Swiss Infant Nutrition Association SINA

VERHALTENSCODEX ÜBER DIE VERMARKTUNG VON

Säuglingsanfangs- und Folgenahrung (0-12 Monate)

Stand: 5. November 2024

WARUM EIN VERHALTENSCODEX?

1981 hat die WHO (World Health Organisation) zusammen mit Herstellern, NGOs und Regierungsvertretern den International Code of Marketing ausgearbeitet. Seither wird dieser Code regelmässig mit Resolutionen von der WHA (World Health Assembly) aktualisiert.

Die Schweiz hat Teile des WHO International Code in die nationale Gesetzgebung übernommen. Zudem befolgen die Unternehmungen, die Säuglingsanfangs- und Folgenahrung (0-12 Monate) herstellen und in der Schweiz verkaufen, seit vielen Jahren Verhaltensregeln. Diese Verhaltensregeln wurden in einem "Verhaltenscodex der Hersteller von Muttermilch-Ersatzpräparaten" festgehalten, welcher erstmals im Jahr 1982 unterzeichnet wurde. Der Verhaltenscodex trug den Empfehlungen der Schweiz. Gesellschaft für Pädiatrie von 1977 und dem WHO International Code Rechnung und wurde in Zusammenarbeit mit (heute) Stillförderung Schweiz und in Absprache mit der Schweiz. Gesellschaft für Pädiatrie (SGP) und dem Bundesamt für Gesundheit (BAG) erstellt. Die revidierte Ausgabe 1994 berücksichtigte die seitherigen Entwicklungen, insbesondere die an die Mitgliedstaaten gerichtete Resolution der WHO von 1986 betreffend die Belieferung der Spitäler mit Gratisware (WHA 39.28), die EU-Richtlinie vom 14. Mai 1991 über Säuglingsanfangsnahrungen und Folgenahrungen (91/321/EWG), die WHO-Resolution von 1992 betreffend die von den Herstellern weltweit unterstützte "Baby-Friendly-Hospital"-Initiative (WHA 45.34) und die WHO-Resolution vom Mai 1994 (WHA 47.5). Der Verhaltungskodex wurde 2017 an die Änderungen im Schweizer Lebensmittelrecht angepasst und in 2021 erweitert und überarbeitet.

Die Vorgaben betreffend Werbung für Säuglingsanfangsnahrung sind im Gesetz (LGV[1] und VLBE[2]) festgehalten. Die vorliegende Fassung des Verhaltenscodex von 2022 beinhaltet Bemerkungen zum Umsetzen des schweizerischen Rechts und weitere Verhaltensregeln.

Die im Anhang aufgeführten Unternehmen verpflichten sich, den vorliegenden Verhaltenscodex einzuhalten und dessen Einhaltung durch alle ihre Mitarbeiter bei sämtlichen Aktivitäten des Verkaufs, der Werbung und der Verkaufsförderung für Säuglingsanfangs- und Folgenahrung (0-12 Monate) zu überwachen.

Die Einhaltung des Verhaltenscodex wird seit 1995 durch ein paritätisch zusammengesetztes Codex-Panel überwacht, in welchem die Stillförderung Schweiz mit verschiedenen Berufsverbänden (SGP, BSS, SHV, SF MVB) und Organisationen (UNICEF, LLL, GIFA), die sich dem Schutz des Stillens verpflichtet haben (Allianz WHO-Kodex), und die Hersteller vertreten sind. Die Arbeitsweise des Panels ist schriftlich festgehalten.

[1] LGV, SR 817.02

[2] VLBE, SR 817.022.104

In diesem Dokument sind die verabschiedeten und aktuell für die SINA geltenden Verhaltensregeln festgehalten. Von der Allianz WHO Kodex bestehen weitere Forderungen zur Erweiterung des Verhaltenskodex, die in einem Arbeitsdokument beschrieben sind. Das Arbeitsdokument wird im Codex Panel fortlaufend diskutiert mit dem Ziel, den Verhaltenskodex fortzuentwickeln.

GRUNDSÄTZE

- Die Muttermilch ist die natürliche Ernährung des Säuglings. Das Stillen soll gefördert und geschützt werden. Die WHO empfiehlt sechs Monate ausschliessliches Stillen und begleitend zur Beikost Weiterstillen bis zu zwei Jahren und darüber hinaus (WHA Resolution 54.2, 2001). Die Eltern sollen informiert werden, dass die Muttermilch eine vollumfängliche und ausreichende Nahrung ist und Säuglingsanfangsnahrung in den ersten Monaten die einzige Alternative dazu darstellt.
- Dem Fachpersonal des Gesundheitswesens (Ärzte und Ärztinnen, Apotheker und Drogisten, Hebammen, Stillberaterinnen, Mütter-VäterberaterInnen, Pflegefachpersonen etc.) obliegt in erster Linie die Verantwortung, die Eltern über die Ernährung ihres Säuglings zu informieren und zu beraten. Falls die Ernährung mit Muttermilch nicht möglich ist, empfehlen sie die altersgerechte Säuglingsanfangs- oder Folgenahrung.

1. Geltungsbereich

Der Verhaltenscodex bezieht sich auf Säuglingsanfangs- und Folgenahrung (0-12 Monate).

2. Werbung allgemein

2.1. Umsetzung des Werbeverbots für Säuglingsanfangsnahrung

LGV, Art. 41

[1]Die Werbung für Säuglingsanfangsnahrung darf nur in wissenschaftlichen Publikationen und in solchen, die der Säuglingspflege gewidmet sind, erscheinen.

[2] Sie darf nur wissenschaftliche und sachbezogene Informationen erhalten. Diese Information darf nicht implizieren oder suggerieren, dass Flaschennahrung der Muttermilch gleichwertig oder überlegen ist.

Erläuterungen und Interpretationen:

- Unter wissenschaftlichen Publikationen fallen Publikationen, die eindeutig an Fachpersonen gerichtet sind.
- Auch in Publikationen, die zwar der Säuglingspflege gewidmet sind, sich aber eindeutig an Eltern richten, halten sich die SINA-Mitglieder an die üblichen Werbebeschränkungen.
- Informationen über Säuglingsanfangsnahrungen, insbesondere in den an Eltern gerichtete Informationsbroschüren der Firmen, auf den Internetseiten der Firmen und in Mailings sind so zu gestalten, dass sie in keiner Weise die Mutter vom Stillen abhalten.
- In der Werbung werden keine Schoppenszenen abgebildet (auch nicht Vater/Kind-Szenen).
- In sämtlichen Mitteilungen an die Eltern, die sich auf die Verwendung der Säuglingsanfangsnahrungen beziehen, ist unter dem Titel "Wichtiger Hinweis" auf die Beratung durch Fachpersonen des Gesundheitswesens (Ärztin/Arzt, Hebamme, Stillberaterin, Mütter-

Väterberaterin) für die Ernährung des Säuglings hinzuweisen und die Überlegenheit der Muttermilch hervorzuheben. Das Codex-Panel legt den Wortlaut fest.

Die Hersteller erwähnen in der Kommunikation als Ergänzung zum "Wichtigen Hinweis", dass die WHO ausschliessliches Stillen während 6 Monaten empfiehlt. Das Codex-Panel legt den einheitlichen Wortlaut fest.

Die kostenlose oder verbilligte Abgabe von Erzeugnissen, Proben und anderer Werbegeschenke ist nach LGV Art.41 Abs. 4 verboten:

LGV Art. 41
[4]*Das Verteilen kostenloser oder verbilligter Erzeugnisse, Proben oder anderer Werbegeschenke an die Bevölkerung, insbesondere an schwangere Frauen, Mütter und deren Familienmitglieder, sei es direkt oder indirekt über Institutionen des Gesundheitswesens oder Beratungsstellen, ist verboten.*

Erläuterungen und Interpretationen:

- Die Hersteller setzen sich gegenüber ihren Handelspartnern dafür ein, dass der Einzelhandel das Verbot gemäss LGV Art. 41 Abs. 4 respektiert.
- Portionenbeutel von Säuglingsanfangsnahrungen dürfen nicht als "Muster“ oder "Gratismuster" gekennzeichnet werden. Sie sind den Endverbrauchern und dem Fachpersonal (Ärztin/Arzt, Hebamme, Stillberaterin, Mütter-Väterberaterin) und den Spitälern, Kliniken und ähnlichen Institutionen zu einem Preis zu verkaufen, der mindestens dem Preis pro kg des Referenzproduktes im Handel entspricht.

2.2. Freiwillige Beschränkung der Werbung für Folgenahrung (6-12 Monate)

- Die Hersteller verweisen auch in der Werbung im Detailhandel und auf der Verpackung für Folgenahrungen, die ab dem 6. Monat empfohlen werden, auf die Vorteile des Stillens mit dem „Wichtigen Hinweis“.
- In der Werbung für Folgenahrungen werden nur Bilder von Kindern verwendet, die sichtbar älter als 6 Monate sind.
- Abgabe von Mustern von Folgemilchen nur auf Anfrage oder Bestellung
- Kein aktives Anschreiben von Eltern mit Werbung (z.B. Gutscheine) für Kinder vor 6 Monaten, ausser zur Information auf Anfrage
- Bis auf Weiteres erfolgt keine TV-Werbung für Folgenahrung (6-12 Monate).

3. Werbung für Säuglingsanfangsnahrung im Detailhandel und über Fernkommunikation

Die Werbung für Säuglingsanfangsnahrungen ist gemäss LGV Art. 41 Abs. 3 verboten.

LGV Art. 41
[3]*Werbung mit der die Konsumentinnen und Konsumenten direkt zum Kauf von Säuglingsanfangsnahrung angeregt werden sollen, wie das Verteilen von Proben, Rabattmarken, Zugabeartikeln oder Lockartikeln, sowie andere Werbemittel, die diesem Ziel dienen, wie besondere Auslagen, Sonderangebote oder Koppelungsgeschäfte, sind verboten. Dieses Verbot gilt analog auch für die Fernkommunikation.*

Erläuterungen und Interpretationen:

- Die Hersteller setzen sich gegenüber ihren Handelspartnern dafür ein, dass der Einzelhandel das Werbeverbot gemäss LGV Art. 41 Abs. 3 respektiert.
- Bei der Präsentation eines gesamten Sortiments in Schaufenstern von Einzelverkaufsgeschäften verzichten die Hersteller auf die Auslage oder Abbildung von Säuglingsanfangsnahrungen.
- Werden Treueprämien (z.B. Sammelpunkte) auf Kindernährmitteln abgegeben, so sind Säuglingsanfangsnahrungen davon auszunehmen.

4. Etikettierung

Die Etikettierung von Säuglingsanfangsnahrungen richtet sich nach Art. 7 und 8 VLBE und den allgemeinen Bestimmungen der Verordnung des EDI betreffend die Informationen über Lebensmittel (LIV)[3]. VLBE Art. 7 Abs. 3 und 5 enthalten die folgenden für den Schutz des Stillens relevanten Bestimmungen:

VLBE Art. 7 Abs. 3 und 5

[3] Die Angaben auf der Packung oder der Etikette müssen zusätzlich zu den Angaben nach Art. 4 Abs. 1 enthalten:

d. eine Angabe wie «Wichtiger Hinweis», gefolgt von:

1. einem Hinweis, dass das Stillen der Verabreichung von Säuglingsanfangsnahrung überlegen ist, und

2. der Empfehlung, das Erzeugnis nur auf den Rat unabhängiger Fachleute auf dem Gebiet der Medizin, der Ernährung, der Pharmazie oder der Säuglings- und Kleinkinderpflege zu verwenden.

[5] nicht zulässig sind:

a. das Kennzeichnen von Säuglingsanfangsnahrung in einer Weise, die vom Stillen abhalten könnte,

b. Bilder von Säuglingen, andere Bilder oder einen Wortlaut, die den Gebrauch dieser Nahrung idealisieren könnten,

c. die Verwendung von Begriffen wie „humanisiert“, „maternisiert“ oder „adaptiert“

Erläuterungen und Interpretationen:

- Das Codex-Panel legt den durch die Hersteller zu verwendenden Wortlaut des "Wichtigen Hinweises" fest. (Anhang 1)
- Das Codex-Panel erstellt zu Art. 7 Abs. 5 VLBE eine Liste der Codex-konformen Formulierungen und der nicht-konformen Formulierungen. (Anhang 1)

5. Beziehungen zum medizinischen Fachpersonal (Ärztin/Arzt, Hebamme, Stillberaterin, Mütterberaterin), zu Spitälern, Kliniken und ähnlichen Institutionen

5.1. Alle für das medizinische Fachpersonal und für die Spitäler, Kliniken und ähnliche Institutionen bestimmten Informationen bezüglich des Produktes, seiner Zusammensetzung, seiner Eigenschaften und seiner Verwendung sollen sachlich sein und dürfen nicht den Eindruck erwecken, die Flaschenernährung sei dem Stillen überlegen oder gleichwertig.

[3] SR 817.022.16

5.2. Das medizinische Fachpersonal entscheidet unabhängig und nach Indikation über die Verwendung von Säuglingsanfangsnahrungen im Spital, damit sichergestellt ist, dass die Mutter in keiner Weise vom Stillen abgehalten wird.

5.3. Jegliches Verhalten ist zu unterlassen, das geeignet ist, den freien und unabhängigen Entscheid des medizinischen Fachpersonals bei der Erstellung des Ernährungsplanes für den Säugling oder in der Beratung der Mütter einzuengen oder zu beeinflussen.

5.4. Insbesondere darf nicht mit direkten oder indirekten Geld- und Sachzuwendungen, ein moralischer Zwang zur Empfehlung oder Verwendung von Säuglingsanfangsnahrungen eines bestimmten Herstellers ausgeübt werden.

5.5. Alle Lieferungen von Säuglingsanfangsnahrungen – sei es zum Zweck des Eigengebrauchs oder zur Abgabe an austretende Mütter –an Spitäler, Kliniken und andere Institutionen, werden fakturiert.

5.6. In der Planung und Durchführung von klinischen Studien mit Beteiligung von Institutionen des Gesundheitswesens (u.a. Kliniken) wird der Schutz des Stillens respektiert und sichergestellt, dass die Grundsätze des Verhaltenscodex auch bei Forschungsprojekten zur Anwendung kommen. Insbesondere wird sichergestellt, dass die Forschungsprojekte nicht das Recht der Eltern auf informierte Entscheidungen und die institutionellen Prozesse zum Schutz des Stillens beeinträchtigen.

5.7 Der SNE (Specialised Nutrition Europe)[4] Code of Practice «Best practices for interactions between the infant nutrition industry and healthcare professionals and healthcare organisations» vom Juli 2023 (Anhang 2) ist integrierender Bestandteil dieses Verhaltenscodex. Sollte es einen Widerspruch zwischen dem nationalen Verhaltenskodex und dem SNE Code of Practice geben, gilt die strengere Verhaltensregelung.

6. Weitergehende Verpflichtungen

6.1. In Ernährungstabellen (Ernährungsplänen), welche die Säuglingsernährung im zeitlichen Ablauf darstellen, ist stets an erster Stelle ab Geburt auf die Muttermilch hinzuweisen.

6.2. Der Ausdruck „Schoppenzusatz“ bei Getreidebeikost wird nicht verwendet. Bei den Zubereitungshinweisen bis 6 Monate wird auf eine Anleitung für eine entsprechende Zubereitung verzichtet.

7. Monitoring der Einhaltung des Codex

7.1. Zur Überwachung der Einhaltung des Verhaltenscodex wird ein paritätisch aus Vertreterinnen und Vertretern von Stillförderung Schweiz und der Hersteller zusammengesetztes "Codex-Panel" eingesetzt.

7.2. Das Panel beurteilt selber festgestellte oder ihm von dritter Seite gemeldete Verhaltensweisen, die eine Verletzung der vorstehenden Bestimmungen darstellen könnten.

7.3. Das Panel nimmt die erforderlichen Abklärungen vor, gibt den betroffenen Firmen Empfehlungen zur Anpassung ihrer Verhaltensweisen ab und setzt für deren Umsetzung angemessene Fristen.

[4] SINA ist via SANI Mitglied des europäischen Dachverbands SNE.

7.4. Das Panel informiert die Öffentlichkeit periodisch über das Ergebnis der Überwachung und die Befolgung seiner Empfehlungen.

7.5. Der Vollzug der lebensmittelrechtlichen Bestimmungen durch die zuständigen kantonalen Organe bleibt vorbehalten.

Der vorliegende Verhaltenscodex wurde von den nachfolgend aufgeführten Firmen unterzeichnet:

- Danone Schweiz AG, Zürich (1982)
- Nestlé Suisse SA, Vevey (1982)
- HiPP GmbH & Co. Vertrieb KG, Pfaffenhofen, Deutschland (1994)
- HOCHDORF Swiss Nutrition AG, Hochdorf (1994)
- holle baby food AG, Riehen (1994)

Anhang:

Anhang 1: *Wichtiger Hinweis, codex-konforme und -nicht-konforme Texte*

Anhang 2: *SNE Code of Practice «Best practices for interactions between the infant nutrition industry and healthcare professionals and healthcare organisations» vom Juli 2023*

Swiss Infant Nutrition Association SINA
Fachgruppe der www.sani.swiss / www.nutritionindustries.ch

Wichtiger Hinweis, codex-konforme und -nicht-konforme Texte

Stand November 2024

Dieses Dokument ergänzt Punkt 4 «Etikettierung» des VERHALTENSCODEX ÜBER DIE VERMARKTUNG VON Säuglingsanfangs- und Folgenahrung (0-12 Monate) Stand: 14. April 2022. Es legt den Wortlaut des durch die Hersteller verwendeten «Wichtigen Hinweis» gemäss Art. 7 Abs. 3 lit. d. VLBE fest und enthält eine Liste der Codex-konformen und nicht-konformen Formulierungen in Bezug auf Art. 7 Abs. 5 lit. c VLBE.

Wichtiger Hinweis

Der wichtige Hinweis richtet sich nach Art. 7 Abs. 3 lit. d. VLBE : « Die Angaben auf der Packung oder der Etikette müssen zusätzlich zu den Angaben nach Art. 4 Abs. 1 enthalten: […] eine Angabe wie «Wichtiger Hinweis», gefolgt von: 1. einem Hinweis, dass das Stillen der Verabreichung von Säuglingsanfangsnahrung überlegen ist, und 2. der Empfehlung, das Erzeugnis nur auf den Rat unabhängiger Fachleute auf dem Gebiet der Medizin, der Ernährung, der Pharmazie oder der Säuglings- und Kleinkinderpflege zu verwenden.» Der gemäss Codex Panel von den Herstellern zu verwendenden Wortlaut ist:

Deutsch	**Französisch**	**Italienisch**
WICHTIGER HINWEIS **Stillen ist ideal für Ihr Kind.** **Lassen Sie sich vom Fachpersonal des Gesundheitswesen beraten, wenn Sie dieses Produkt verwenden wollen.**	AVIS IMPORTANT **L'allaitement maternel est idéal pour votre enfant.** **Demandez conseil auprès d'un professionnel de santé si vous aimeriez utiliser ce produit.**	COMMUNICAZIONE IMPORTANTE **L'allattamento al seno è ideale per il suo bambino.** **Chieda consiglio al personale qualificato del servizio sanitario se desideri utilizzare questo prodotto.**

Codex-konforme Formulierungen

Die Vorgaben von Art. 7 Abs. 5 lit. c. VLBE werden vom Codex Panel als erfüllt angesehen bei der Verwendung der folgenden Formulierungen:

Deutsch	**Französisch**	**Italienisch**
Nach dem Vorbild der Muttermilch Dem Vorbild der Muttermilch nachgebildet Nimmt sich die Muttermilch als Vorbild	sur le modèle du lait maternel élaboré après le modèle du lait maternel en prenant le lait maternel comme modèle	All'esempio del latte materno elaborato all'esempio del latte materno prendendo l'esempio del latte materno

Nicht Codex konforme Formulierungen

Gemäss Art. 7 Abs. 5 lit. c VLBE: "[…] nicht zulässig sind: […] die Verwendung von Begriffen wie "humanisiert", "maternisiert" oder "adaptiert"". Folgende Formulierungen werden als gleichbedeutend und somit nicht-konform angesehen:

Deutsch	**FRANZÖSISCH**	**Italienisch**
der Muttermilch gleichwertig der Muttermilch gleichgestellt	équivalente au lait maternel analogue au lait maternel égal au lait maternel	equivalente al latte materno analogo al latte materno
Der Muttermilch nah	Similaire au lait maternel proche du lait maternel	Simile al latte materno
der Muttermilch sehr ähnlich	très proche du lait maternel très similaire au lait maternel	Quasi uguale al latte materno
der Muttermilch nachgebildet	calquée sur le lait maternel	Copiato al latte materno
der Muttermilch weitgehend angepasst	imite le lait maternel	Addattato al latte materno
dem Vorbild der Muttermilch sehr/besonders nahe der Muttermilch so nahe wie nie zuvor	selon la formule du lait maternel semblable au lait maternel à l'exemple du lait maternel	Molto simile al latte materno / Il più simile possibile al latte materno
Humanisiert	humanisé	umanizzato

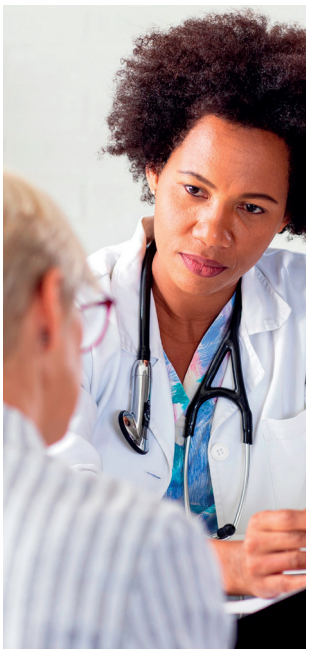
Maternisiert	maternisé	maternizzato
falls Sie nicht mehr stillen können	Au cas où vous ne pouvez pas allaiter	Nel caso lei non potesse allattare al seno
wenn es mit dem Stillen nicht klappt	Au cas où l'allaitement ne fonctionne pas	Nel caso l'allattamento al seno non funzionasse

Diese Liste ist nicht abschliessend.

SNE Specialised Nutrition Europe

SNE CODE OF PRACTICE

Best practices for interactions between the infant nutrition industry and healthcare professionals and healthcare organisations.



Published in July 2023

The SNE Code of Practice gathers best practices for SNE member associations and their member companies. Its objective is to guide the European infant nutrition industry to ensure that its interactions with healthcare professionals respect the highest ethical standards. The Code covers interactions organised or sponsored in the countries of SNE's member associations, by national association members, and addressed to healthcare professionals, healthcare organisations or health care facilities. Those interactions include the promotion of infant nutrition products to healthcare professionals, hospitality, gifts and grants, and lifelong learning activities.

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DEFINITIONS AND ABBREVIATIONS

SNE member associations means national associations represented by SNE and listed on the SNE website here: https://www.specialisednutritioneurope.eu/about-us/our-members-2/

Manufacturers means manufacturers of Products or companies that are members of an SNE member association.

Healthcare Facility means any facility where health care is provided to pregnant women, new mothers and infants. This includes facilities where Healthcare Professionals provide health care in private practice but does not include private homes or pharmacies or other established sales outlets.

Healthcare Professional (**HCP**) means any member of the medical, dental, pharmacy, midwifery, dietetic, nutrition and nursing professions, or students thereof, or any other person who may prescribe, purchase, supply, recommend or administer a nutritional or medicinal product. For the purpose of this definition, the terms "profession" or "professional" also refer to voluntary unpaid workers who provide healthcare services on a regular basis (i.e., not merely occasionally)

Healthcare Organisation (HCO) means any legal person/entity (i) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university, or other teaching institution or learned society, whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCPs provide services.

Label means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to the packaging or container of food.

Infant means a person from 0 to 12 months of age.

Products means the following products:

- **Infant Formula (IF)** means food used by Infants during the first months of life and satisfying by themselves the nutritional requirements of such Infants until the introduction of appropriate complementary feeding.
- **Follow-on Formula (FOF)** means food used by Infants when appropriate complementary feeding is introduced and constituting the principal liquid element in a progressively diversified diet of such Infants.
- **Foods for Special Medical Purposes intended for Infants (iFSMPs)** means foods specifically processed or formulated and intended for the dietary management of Infants, to be used under medical supervision. They are intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or metabolites, or with other medically determined nutrient requirements, whose dietary management cannot be achieved by modifications of the normal diet alone.

Product for Professional Evaluation (**PFPE**) means a small quantity of a Product provided at no cost to HCPs for the purpose of allowing them to become more familiar with a Product and, when relevant, and in particular in the case of an iFSMP, to evaluate a patient's tolerance, acceptability and clinical response.

Continuous Medical Education (CME) means certified educational programs which serve to maintain the professional certification of HCPs. For example, CME is accredited by certified providers such as The European Accreditation Council for CME (EACCME®).

Lifelong Learning in Specialised Nutrition & Healthcare means events, activities and initiatives (e.g., symposia) that are aimed at refreshing, updating or increasing the medical and scientific knowledge and competence of HCPs with the purpose of enhancing their healthcare practice and improving infant health outcomes. When relevant, and in particular as regards iFSMPs, these activities also cover topics such as the relevant medical condition and the safety, suitability and efficacy of the Product for that medical condition, as well as the evaluation of patients' tolerance, acceptability, and clinical response.

- Continuing Medical Education ("**CME")** is one of three categories (category 1) of Lifelong Learning in Specialised Nutrition & Healthcare. CME is usually organised under the direction and supervision of accredited providers such as professional societies, Healthcare Organisations, educational providers, or other independent stakeholders.
- Lifelong Learning through collaborations or partnerships is one of three categories (category 2) of Lifelong Learning in Specialised Nutrition & Healthcare. The collaborations or partnerships are between the national association members (e.g., Manufacturers) and independent providers led by professional societies, HCOs, educational providers, or other independent stakeholders.
- Lifelong Learning provided by the private sector is one of three categories (category 3) of Lifelong Learning in Specialised Nutrition & Healthcare. It may address human health, and disease-specific learning needs. These activities may involve HCPs, scientific committees, and/or independent scientific and professional organisations. Ownership, accountability and funding remains with the organisers of these activities.

Promotion means the dissemination of useful information to HCPs regarding Products and brands. This information may cover, for example, the characteristics of Products and brands, their intended use and conditions of use, and claims and health benefits. In the case of iFSMPs, it also covers information about Products of a factual and scientific nature to health care professionals in line with the provisions of Article 8 of Delegated Regulation (EU) 2016/128.

Promotional Material means any material, whether written, oral, or visual, intended to support the Promotion of Products and/or brands.

Educational and/or Informational Materials means any material, whether written, oral, or visual, that includes information which is intended for HCPs exclusively, with the purpose to provide them with new knowledge or skills or to refresh, or enhance their knowledge or skills about nutrition, healthcare, growth or development of infants, as well as the management of certain medical conditions as regards or in connection with nutrition. These materials are used at international and national congresses events / symposia and in health care facilities.

Research Activities means any laboratory research, clinical studies, health economic studies, market research and surveys regarding the Products.

1. PREAMBLE

1.1 The infant nutrition industry in Europe is represented by Specialised Nutrition Europe ("**SNE**"). SNE and the Manufacturers it represents via its member associations strongly support efforts to ensure that every infant has access to – and receives – optimal nutrition. While breastmilk is the best source of nutrition in early life, there are certain situations when breastfeeding might not be possible or might not be chosen by the parents. SNE and the Manufacturers acknowledge the importance and respect the aim and principles of the World Health Organisation's 1981 International Code of Marketing of Breast-Milk Substitutes ("WHO Code"). The stated aim of the WHO Code is *to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breastfeeding, and by ensuring the proper use of breast-milk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution.*

1.2 Through a continual process of research and development, the manufacturers work to innovate safe, nutritious and scientifically advanced foods to meet the special needs of Infants. The Manufacturers also develop specially formulated products to address specific nutritional requirements which are helping to improve treatments, survival rates and long-term outcomes of premature babies and infants who suffer from diseases, disorders or medical conditions.

1.3 SNE and the Manufacturers are committed to appropriate communication with Healthcare Professionals ("**HCPs**") directly or through HCPs' affiliate Healthcare Organisations ("**HCO**s") about Products for Infants in Europe. Appropriate communication enables HCPs to obtain accurate, science-based information on latest innovations, formulations and Products, thereby enabling HCPs to support caregivers in making appropriate nutritional choices for Infants who are healthy and those who suffer from diseases, disorders or medical conditions, in a manner that protects breastfeeding. SNE's position is further detailed on the SNE Website.[1]

1.4 SNE and the Manufacturers support the European Commission framework of making Europe an area of "Lifelong Learning",[2] which includes all learning activity undertaken throughout life, with the aim of improving knowledge, skills, competences within a personal, civic, social and/or employment related perspective.

1.5 Through adoption of this Code of Practice, SNE seeks to promote ethical and fair business practices that:

- are clear, unambiguous, and transparent;
- help advance infant nutrition and long-term health;
- encourage best practices by all Manufacturers and other parties with a commercial interest involved in the process of bringing to the consumers and the patients infant formula (IF), follow-on-formula (FOF) and foods for special medical purposes intended for infants (iFSMPs).

1.6 IF, FOF and iFSMPs constitute distinct product categories which are each subject to a different regulatory and legal framework. In particular, iFSMPs are specially formulated for the dietary management of a range of diseases, disorders, or medical conditions. Differences among the aforementioned categories are acknowledged in this Code.

1.7 In the interest of consumers and patients, HCPs should have access to the expertise which Manufacturers acquired when developing specialised foods for infants in order to ensure an appropriate use of these products and, as regards Food for Special Medical Purposes intended for infants, allow HCPs to assess properly the suitability of the Products for their intended use and to exercise appropriate medical supervision over the use of the Products.

1 SNE position paper "Scientific Dialogue is Essential" (October 2022)
2 See Communication from the EU Commission: Making a European Area of Lifelong Learning a Reality, 21 November 2001 (COM(2001) 678 final).

2. SCOPE

2.1 This Code of Practice lays down best practices for SNE member associations and their members.[3] It covers any interaction listed in this Code of Practice, organised or sponsored in the countries of SNE's member associations, by national association members (e.g. Manufacturers), and addressed to HCPs, HCOs or health care facilities regarding the following Products: (1) infant formula ("**IF**"); (2) Follow-on Formula ("**FOF**"); and (3) Foods for Special Medical Purposes intended for infants ("**iFSMP**").

2.2 Where indicated, some parts of this Code apply only to IF and FOF. The provisions of this Code of Conduct shall not prevent national association members (e.g., Manufacturers) from providing appropriate information about the Products to HCPs in order to ensure an appropriate use of the Products and, as regards iFSMPs, an adequate medical supervision. Furthermore, the provisions of this Code of Conduct shall not prevent HCPs from assessing the safety, efficacy and suitability of Products for their intended use in collaboration with Manufacturers.

2.3 National association members (e.g., Manufacturers) comply with applicable laws and regulations in the countries where they do business.

2.4 In the event of a conflict between any applicable laws and regulations and this Code, the laws and regulations shall prevail.

2.5 The SNE Code of Practice does not prevent the existence of national codes of practice. If there is any conflict between the national code of practice of an SNE member association and this SNE Code of Practice, the stricter recommendation or provision should prevail.

2.6 SNE and its member associations encourage competition and compliance with competition law and regulations among Manufacturers producing specialised nutrition for infants. The Code is not intended to address or regulate commercial terms and conditions relating to the price, sale and distribution of products and services by manufactures of specialised nutrition products, which must always be in compliance with applicable laws and regulations.

3 SNE members: https://www.specialisednutritioneurope.eu/about-us/our-members-2/

3. PROMOTION OF PRODUCTS TO HCPS

Manufacturers may promote Products by providing relevant information to healthcare professionals to assist in their decision-making. Materials and information must comply with local requirements in every country in which they are used or disseminated.

3.1 Acceptability of Promotion

SNE and national association members (e.g., Manufacturers) must maintain high ethical standards at all times. Promotion:

a. should not discredit or undermine confidence in the industry; and

b. must be of a nature which recognises the special nature of the Products and the professional standing of the intended audience.

c. must not discourage from breast-feeding or feeding breast milk to Infant

3.2 Promotion and its Substantiation

a. Promotion must be accurate, science-based, balanced, fair, objective and sufficiently complete to enable the HCP to form his/her own opinion of the value of the Products concerned. It must not mislead by distortion, exaggeration, undue emphasis, omission or in any other way.

b. Promotion must be transparent and must not be disguised.

c. Promotion must be capable of substantiation which must be promptly provided in response to reasonable requests from HCPs. In particular, statements must be based on, and reflect, available medical or scientific evidence.

d. When Promotion refers to published studies, clear references must be given.

e. Any comparison made between different Products must be based on relevant and comparable aspects of the Products and must not be misleading or disparaging.

f. Promotion must be consistent with the user information and recommendations on the label and the packaging of the Products.

3.3 Promotional Materials

a. Promotional Material relating to the Products must clearly indicate the company or organisation that commissioned the material.

b. Quotations from medical and scientific literature, from HCPs, as well as quotations from personal communications included in the Promotional Material must be faithfully reproduced and the precise source(s) identified.

c. Any written Promotional Material addressed to HCPs should include: (1) the date on which it was developed or last revised, (2) a statement that the material is for HCPs only; and (3) any other information required to identify the product and its intended use – for example for iFSMPs the target patient population.

d. All artwork, including graphs, illustrations, photographs and tables taken from published studies included in Promotional Material must: (a) clearly indicate the precise source(s) of the artwork; (b) be faithfully reproduced, except where adaptation or modification is required, in which case it must be clearly stated that the artwork has been adapted and/or modified.

4. HOSPITALITY, GIFTS AND GRANTS

4.1 Prohibition of Gifts

a. No gift, benefit in kind, or monetary advantage shall be offered to HCPs or their families as an inducement for the supply, recommendation, use or sale of the Products or for the purpose of promoting the Products.

b. HCPs may be given practice-related items, such as pens or notepads, provided it is allowed under local rules and such items are of a minimal value that cannot be considered as an inducement in the local context.

c. If allowed under applicable laws and regulations, an inexpensive gift not related to the HCPs practice may be given on an infrequent basis in acknowledgment of significant national, cultural or religious events.

4.2 In-Kind Donations and Financial Grants

a. In-kind donations of Products and financial grants may be given to HCPs, HCOs, educational or research institutions to support genuine independent research, advancement of science, education, in relation to Infant nutrition and in particular to the Products. However, it is important that support of these programmes and activities is not viewed as a price concession, reward to favoured HCPs or inducements to recommend, prescribe, purchase, supply, use or sell any particular products or services. Therefore, appropriate documentation should be made in respect of all grants and donations provided under this section.

b. Grants and donations shall comply with all aspects of relevant codes of conduct.

c. Grants and donations shall not be tied in any way to the use of any Product by HCPs or their institutions.

d. When a grant or donation is provided, a written agreement should be put in place between the provider and the recipient of the grant or donation. The agreement should

v. specify the nature of the amount of the grant or donation, and its purpose (e.g., conduct of a specific research project); and

vi. require that the recipient acknowledge clearly and publicly the donation or grant and the donor of this support (e.g., in the publication or the presentation of the results of the research project supported by the donation or grant).

5. INTERACTIONS WITH HCPS REGARDING LIFELONG LEARNING ACTIVITIES

The purpose of this section is to avoid that HCPs are unduly influenced in the choice of Products they recommend or prescribe.

5.1 Lifelong Learning Activities in Specialised Nutrition & Healthcare

a. Lifelong learning activities must not be conditional upon an obligation to recommend, prescribe, purchase, supply, administer or sell any Products.

b. Lifelong learning activities shall comply with all relevant aspects of applicable codes of conduct, ethical rules or statutes of HCPs and their institutions.

c. When lifelong learning activities are organised or funded, directly or in collaboration with certified providers of medical education according to national & international guidance such as the Union of European Medical Specialists (UEMS), the organiser or funder of the lifelong learning activities should:

i. ensure transparency, when supporting conferences and congresses focused on professional development, education, and training for HCPs, according to Medical Societies' Codes and national laws;

ii. enter into a documented arrangement with the providers of any Lifelong Learning activities to ensure that they disclose any conflict of interest – in any publication or presentation, or to the audience of any other event – including any collaboration, or other financial support;

iii. only reimburse HCPs for reasonable travel, meals, accommodation and registration fees. As a general rule, the level of reimbursements may not exceed what HCP recipients would normally be prepared to pay for themselves; no payments must be made to compensate HCPs for time spent in attending llifelong learning activities;

iv. not give payments to individuals accompanying invited HCPs (e.g., spouses, children or other relatives), neither shall they be allowed to attend any of the activities or any hospitality, such as meals or coffee breaks, provided during these activities unless such individuals independently qualify for payment of such costs in their own right;

v. hold all lifelong learning activities in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the meeting; use of extravagant and lavish venues must be avoided;

vi. not provide or pay for stand-alone entertainment or other leisure or social activities.

d. National association members (e.g., Manufacturers) may pay reasonable fees (as considered in the context of the HCP's home market) and reimburse out of pocket expenses, including travel and accommodation, to HCPs who are providing genuine services as speakers, presenters or moderators on the basis of a written contract.

e. The public use of an HCP's or HCO's logo and/or proprietary material by SNE, its national associations or national association members (e.g., Manufacturers) requires written permission from the HCP or HCO. In seeking such permission, the specific purpose and the way the logo and/or proprietary material will be used must be clearly stated in a written agreement.

5.2 Overview of the categories of Medical Education and Lifelong Learning Activities

For the purpose of this Code of Practice, the following three categories are defined in the definitions section[4] and detailed in the sections below

a. Category 1: Continuing Medical Education ("**CME**") provided by independent non-industry organisations, as detailed in section 5.3 below.

b. Category 2: Lifelong Learning provided through collaborations or partnerships, as detailed in section 5.4 below.

c. Category 3: Lifelong Learning provided by the private sector, as detailed in section 5.5 below.

5.3 Category 1: Continuing Medical Education (CME)

a. Lifelong learning activities providing CME can be organised or funded, directly or in collaboration with certified providers of medical education according to national & international guidance.

b. Lifelong learning activities providing CME points are solely organised by certified provider entities which are neither owned nor controlled by Manufacturers.

c. SNE and its members acknowledge that CME education is provided under the direction and supervision of accredited providers. This can include medical societies or other specialty societies, HCOs, education providers, or other independent stakeholders – with or without accreditation of CME or Continuous Professional Development ("**CPD**").

5.4 Category 2: Lifelong Learning provided through collaborations or partnerships

a. Lifelong Learning provided through collaborations or partnerships between the national association members (e.g., Manufacturers) and independent providers led by professional societies, Healthcare Organisations, educational providers, or other independent stakeholders. Where there is such a collaboration, the following should be documented in a joint written agreement:

i. the goals of such collaboration;

ii. the structure of the collaboration;

iii. the respective roles and responsibilities of the entities involved, and

iv. whether the event may provide CME points for maintenance of professional accreditation.

b. The programme and content of this CME activity is subject to prior review and approval of the recognised, independent provider.

c. The exchange of up-to-date scientific knowledge in the most objective way among HCPs and experts should be facilitated.

4 These three categories follow the logic of the EFPIA Guideline on a Quality Framework Principles in Lifelong Learning in Healthcare (October 2021): https://www.efpia.eu/media/636559/efpia-llh-qf-final-20211021.pdf

5. INTERACTIONS WITH HCPS REGARDING LIFELONG LEARNING ACTIVITIES (CONTINUED)

5.5 Category 3: Lifelong Learning organised by the private sector

Lifelong learning organised by the private sector, such as national associations members (e. g. Manufacturers), may address human health and disease-specific learning needs. These activities may involve HCPs, scientific committees, and/or independent scientific and professional organisations. Ownership, accountability and funding remains with the organisers of these activities. Such events:

a. may use the brand names of Products only together with scientific data;

b. may not provide CME points for maintenance of professional accreditation, unless meeting the requirements established in section 5.4.

5.6 Educational Materials for HCPs

Manufacturers can provide Educational Materials to HCPs inter alia at medical conferences. Such materials discuss the latest research findings, treatment guidelines, and nutritional interventions for specific conditions. This type of material should be helpful to HCPs who are looking to stay up to date with the latest developments in the field of nutrition. Therefore:

a. Educational Materials should include a statement indicating that they are intended for use by HCPs only.

b. Educational Materials should not be presented in such a way as to discourage HCPs from recommending breastfeeding to caregivers.

c. Educational Materials should not be misleading and should be balanced, accurate, supported by sound science and compliant with applicable law.

d. Educational Materials can include the name of a particular company which places Products on the market.

e. Specific information on Products in educational material (incl. brand name) should only be directed to HCPs whose need for, or interest in, the particular information can reasonably be assumed (for example for usage in clinical studies).

5.7 Products for Professional Evaluation ("PFPEs") for IF and iFSMP

a. PFPEs for IF and iFSMP may only be provided to HCPs for the purpose of allowing the HCP to become more familiar with a product or recipe, and, when relevant, and in particular in the case of iFSMP, to gain experience on efficacy, including evaluating suitability, tolerance, acceptability, and clinical response. PFPEs are not intended for repeat or extended consumption by the Infant. Distribution of PFPE shall be strictly limited in regularity and quantity to avoid excessive allocation of PFPE to an HCP.

b. PFPE should never be distributed to HCPs with the purpose to discourage caregivers from feeding breast milk to an Infant.

c. PFPE should not be provided by Manufacturers directly to the general public, including pregnant women and mothers of Infants.

d. PFPEs should not be distributed to HCPs as an incentive to purchase or resell or recommend a particular brand of Products. Clear information should be provided that it is a "Sample for Professional Evaluation" or "Not for Resale", or any similar indication, except in exceptional circumstances where, in the context of a specific patient or a specific clinical circumstance, an HCP needs to request an emergency supply or access to iFSMP for professional evaluation.

e. All distribution of PFPE should be in response to a request from the HCP. The national associations members (e. g. Manufacturers) should document the amount of the delivered PFPE and the HCP shall agree that:

i. The requested PFPE for IF is to become more familiar with a product or recipe.

ii. The requested PFPE for iFSMP is solely for purposes of evaluating tolerance, acceptability, efficacy, suitability and/or clinical response, as relevant.

iii. The HCP is aware of the obligations set forth under the relevant laws of the country.

iv. The PFPE for IF or iFSMP is not being provided as an incentive to purchase or resell or recommend a particular brand of Products; and

v. The PFPE provided for IF or iFSMP is not to be resold or taken for personal use by the HCP or their staff.

f. In the case of requests for advice on personal medical matters pertaining to an Infant, the enquirer must always be advised to consult an HCP. Medical advice relating to a specific infant should never be provided. Answering questions on Product composition and preparation is allowed.

5.8 Supplies of IF to healthcare facilities

a. Healthcare facility supplies of IF should be made only to and on request of a healthcare facility and in accordance with a healthcare facility's invoicing and payment process.

b. Healthcare facility supplies of IF should be provided in quantities determined by an established process to be reasonable and intended for primary use at the requesting HCF only by Infants who, pursuant to medical advice, have to be fed with Products during their stay at the HCF.

c. Healthcare facility supplies of IF should not be provided as an incentive to HCPs, or accompanied by other incentives directed at HCPs, to purchase or use a particular brand of Products or to purchase or use other products offered by the same donor or supplier regardless of whether those other products are subject to this Code of Practice.

6. OTHER CONTRACTED SERVICES

When contracting HCPs or HCOs as consultants, whether in groups or individually, for services not otherwise covered by this Code of Practice, such as speaking at and/or chairing meetings, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research, and where such participation involves remuneration and/or hospitality, the following conditions should be met:

6.1 These services are provided for the purpose of supporting healthcare, research or education and do not constitute an inducement to recommend, prescribe, purchase, supply, use or sell specific Products.

6.2 A written contract, which is agreed in advance of the commencement of the services, specifies the nature of the services to be provided and the amount and basis for payment of those services.

6.3 the service providers declare that they are consultants of a company, whenever they write or speak in public about a matter that is the subject of the agreement. Service providers should disclose their service agreement to their employer, or as required by law. This obligation is stipulated in the written contract.

6.4 the number of consultants retained, and the extent of the service should not be greater than reasonably necessary to achieve the identified need, and the remuneration for the services reflects the fair market value of the services provided.

7. TRANSPOSITION

SNE acknowledges that some Member Associations address best practices for interactions between the infant formula industry and healthcare professionals and healthcare organisations in their respective National Codes. National Associations are encouraged, in line with their statutes and national context, to either adopt this Code of Practice and/or to review and update their existing Codes by 31 December 2024.

About SNE

Specialised Nutrition Europe (SNE) is the trade association representing the interests of the specialised nutrition industry across the European Union. SNE members are the national associations of 19 European countries, whose members are companies producing tailor made dietary solutions for populations with very specific nutritional needs. These include infants and young children, patients under medical supervision, sportspeople, overweight and obese consumers, and those suffering from coeliac disease.

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