

## Ministry of Health

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#### **Executive Summary**

The Omani Standard Specification for Marketing Regulations of Designated Products for Infants and Young Children (OSSDP) was developed by the Ministry of Commerce, Industry, and Investment Promotion in collaboration with the Department of Nutrition within the Ministry of Health (MoH). This specification has been mandated through a ministerial decree Number 74/2021 and released on 20th of May 2021 from ministry of commerce, industry and investment promotion

The goal of the Omani standard is to protect breastfeeding by regulating the commercial promotion of breast-milk substitutes and its potential effects on mothers, infants, and young children. Additionally, it seeks to promote the provision of suitable and safe nutrition for infants and young children while ensuring the appropriate usage of breast-milk substitutes (BMSs) when required.

The guideline is part of a broader effort to increase breastfeeding rates in Oman, reduce healthcare costs, and protect children's health by limiting the negative impacts of BMS marketing.

This guideline is designated for healthcare workers. As part of their role, healthcare workers educate and inform mothers and other caregivers about the ideal nutrition for infants and young children. It's essential to support mothers in making unbiased, informed decisions, unaffected by commercial influences from Breast Milk Substitutes (BMSs) companies. Omani child law focuses on protecting children's rights and ensuring their well-being. It highlights the importance of providing children with the best healthcare, including access to medical services, proper nutrition, and emotional support. it ensures that children grow up in a safe and healthy environment, with the state and society working together to protect their rights and promote their overall development.

Any kind of promotion of BMSs within health services is strictly prohibited. Additionally, there are clear guidelines for health workers on avoiding any influence from BMSs companies.

## Acronyms

BF	Breastfeeding
BMS	Breast Milk Substitutes
EBF	Exclusive Breast Feeding
HCW	Health Care Worker
МоН	Ministry of Health
OSSDP	Omani Standard Specification of Designated Products for Infants and Young Children
BFHI	Baby Friendly Hospital Initiative
IRLS	Incident Report Learning System

#### Definitions

- 1. The Omani standard specification of marketing regulation of Designated Products for Infants and Young Children: A specification, jointly issued by the Ministry of Commerce, Industry & Investment Promotion and the Ministry of Health, aims to regulate the marketing of designated products. Its guidelines draw upon Gulf and international standards, the International Code of Marketing of Breast-Milk Substitutes, and other relevant literature.
- 2. Designated Products: Products classified as:
  - Foodstuffs such as breast-milk substitutes, complementary food, or any other food product marketed as fit for children up to three (3) years of age,
  - Infant feeding supplies e.g. (Bottles, and teats, etc.) for children up to three years (3) of age.
  - Pacifiers for children up to 3 years of age.
- 3. Breast-milk Substitutes: Any milks (or products that could be used to replace breast milk, such as fortified soy milk), in either liquid or powdered form, that are specifically marketed for feeding infants and young children up to the age of 3 years (including follow-up formula and growing-up milks).
- 4. Formula for Special Medical Use: a substitute for human milk or infant formula is specially manufactured to satisfy, by itself, the special nutritional requirements of infants with specific disorders, diseases or medical conditions from birth to 3 years.
- 5. Infant: Any child under the age of twelve (12) months (one year);
- 6. Young Children: Children between the age of twelve (12) months and thirty-six (36) months (three years);
- 7. Companies BMSs representative: Medical and non-medical representatives of companies producing breast milk substitutes who promote, distribute and provide information about infant formula and related products to health care workers.
- 8. Medical Representative: Are those individuals employed by commercial enterprises whose responsibility may include the marketing, sale, provision of information, or other form of promotion of drug products, drug related devices and other medical equipment.
- 9. Marketing: A means to promote, distribute, sell or advertise a designated product.

- **10. Promotion:** A mean to encourage consumers to buy or use a designated product in a direct or indirect manner.
- **11.** Advertising: A means to familiarize consumers with a designated product in whatever way or manner.
- **12.** Al Shifa System:-An electronic medical record provides the necessary clinical information for patients.
- **13.** Aman System: Patient safety incident reporting and management system in health institutions.
- 14. Clinical health worker: a healthcare professional directly involved in providing medical care and treatment to patients. They have specific training and qualifications to diagnose, treat, and manage various health conditions e.g. Physician, nurses, midwifes, medical orderly, dietician, counselors and pharmacists
- 15. Non clinical Health worker: a professional who supports healthcare institution but does not directly engage in clinical treatments or medical procedures e.g. social workers,-administrators, housekeeping, medical record.

# CHAPTER ONE

#### 1. Introduction

Breastfeeding has numerous health benefits for both mothers and infants. Babies who are breastfed have lower risks of infections, allergies, and chronic diseases, while mothers experience reduced risks of breast and ovarian cancers (1). According to the Oman national nutrition Survey (ONNS 2017), the rate of Exclusive Breastfeeding among infants 0-6 months old was only 23%, which is considered low compared World Health Organization target that is **50% by 2025** (2).

Therefore, increasing breastfeeding rates in Oman is a necessary public health demand. It also reduces healthcare costs by lowering the incidence of certain illnesses and diseases that is associated with (BMSs) consumption.

Ministry of Health has activated the Baby Friendly Hospital Initiative (BFHI) as one of the action plans to raise the national breastfeeding rates. The first step of the Ten Steps, which make the basis of BFHI, is that all health institutions must comply fully with the International Code of Marketing of Breast-milk Substitutes and relevant World Health Assembly resolutions (3). The Code and subsequent resolutions entail a number of regulations to ensure that there is no advertising of formula milk, commercially produced food (for children 6-36 months), bottles, and teats to the mothers and their families.

Recognizing the detrimental effects of aggressive marketing of BMSs on breastfeeding promotion efforts, Oman introduced the Omani Code for marketing of BMSs in 1998. Therefore, the Omani Code for marketing of BMSs was released in 1998, which has been updated in 2021 and released as a compulsory Omani standard specification for "Regulating Marketing of Classified Products for Infants and Young Children" OS 649/2021. Its goal is to ensure that all parents, regardless of how they choose to feed their child, have access to reliable and practical information free from the impact of advertising efforts that prioritize profit over the needs of infants.

Health care workers must follow this guideline, which is written based on national regulations and laws. Any violation by health care workers against any of its articles will Expose them to accountability in accordance with the provisions of the laws. These regulations are:

- The Omani Standard Specification "Regulating Marketing of Classified Products for Infants and Young Children" OS 1649/2021.
  Please refer to Appendix 1
- 2. Code of conduct of Ministerial decision, No. 2014/16, Issuing the organizational regulations for employment affairs for medical and allied medical positions in medical institutions (government, civil and military). The following clauses in professional codes of practice should be considered by health workers in the context of BMSs marketing:
  - Article (169) the employee is prohibited from engaging in the following activities:
    - Negligence, and refusal to follow applicable laws, regulations, rules and instruction With it.
    - Exploiting his job to achieve personal goals.
    - Accepting gifts, rewards, grants, loans, commissions, or benefits in cash or in kind, it has an impact on his job duties.
- 3. Code of professional conduct on the 8th of Shawwal 1442 A.H, corresponding to May 20th 2021 A.D. For civilian employees in units of the state's administrative apparatus. The following clauses in professional codes of practice should be considered by health care workers in the context of BMSs.
  - Familiarity with applicable laws, regulations, decisions, and circulars related to his/her job affairs and adherence to them.
  - Refrain from requesting or accepting any gifts, rewards or commission of any kind, regardless of their value, or other benefits that would have an impact on his/her. job' duties. If he/she receives a gift in any event, he/she must immediately notify his/her direct supervisor.
- 4. comply fully with the International Code of Marketing of Breast-milk Substitutes and relevant World Health Assembly resolutions (3). The Code and subsequent resolutions entail a number of regulations to ensure that there is no advertising of formula milk,

commercially produced food (for children 6-36 months), bottles, and teats to the mothers and their families.

#### **Scientific Rational**

Commercial companies, including those involved in the production of BMSs, primarily aim to maximize profits by selling their products in large quantities. Health services either public or private provide cost-effective environment for BMS's manufacturer to advertise for their products. They provide an easy access for companies to their target group. Parents frequently view health care workers as trustworthy sources of health information, including guidance on feeding practices. The regular contact with expectant and new parents makes them a strategic target for marketing by companies. Even though health care workers recognized the marketing goals of BMS companies, some other marketing strategies may be indirect or subtle, such as providing support for scientific events or distributing branded gifts. Therefore, this guideline is written to address the main areas of interaction between health care workers and BMS's companies and the action they should take when they encounter any inappropriate marketing of BMSs.

#### 2. Purpose

- To support the provision of safe and adequate nutrition for infants by promoting and protecting breastfeeding practices, with the goal of increasing breastfeeding rates in Oman.
- To prohibit the marketing of feeding bottles, teats, nipples, and breast-milk substitutes among healthcare workers.
- To equip healthcare workers with the skills to document and report any violations of breastfeeding promotion policies

#### 3. Scope

This guideline applies to:

- All institutions within the health sector, including both government, military and private organizations.
- All staff working in the health sector that include:
  - ➤ Clinical and non-Clinical staff
  - Voluntary and unpaid workers.

#### 4. Structure

The guideline consists of four chapters. Chapter one cover brief introduction to the guideline as well as the purpose, scope and structure. Chapter two explain the procedure of marketing regulations of breast milk substitutes for health care workers. Chapter three covers the responsibilities. Chapter four comprises of the document history and version control, reference and Annexes.

# Chapter Two

#### 5. Procedures:

### 5.1 Prohibited Practices for the Promotion of Breast-Milk Substitutes (BMS)

Advertising or promoting classified products, including breast-milk substitutes (BMS), by any means is strictly prohibited in all governmental and private health institutions. The following practices are considered violations of this guideline though the list is not exhaustive:

#### **5.1.1 Prohibited Activities**

#### **1 Acceptance of Contributions and Gifts**

 Healthcare workers or institutions must not accept contributions, gifts, materials, or other benefits from BMS companies or their representatives, regardless of value. Examples include scholarships, pens, calendars, free meals, diaries, discount vouchers, and similar items.

#### **2 Distribution of BMS Samples or Gifts**

• Healthcare workers or institutions must not accept or distribute free BMS samples, designated products, or gifts provided by BMS company representatives to mothers or their families.

#### **3 Use of Educational Materials from BMS Companies**

• Institutions must not receive or display any educational materials produced by BMS companies.

#### 4 Sponsorship of Events by BMS Companies

• Events such as workshops, scientific days, conferences, open days, contests, and campaigns must not be fully or partially sponsored by BMS companies.

#### **5** Contact with Mothers or Families

• Representatives of BMS companies must not be allowed to contact mothers or their families within health institutions.

#### **6 Interaction with Healthcare Workers**

• BMS company representatives must not meet with any healthcare workers, including clinical and non-clinical staff, within health institutions.

• If it becomes necessary to meet with doctors to provide information about a new formula for special medical use, medications, or equipment, prior approval must be obtained from the head of the health institution. The head of the institution will evaluate the necessity of the meeting and, if deemed essential, the meeting must take place in their presence. This exception is strictly limited to doctors who are directly involved in prescribing the specific medical formulas or medications for their patients. No other doctors or healthcare workers are permitted to attend such meetings. Additionally, this exception applies exclusively to new products and does not extend to existing or previously introduced products.

#### **5.1.2** How to report the violation?

#### • Government health care institutions:

Any observed violation must be reported by healthcare workers without delay. It is the responsibility of the healthcare worker to document such incidents using the **Incident Report Learning System (IRLS)** in the Al Shifa 3+ system, under the category of **Omani Code Violation**. Failure to report a violation may result in the staff member being held accountable and subject to formal inquiry. All required fields, including details of the violation (location, type of violation, product involved, etc.), must be completed. The incident report will then be received in the quality department at the institution and then will be reported to the Department of Nutrition through the Aman system. **Please refer to Appendix 2** 

#### • Private Health Care Institutions:

The violation should be reported to the Quality and Patient Safety Department in the Directorate General of Private Health Institutions, in the Ministry of Health by emails from the private hospital administrations (till the system of Information Technology system in private institutes is connected to MOH). Then the incident will be forwarded to the department of nutrition by Al Barwa system, which, in turn, forwards it to the legal affairs section within the Ministry of Health for further action. Alternately, the Private Health Institution can send the violations directly to the Nutrition department by email.

Please refer to Appendix 3

#### 5.1.3 Measurement of effect

- Increase the reporting of violations among Health Care workers due to increase in the awareness
- Increase the rate of Exclusive breastfeeding in the community.
- Conducting simple survey to measure HCW awareness of the marketing regulations of BMS pre and post the release of the guideline.

### 6. Responsibilities

### 6.1 Nutrition Department

#### Department of Nutrition is responsible to:

- Conduct a training for this guideline.
- Receive the violation reports in Aman system and direct it to the corresponded sector for further actions.
- Follow up the violation to ensure that appropriate measures have been implemented.
- Compile all recorded violations and prepare a regular report to be distributed to the relevant departments.

## 6.2 Hospital Directors / Director General of Directorate of Health Services in all governorates, Head of Department at Hospital at MOH and directorate level /Executive Directors / Head of Medical officer in charge in local Hospital, polyclinic, health center

- Ensure protocol dissemination to all staff through proper channels.
- Endorsing and supporting local implementation of the guideline and ensure compliance through agreed monitoring process.
- Aligning appropriate resources and assign a focal point to support the implementation of this guideline.
- Monitor and address violations that occur within the health institution.
- Issuing circulars related to implementations and violations if needed.

#### 6.3 Clinical directors/in charges at service level and Head sections

- Ensuring staff adherence to this guideline.
- Offering leadership and guidance to staff regarding articles of this guideline.
- Addressing concerns related to breast milk substitute marketing and support violation reporting if indicated.

## 6.4 Baby friendly hospital initiative committee responsibilities

- Creating and enforcing BFHI-compliant policies, banning any BMS promotion in the health facility in accordance to this guideline.
- Ensuring hospital compliance with BFHI standards, including marketing regulations.
- Educating staff on the importance of exclusive breastfeeding and risks of BMS promotion.
- Resolving any breast milk substitute marketing concerns in the hospital.
- Monitor the recorded violations and ensure that appropriate measures are taken to prevent further occurrences.

## 6.5 Pediatrician

- Should support, promote, and protect breastfeeding.
- Restrict BMS prescriptions for medically indicated cases only.
- Comply fully with the rules mentioned in this guideline and integrate it into their work practices and responsibilities.
- Should not engage in any meetings with the BMSs representatives unless it is organized by head of health institutes or directors to provide information about a new formula for special medical use, medications, or equipment. Information on formulas, including special formulas, should be made accessible through transparent sources (pharmacy department).
- Should ensure that Medical Representatives not providing any sort of promotion or distribution of BMS in pediatrics' wards or clinics.
- Report any violation for this guideline.

#### 6.6 All other Clinical health workers

- Should support, promote and protect breastfeeding and refrain from any BMS marketing practices.
- Comply fully with the rules mentioned in this guideline and integrate it into their work practices and responsibilities.
- Should ensure that Medical Representatives not providing any sort of promotion or distribution of BMS in the institution.
- Should report any violations for this guideline.

### 6.7 All other non-clinical health workers

- Comply fully with the rules mentioned in this guideline and integrate it into their work practices and responsibilities.
- Report any violation to this guideline.

## 6.8 Drug Safety Center

- Implement the legal control action for the violators under their scope (medical representatives of BMS companies), according to the regulations and laws in force in the Licensing Department.
- Motivate all Pharmacist at all health institution who are under them to report Violation in IRLS system.
- Report any violation for this guideline to Nutrition Department.

## 6.9 Quality Assurance department at service level

- Disseminate this guideline to all relevant departments within the institution.
- Verify that all departments have received this guideline in the institutions.
- Incorporate this guideline into the quality assurance system and ensure its implementation across all departments.
- Train healthcare workers on the Incident Report Learning System (IRLS) for reporting any violations for this guideline.
- Conduct regular audits of hospital wards to ensure the proper implementation of the guideline.
- Forward the reported violation which received from the departments in the institution to the Nutrition department

#### **6.10 Directorate General of Private Health Institutions**

- Distribute the guideline to all private institutions
- Ensuring private institutions' adherence to this guideline and to the Omani Standard Specification OS 649/2021.
- Encourage private health institutions to amend practices to support, promote and protect breastfeeding while refraining from engaging in any marketing practices for BMS.
- Encourage private health institutions to report any violation to this guideline.
- To do an audit for the hospital wards for proper implementation of the guideline.

### **6.11 Private Health Institutions:**

- Ensure guideline dissemination to all staff.
- Comply fully with the rules mentioned in this guideline and integrate it into their work practices and responsibilities.
- Report any violation for this guideline.

## 6.12 Information Technology

• Insure that all departments in the health institutions are having the IRLS in place and well-functioning.

## **6.13 Public Relation Officer**

- Prohibit access of BMS company representatives to enter the health institution
- When dealing with Medical representatives, the fallowing should be followed:
  - Medical Representative's access is prohibited in any patient care area, laboratories and Pharmacy & medical store (drug dispensing area)
  - They are only allowed to visit MOH Healthcare Units to present product information on appointment only
  - Not allow to provide any promotion (including information exchange with staff) or distribution of the BMS
- Ensure that all security staff are aware of their roles in accordance to this guideline.

## CHAPTER FOUR

#### 7. Document history and version control table

Version	Description	Review Date
01	Initial Release	April 2030

#### 8. References

- 1. The Omani Standard Specification for Marketing Regulation of Designated products for infant and young children OS 1649/2021.
- 2. https://www.aliveandthrive.org/sites/default/files/bms code\_pamphlet\_9feb22.pdf
- 3. https://www.globalbreastfeedingcollective.org/international-code-marketing-breastmilk-substitutes-0
- 4. https://apps.who.int/iris/bitstream/handle/10665/254911/WHO-NMH-NHD-17.1eng.pdf
- 5. UNICEF. "Baby-Friendly Hospital Initiative." Www.unicef.org, www.unicef.org/documents/baby-friendly-hospital-initiative.

#### 9. Annexes

9.1 Appendix 1

Article of the Omani Standard Specification

The staff should comply with the following:

It was decided in the (Qarar OS 649/2021) Omani standard as follows:

4.11 Advertising or promotion of classified products by any means is prohibited, any of the following specific practices this includes, but not limited to - are considered as prohibitions. An exception to this is obtaining the approval of the Ministry of Health.

4.11.1 Offering any samples of the products to pregnant women, mothers or nannies by a producer or distributor, whether in a direct or indirect way;

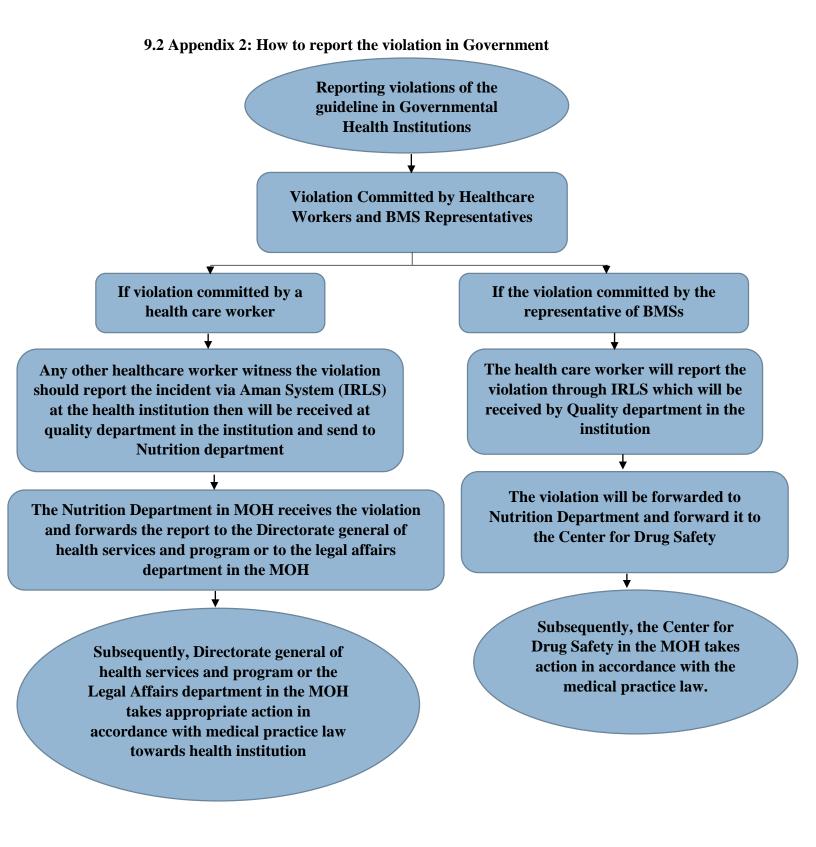
4.11.2 Offering any gifts, material, tools or discount vouchers, or any other offers that encourage the use of designated products;

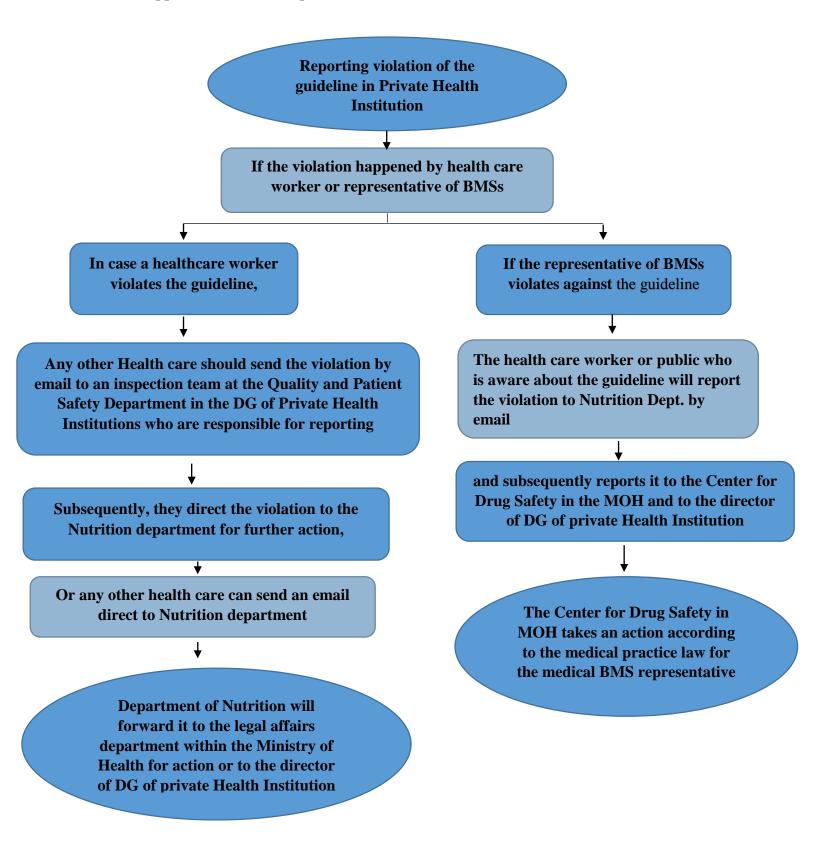
4.11.3 Participating in any events or exhibitions or any other means for the purpose of promoting designated products;

4.11.4 The marketing staff should not have any direct or indirect contact with pregnant women, mothers, nannies or any of the relatives thereof;

4.11.5 Advertising by any means

4.11.6 It is prohibited for the manufacturer, importer, distributor or their representatives to provide the classified products in any form, with the exception of providing the classified products to government health institutions, for the purposes of scientific research in related fields, subject to obtaining the approval of the Ministry of Health





#### 9.3 Appendix 3: How to report the violation in Private health care Institution