HCP CODE:

GLOBAL CODE ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS

GALDERMA

HCP CODE:

GLOBAL CODE ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS

PREAMBLE:

We, at Galderma, are committed to delivering innovative medical solutions to meet the dermatological needs of people throughout their lifetime while serving healthcare professionals around the world.
Both as individual employees and as a company, we are committed to acting responsibly in our relationships with healthcare professionals.
We have a duty to preserve the good reputation of Galderma, Nestlé Skin Health as well as Nestlé towards all of our stakeholders.

This Code establishes principles that all Galderma Entities need to comply with when interacting with healthcare professionals. These principles are in line with the principles set forth in the Code of Ethics. The HCP Code provides more detailed guidance on Galderma's interactions with healthcare professionals.

The HCP Code is a resource for, and applies to, all Galderma executives, managers, employees, agents and consultants when interacting with HCPs.

SCOPE

All Galderma activities including but not limited to the 3 Global Business Units (Prescription, Self-Medication and Aesthetic & Corrective), the geographical Regions (APAC, EMEA, LATAM and North America), affiliates, Legal Affairs (including the HCP Compliance function), Medical Affairs, R&D, Regulatory Affairs, M&TO, other global and local functions…

For other businesses operated by Galderma (i.e Consumer Skin Health), the HCP Code will apply if such interaction is also subject to an applicable local HCP legal norm (or higher industry norm if so chosen by the affiliate).

External partners of Galderma, such as subcontractors, vendors, agents and clinical research organizations, serve as an extension of Galderma. Our partners are expected to adhere to the spirit of the Code when working on Galderma's behalf, and we may terminate our relationships with them if they violate our standards. Those who oversee external partners must never ask them to take actions prohibited by our HCP Code, and must ensure that they are familiar with and trained in the relevant requirements of the HCP Code and all applicable laws and regulations.

DEFINITIONS

Healthcare professional or HCP: any member of the medical, dental, pharmacy or nursing professions or any other person or entity who in the course of his, her or its professional activities may prescribe, recommend, purchase, supply or administer a Product.

HCP Code: Galderma standards which all Galderma Entities must comply with as defined in this document.

Galderma Entities or Galderma: all Galderma entities including but not limited to the GBUs, the Regions, affiliates, R&D, Legal Affairs, Medical Affairs, Regulatory Affairs, M&TO, other global and local functions …

Galderma Products or Product: means all products and services marketed by Galderma.

Promotion: any activity undertaken, organised or sponsored by Galderma, or with its authority, which promotes to the HCPs the prescription, supply, sale, administration, recommendation or consumption of its products through all methods of communication.

RESPONSIBILITIES

Compliance with the HCP Code is the responsibility of everyone in Galderma.

Heads of Global Business Units, Heads of Global Functions, Heads of Regions and Country/General Managers are responsible for ensuring compliance with the HCP Code, in particular through the implementation and oversight of appropriate processes in their respective areas of responsibility either at global, regional or local level.

Legal Affairs is responsible for designing and implementing the HCP Compliance Program.

JOINT PRINCIPLES FOR ALL ACTIVITIES

COMPLIANCE WITH LAWS, REGULATIONS AND INDUSTRY CODES

The HCP Code governs interactions with HCPs around the world. It defines global standards applied by Galderma for the most common practices.
All interactions must comply with applicable local laws, regulations and industry codes, as well as with any Galderma policies & procedures. In the event of a conflict between the HCP Code and local applicable laws, regulations and industry codes or any Galderma policies & procedures, the more restrictive provision applies.

KEY PRINCIPLES

Independence of the HCP's medical judgment
It is our duty to preserve the integrity of HCP-patient relationship. Galderma's interactions with HCPs must be consistent with the responsibilities HCPs have to their patients and customers. They will at all times be ethical, appropriate and professional. Nothing should be offered or provided in a manner or on conditions that would have an inappropriate or improper influence.

Purpose of the interaction
The ultimate purpose of interactions with HCPs is to enhance patient care and/or the practice of medicine. When promoting our Products our interactions should be focusing on

informing HCPs about our Products, providing scientific and educational information and supporting medical education.

Transparency
In accordance with applicable transparency regulations, industry codes and/or Galderma policies, interactions with and transfers of value to HCPs must be disclosed accordingly.

In addition, when interacting with HCPs employed or affiliated to governments, regulatory authorities or public institutions or otherwise subject to external requirements, Galderma Entity must comply with any specific requirements set by applicable regulations or industry codes.

Separation between promotion and non-promotion
Interactions which have the objective to promote products must be openly considered as promotion, not disguised and must be managed accordingly.

Interactions which are conducted to obtain scientific data, receive knowledge enhancing data or foster scientific exchange must be managed and structured accordingly and must not have the promotion of products as their purpose. Such non-promotional activities include clinical studies, advisory boards, scientific and regulatory consultations, market research, publication, scholarship, scientific presentations at congresses, donations, grants…

1. PROMOTIONAL MATERIAL

TRUTHFUL AND NOT MISLEADING PROMOTION
Promotion must be accurate, balanced, fair, objective and sufficiently complete to enable the HCP to form his or her own opinion of the therapeutic, corrective or cosmetic value of the product concerned. It should be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It must not mislead by distortion, exaggeration, undue emphasis, omission or in any other way.
All promotional claims must be supported by evidence which must be promptly provided in response to reasonable requests from HCPs. In particular, promotional claims about efficacy, safety and tolerability must reflect available evidence or be capable of substantiation by clinical experience and data.

TRANSPARENCY OF PROMOTION
Promotion must not be disguised.

Clinical assessments, post-marketing surveillance and experience programmes and post-authorization studies (including those that are retrospective in nature) must not be disguised promotion. Such assessments, programmes and studies must be conducted with a primarily scientific or educational purpose.
Material relating to Galderma Products and their use, whether promotional in nature or not, must clearly indicate that it has been sponsored by Galderma.

Promotional material – Relation between global and local review/approval

- All promotional materials created at a global level need to be reviewed and approved on global level in accordance with the relevant policies and procedures prior to dissemination

- All promotional materials either created globally or locally need, prior to local use, to be reviewed and approved locally in order to comply with local regulations.

Each Galderma entity must have policies and procedures in place for the review and approval of promotional materials. These procedures must include as a minimum standard, representatives of Regulatory Affairs and Medical Affairs.

Medicines: no pre-approval and off-label promotion

A medicinal product must not be promoted in a territory prior to the grant of the marketing authorization or required approval allowing its sale or supply in that territory. Medicinal products must only be promoted for uses as approved by the local authorities and as stipulated on the label.

Promotion must be consistent with the particulars listed in the approved labelling documents (SmPC, PI, etc…) of the relevant medicine.

Medical devices: no pre-approval and off-label promotion

Medical devices must not be promoted prior to their approval by the relevant regulatory body. In the event of specific needs and only if authorised by local regulations, a case by case decision may authorise pre-approval promotion. Such decision requires approval by Regulatory Affairs and Legal Affairs.

Promotion must be consistent with the particulars listed in the approved labelling documents (Instructions for Use or similar) of the relevant device.

Cosmetics and food supplements: no pre-approval and off-label promotion

Cosmetics and food supplements must not be promoted prior to their approval by the relevant regulatory body. In the event of specific needs and only if authorised by local regulations a case by case decision may authorise pre-approval promotion. Such decision will need to be approved by Regulatory Affairs and Legal Affairs.

Promotion must be consistent with the particulars listed in the approved labelling documents (packaging) of the relevant product.

In addition to the requirements mentioned above, all products must only be promoted using messaging and information approved in accordance with the locally applicable procedure for approving promotional and marketing materials. At least, this means approval by Regulatory Affairs.

SALES REPRESENTATIVES

Each Galderma Entity shall ensure that its Sales Representatives and any other company representatives who call on HCPs, pharmacies, hospitals or other healthcare facilities in connection with the promotion of Products ("Sales Representative") are familiar with the relevant requirements of the HCP Code, local regulations/industry codes and are adequately trained and have sufficient scientific knowledge to be able to provide precise and complete information about the Products they promote.

a. Sales Representatives must comply with all relevant requirements set forth in the HCP Code, applicable laws/regulations, industry codes, and Galderma policies and procedures;

b. Sales Representatives must approach their duties responsibly and ethically;

c. Sales Representatives must not discuss potential scientific collaborations with HCPs (i.e Investigator Initiated Trials...). They must refer such discussions to the appropriate functions (i.e Medical Affairs, R&D...).

2. EVENTS

The purpose of all promotional, scientific or professional meetings, congresses, conferences, symposia, satellite symposia, and other similar events organised or sponsored by Galderma ("Events") should be to provide scientific or educational information and/or inform HCPs about Galderma products.

The following requirements must be complied with:

Appropriate Venue
Events must be held in an appropriate venue that is conducive to the scientific or educational objectives and the purposes of the event.

An "appropriate venue" is a geographic location in or near a town which is a recognised scientific or business centre, suitable for hosting an Event, which is conducive to the exchange of ideas and the transmission of knowledge. It should provide ease of access (for example, close proximity to airports, train stations and highways) and have a good ground transportation infrastructure. The geographic location selected should not be the main attraction of the Event. Galderma Entities must consider at all times the image and the perception that may be projected to the public by their choice of location.

Galderma must avoid using venues that are "renowned" for their entertainment or are "extravagant".

Sponsorships of HCPs
If permitted by the regulations/industry codes of the country where the HCP carries out his/her profession, Galderma may sponsor HCPs to attend Events that meet the requirements set forth above.
Sponsorship is limited to reasonable travel, meals, accommodation and registration fees.

No financial support to spouses or guests
Galderma must not pay for any costs associated with persons accompanying HCPs (spouses, partners or other guests of the HCP) unless they are qualified in their own right to attend.

For international Events, the sponsorship of an HCP is subject to the rules of the country where such HCP carries out his/her profession. The rules of the country in which the international Event takes place may also need to be taken into account.

Modest meals
When Galderma organises an Event refreshments and/or meals incidental to the main purpose of the meeting may be provided. The purpose of the meeting must be to provide scientific or educational information relating to Galderma's products or therapeutic areas.

Refreshments and/or meals offered to HCPs should be moderate and reasonable as judged by local standards. Galderma must not pay for any costs associated with persons

accompanying HCPs (spouses, partners or other guests of the HCP) unless they are qualified in their own right to attend.
Expenses must be appropriately reported in accordance with local procedures.

No entertainment
Galderma must not pay for or provide any entertainment or leisure activities (golfing, attendance at sporting events, theatres, concerts, vouchers…).

Each Galderma Entity must have in place policies and procedure for the review and approval of Events to ensure compliance with the HCP Code and local requirements.

International Event
A Galderma Entity may organise an Event outside the home country if:
- a significant portion of the invited HCPs are from outside the Galderma's Entity country and it makes greater logistical or security sense to hold the event in another country; or
- the relevant resource or expertise that is the object or subject matter of the event is located outside the country of the Galderma Entity

Any hospitality, promotional items, or medically relevant items must be in compliance with local law/applicable industry code and local Galderma standards (i.e requirements of the country where the event takes place, the "host country"). If applicable, requirements of the country in which the HCP practices will also need to be complied with.

International Events must be organised by qualified representatives and in compliance with Galderma policies & procedures.

Third party conferences (Non- Galderma events)
Galderma Entities may support independent educational and scientific conferences and meetings. The purpose of such third party events must be to provide scientific or educational information. Such conferences should be generally recognised and respected within the medical community and relate to Galderma therapeutic areas. Such support must be disclosed, as required.
Hospitality provided in connection to the event must be appropriate as defined in the HCP Code and will not include Galderma support or organisation of entertainment events (i.e leisure, sporting, theatres…).

Each Galderma Entity must have in place policies and procedure for the review and approval of sponsorship of third party conferences to ensure compliance with the HCP Code and applicable local requirements.

3. SPEAKERS

Galderma Entities may engage HCPs to speak at Events. The purpose of such engagement is to share scientific/educational information relating to Galderma Products or relevant therapeutic area.

Requirements regarding selection of HCPs, fees reflecting fair market value, contracts, payment of expenses as set forth below under section 7 “Consultants and Advisory Boards” must be complied with.

Each Galderma Entity must have a policy and procedure in place to ensure compliance with these requirements including notably the approval process, template agreements, and guidance on fair market value in the relevant market/BU.

4. EDUCATIONAL ITEMS AND GIFTS

Except in the limited circumstances mentioned below, gifts to HCPs are prohibited.

It is prohibited to give items such as cash or cash equivalents (such as gifts certificates). In addition, except for the limited exception of courtesy gifts mentioned below, giving personal items (such as sporting, entertainment tickets…) is also forbidden.

I**f authorised by local regulations/industry codes** where the HCP practises**,** educational items may occasionally be offered to HCPs only if they are **inexpensive** and **relevant to the practice of medicine or pharmacy**. Items may include for example an anatomical model for use in an examination room, or medical textbooks, as both primarily involve a patient benefit. Items should not be offered on more than an occasional basis, even if each individual item is appropriate.

Local regulations/industry codes may also authorise giving small inexpensive items such as pens, mouse pads, notepads…

Courtesy gifts: In certain countries, if allowed under local law and in accordance with local practice, an inexpensive customary gift not related to the practice of medicine may be given on an **exceptional** basis to an HCP as part of customary interactions with HCPs. However, even in these circumstances such gifts may not be provided on occasions when it could be perceived as interfering with the independence of a HCP’s decision to prescribe, recommend or purchase Products.

Each Galderma Entity must have a policy and procedure in place to cover this topic. In markets where local regulations/industry codes allow the giving of educational items or courtesy gifts the Galderma Entity must provide guidance on this topic (notably what is considered inexpensive, maximum amounts for such items, what is an educational item and the approval/documentation process).

The description and purpose of all items given must be documented and approved through an appropriate authorisation process.

5. SAMPLES

A sample is a unit of a medicine, device, or cosmetic product that is not intended to be sold and is intended for HCP or consumer education, training, evaluation or demonstration purposes.

Free samples of Products may be provided to HCPs in accordance with applicable regulations/industry codes. Different standards will apply depending on whether the product is a prescription product or a non-prescription product or whether it is a medicine, a medical device, a cosmetic product or is governed by another regulatory status.

Free samples may be provided to HCPs for distribution to their patients but only in accordance with local regulations/industry codes and if such local standards allow this. In certain cases local regulations/industry codes may authorise the provision of samples for the HCP's use.

In all cases however product samples are provided so that patients and/or their HCPs may familiarise themselves with the Products.

Galderma Entities may provide samples of Products only to HCPs who are licensed and authorised to receive such sample.

Samples may not be sold or purchased.

If required locally, samples must be marked "free sample" – not for sale" or words to that effect (in accordance with local requirements) and, as appropriate, must be accompanied by a copy of the approved product labelling.

Galderma Entities must have a policy and procedure in place to cover this topic and have in place adequate systems of control and accountability for samples that are distributed.

6. CLINICAL TRIALS

When contracting for research and development (R&D) services, there must be a written agreement concluded prior to the initiation of the services specifying all services to be provided and a written protocol for a genuine R&D purpose. Well-defined milestones and deliverables must be documented in detail.

The research should be legitimate scientific work, meaning Galderma has a pre-determined legitimate need for the information or data expected to result from the work. Selection of the HCP should be made on the basis of qualifications and expertise to address the identified purpose.

The research funding should not be linked to or contingent upon past, present or future prescription of Products by the HCP.

R&D Agreements must be approved by the administration/management of the institution with which the HCP is affiliated.

Fees paid to HCP should be consistent with fair market value for the services provided and must be documented.

There should be a defined plan for the use of such results as Galderma is entitled to under the R&D agreement.

Galderma will only pay for expenses (accommodation, meals, travel…) which are reasonable, comply with applicable local regulations/industry codes and incurred by the HCP in the framework of its assignment.

7. CONSULTANTS AND ADVISORY BOARDS

The purpose of engaging HCPs as consultants or members of advisory boards is to obtain expert advice and specific knowledge enhancing information. Service agreements must be entered only where a legitimate need for the services has been clearly identified in advance of requesting the services.

The selection criteria of the consultants must be directly related to the identified need and the Galderma employees responsible for selecting the consultants must have the necessary expertise to evaluate whether the particular HCPs meet those criteria.

The number of HCPs retained to provide services must not be greater than the number reasonably necessary to achieve the identified need.

Services agreements
A written contract must be agreed in advance of the provision of the services and entered into prior to the start of the services and payment. The contract must specify the nature of all services to be provided and the fees. In addition to the contract, Galderma Entity must maintain adequate records documenting the selection of the HCPs, use of the services provided and follow-up and reasonableness of the fees paid.

Compensation may not exceed fair market value of the services provided.
The compensation for the services should be reasonable and reflect the fair market value of the services provided.
The following objective criteria should be taken into account in determining the fair market value: expertise and reputation of the HCP (i.e national, regional, international reputation), qualifications (including number of publications), tasks, type of meeting (i.e board of experts, symposium, round table…) and responsibilities assigned (i.e chairman, co-chairman, speaker…), in certain cases experience with the use of a Galderma products (specifically for A&C activities), available benchmarking from independent external resources…

In all cases the engagement of an HCP to provide services must not be an inducement to recommend, prescribe, purchase, supply, sell or administer a Product.

Galderma will only pay for expenses (accommodation, meals, travel…) which are reasonable, comply with applicable local regulations/industry codes and incurred by the HCP in the framework of its assignment.

Each Galderma Entity must have a policy and procedure in place to ensure compliance with these requirements including notably the approval process, template agreements, and guidance on fair market value in the relevant market/BU.

8. MEDICAL AND SCIENTIFIC INFORMATION

The exchange of medical and scientific information covers the exchange of information either in a non-promotional context (i.e publications, exchange related to Galderma sponsored clinical trials…) or in response to an unsolicited query from an HCP. It excludes the communication of any promotional information.

Such exchange must only be managed by Galderma's Medical Departments.

9. GRANTS AND CHARITABLE CONTRIBUTIONS

Grants

- Grants (in cash or in kind or otherwise) to recognized medical associations, societies, institutions, academies, and other related healthcare organizations (i.e hospital, foundation, university or other teaching institution, learned society…) are only allowed if: (i) they are made for the purpose of supporting healthcare or research; (ii) they are documented and kept on record by the grantor; and (iii) they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer products.
- Such healthcare organisations should be recognised for being able to conduct bona-fide research or education.
- No grants may be made to individual HCPs

Charitable contributions

- Galderma may make charitable contributions to reputable healthcare or healthcare related organisations for altruistic and charitable purposes. The purpose is to support educational or health-related causes/projects with an affinity to Galderma's missions in the field of healthcare or to support initiatives in communities where Galderma has a presence.
- Such contributions must be documented and kept on record and must not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer products.
- No charitable contributions may be made to individual HCPs.

Requests for funding are reviewed on their merits and in accordance with applicable laws and regulations and industry codes.

Each Galderma entity must have a policy and procedure in place for the review and approval of grants and charitable contributions in line with the standard set at global level.

10. TRANSPARENCY OBLIGATIONS

Galderma Entities must comply with all applicable international and local regulations/industry requirements regarding the reporting and disclosure of interactions with HCPs and healthcare organisations as set forth in Galderma policies & procedures.

STANDARDS FOR CERTAIN SPECIFIC BU ACTIVITIES

A&C GBU

a) Injection training sessions

As part of the safe and effective use of Galderma A&C products, Galderma Entity may facilitate the training of HCPs by other HCPs ("HCP Trainers").

If the educational meeting requires "hands on" training in medical procedures it must be held at a training facility, medical institution or other appropriate facility which offers an adequate safety and medical environment (for example, a medical practice or a clinic).

The injection training will be under the medical responsibility of the HCP(s) Trainers.

The HCP Trainers must be authorised to perform injections in the country where the training session takes place. The HCP must be qualified to provide instruction on the particular subject and demonstration of the products that are utilized in the training session. If the HCP Trainer is not practicing in the local geographic area where the subject (patient) resides a local physician of record must be involved in all aspects of the consultation process, supervision of the trainer's actions, and provide medical follow up to the subject.

Training sessions involving volunteer subjects as patients for assessment and treatment must be organised by qualified Galderma staff members and the activities conducted in compliance with Galderma's Medical Affairs guidance documents.

b) Customer Support Services

A Galderma Entity may offer customer support services that are intended to help an HCP integrate Galderma A&C products into its practice and improve patient management capabilities.

The selection of HCPs who are offered customer support services should be based on objective pre-determined criteria.

TRAINING

It is the responsibility of each head of Galderma Entity, in close cooperation with Legal Affairs, to ensure that Galderma associates under its responsibility are regularly trained on the HCP Code and local requirements. Training sessions should be periodically held.

Evidence of such training (including consultation of Legal Affairs) and attendance must be retained for audit purposes.

REPORTING

Any **compliance issue** or **compliance concern** (violation of the provisions of the HCP Code or suspicion of a violation based on evidence, signs that a violation could be or has been occurring) should be promptly reported using the following channels:

- To the Ethics Council as instructed by the Code of Ethics, or
- To Legal Affairs, or
- If applicable, to a local internal compliance representative or committee. In this last case the issue or concern must also be reported either to the Ethics Council or to Legal Affairs

MONITORING

It is the responsibility of each head of Galderma Entity, in close cooperation with Legal Affairs and Internal Control to put in place appropriate processes to regularly monitor compliance with the HCP Code and also set frequency for such monitoring.

INVESTIGATIONS

The reporting of a compliance concern or issue will be followed by an appropriate, fair and thorough investigation as set forth in the Code of Ethics. The investigation will be under the lead of Legal Affairs.

OVERALL REQUIREMENTS

For all requirements set forth in this HCP Code, Galderma Entities must retain evidence of Legal Affairs sign off on each policy and procedure put in place.

EXCEPTIONS

The Ethics Council may grant exceptions. No exceptions can be granted from compliance with applicable laws and regulations.