a positive list in many countries. Prior to their approval and placement on a positive list in the EU, the United States and Japan, UV filters have to pass a stringent toxicological safety evaluation. This includes studies on acute toxicity, subchronic and chronic toxicity, reproductive toxicity, genotoxicity, photogenotoxicity, carcinogenicity, irritation, sensitization, phototoxicity and photosensitization.”[58]

J. SUMMARY OF AVAILABLE DATA ON COMPARATIVE COST AND COST-EFFECTIVENESS

Various studies have concluded that systematic sunscreen use at a population level will prevent substantial numbers of new skin lesions and reduce the costs of treatment and in loss of life.[61,62,63] This conclusion holds even more true for the population of persons with albinism due to their higher risk to develop skin lesions. Furthermore, one study states that “There is a significant cost burden of skin cancer for many countries and health expenditure for this disease will grow as incidence increases. Public investment in skin cancer prevention and early detection programmes show strong potential for health and economic benefits.”[64] Yet another study conducted in Australia provides additional evidence of the cost effectiveness of promoting use of sunscreen in populations at higher risk of developing UV-induced skin cancer. This study concluded that “Compared with usual practice (discretionary use), the sunscreen intervention cost an additional USD 106,449 (2007) to prevent 11 basal cell carcinomas, 24 squamous cell carcinomas, and 838 actinic keratoses among 812 residents over 5 years. These health outcomes required an annual average investment of USD 0.74 per person and saved the Australian government a total of USD 88,203 in health-care costs over the same period.”[63]

While many persons with albinism are aware of the need to protect themselves from the harmful effects of the sun’s rays, studies have shown that they are prevented from doing so due to the cost of sunscreen, as well as cost of travel and travel distance to enable them to obtain sunscreen.[65] Adding sunscreen to the
EML/EMLc will contribute to ensuring free or reduced cost of sunscreen for person with albinism, who are disproportionately affected by poverty, particularly in developing and least developed countries.\[31\]

K. REGULATORY STATUS, MARKET AVAILABILITY AND PHARMACOPOIEIAL STANDARDS

1. Regulatory status of the proposed medicine(s)

Definitions of and labeling standards for sunscreen are set by several regulatory agencies including the following.

- **Commonwealth of Australia** – Department of Health / Therapeutic Goods Administration
- **Federal Republic of Brazil** – National Health Surveillance Agency
- **Canada** – Health Canada / Health Products and Food Branch
- **People’s Republic of China** – National Medical Products Administration
- **European Union** – Cosmetics Products Regulation
- **United States of America** – Food and Drug Administration

2. Market Availability of the Proposed Medicine(s)

Sunscreens are available as personal care products or over the counter medicines in most middle- and upper-income level countries. Availability and affordability in lower income countries will need to be supported by government programs.
References


43. Standing Voice [Internet]; 2022. Skin Cancer Prevention; [updated date unknown] [cited 2022 Dec 14]; [about six screens]. Available from: https://www.standingvoice.org/programmes/skin-cancer-prevention


48. HPRA [Internet], Health Products Regulatory Authority 2014. Sunscreen; [Date of Last Update unknown] [cited 2022 Dec 12]; [about five screens]. Available from: http://www.hpra.ie/cosmetics/sunscreen


52. Agence Nationale de la Sécurité du Médicament et des Produits de Santé [Internet], 2022; Le point sur vos produits solaires [2021 Jul 30] [cited 2022 Dec 14]; [about five screens]. Available from: https://ansm.sante.fr/dossiers-thematiques/le-point-sur-vos-produits-solaires


