REGULATION

From the Pharmaceuticals and Medical Devices Institution of Turkey:

REGULATION ON THE CHANGES TO BE MADE

CONCERNING THE REGULATIONS ON

HUMAN MEDICAL PRODUCTS PROMOTIONAL ACTIVITIES

ARTICLE 1 – Subclause (a) of the first clause in article 3 of the Regulation on Human Medical Products Promotional Activities which was published in the Official Newspaper edition 28037 date 26/8/2011has been changed as follows.

“a) based on the Ministry of Health Statutory Decree on the Organization and Tasks of the Ministry of Health and affiliated Institutes no 663 dated 11/10/2011 and the Pharmaceuticals and Medical Preparations Law no 1262 dated 14/5/1928,”

ARTICLE 2 – Subclauses (f), (g), (ğ) and (h) of article 4 in the same regulation have been changed as follows and subclause (ı) below has been added to this article.

“f) Health profession members: Physician, dentist, pharmacist, nurse, midwife and the other professions that are defined in supplemental article 13 of the Law Concerning the Mode of Execution for Medicine and Medical Sciences No. 1219 dated 11/4/1928,”

“g) Promotion: The activities organized by the owners of licenses/permits concerning the medical-scientific features of human medical products in the scope of this Regulation or all of the informative activities which will take place for the members of the health profession with the name, request, contribution, support of the license/permit owners, the activities of the product promotion employees within this scope, advertisements to be given to medical and professional books and journals, direct mailing, announcements made through the press and other communication tools, scientific/educational activities, meetings and similar events,”

“ğ) Promotional Materials: Printed materials such as books, booklets and brochures that contain sufficient information about the product; films and slides; storage devices such as flash disc and CD/DVD and presented audio/video materials; all manner of broadcasts that can be used in the relevant communities as information/data/application sources, free samples, programs and materials for patient training; reminder of visit materials such as pens, penholders, notepads and calendars which have a monetary value not exceeding 2.5% of the minimum monthly wage in force,”

“h) Product promotion employee: Individual with sufficiency certificate who introduces a product through direct visits to physicians, dentists and pharmacists,”

“ı) Sufficiency Certificate: A certificate issued directly to the graduates of Medical Promotion and Marketing Programs of Universities or by the Ministry as a result of passing an exam after an in-service training course,”

ARTICLE 3 – Subclause (c) of the second clause in article 5 of the same Regulation has been changed as follows.

“c) By having product promotion employees visit physicians, dentists and pharmacists; and by informing the other profession members on subjects like the application and side effects of products,”

ARTICLE 4 – Article 6 of the same Regulation has been changed as follows.

“ARTICLE 6 – (1) In situations of importance for public health like immunization campaigns and fighting infectious diseases or about products to be used in campaigns conducted by the Ministry for the encouragement of health, the public can be informed within the framework of principles and procedures determined by the Ministry by obtaining permission from the Ministry.

(2) Other than the promotions to be done in international conferences organized in the country and the information provided in person by the science service authority of the license/permit owner on the written request of health profession members the following may not be introduced to health profession members;

a) Human medical products which have not been licensed in accordance with relevant regulations,

b) Human medical products that have been licensed or permitted according to the relevant regulations outside of their areas of use defined in their PIS (Product Information Summary).

(3) The introduction of a product must be in accordance with the information and data that is in their PIS.

(4) The introduction of a product must include informative and evidence based medical information about the product so as to allow the health profession members to form their own opinions about the therapeutic value of the product.

(5) If the introductory material is created with excerpts, tables and other visual materials from medical journals or other scientific work these materials may only be used in their original form and by identifying the exact source.

(6) Introduction may not be created using misleading, exaggerated information or information which has not been medically proven to encourage the use of human medical products unnecessarily and in a way that could result in unexpected risks or by using attention grabbing images and images which do not have direct relevance with the actual product.

(7) Promotion cannot be done using drawings or games of chance.

(8) No manner of cash or in kind advantage may be provided or even offered and mentioned when introducing human medical products to doctors, dentists and pharmacists. The said health profession members may not accept or demand any kind of incentive during introductions of products made to them.

(9) Health profession members are required to declare any kind of support they have received from license/permit owners:

a) At the end of every article,

b) At the beginning of every speech/presentation.

(10) License/permit owners may make donations to public health organizations/institutions under the following conditions:

a) Obtaining prior permission from the administration of the institution, organization or family health center they wish to donate to,

b) Not affecting the product tender decisions within the scope of this regulation,

c) Not causing any manner of unethical application that could be connected with the sale of the product,

ç) Not encouraging prescriptions to be written for a specific human medical product,

d) Having the objective to improve research, education, health and patient care,

e) Not just addressing the use of one individual but addressing the general use of institutions or organizations,

f) Not writing in the product name in exchange for the license/permit holder name being present on the donated material,

g) Entering the donation in the official records of the license/permit holder,

ğ) Making human medical product, laboratory kits and similar donations for clinical research directly to the assigned researcher."

ARTICLE 5 – The subclauses (a) and (b) of clause one in article 7 of the same regulation have been changed as follows
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"(1) Scientific and educational activities concerning the introduction of the human medical product may not be done for any other purpose than to convey existing medical information and/or to present new information. The license/permit holders may not directly or indirectly cover the travel and accommodation expenses of the participants in these activities."

"a) The meeting must be relevant to the specialty/field of assignment of the health profession member."

"b) One health profession member may benefit from this support a total of three times in the same year; only two out of three assistances may be made by the same license/permit holder and also only one of these assistances may be used for a meeting abroad. Meetings in which participation is made with the support of license/permit holders where the health professional is the speaker or presenter of the information shall not be considered within this scope."

"(7) In at least 60% of the meetings exceeding six hours organized by the license/permit holders within a calendar year shall include a session about rational medicine use. The content of the presentations within this session shall be in the framework of educational material and diagnosis and treatment guides approved by the Ministry and shall be presented to the Ministry as specified in the guide."

ARTICLE 6 – Clause two of article eight in the same regulation has been changed as follows.

"(2) Reminder of visit materials may not have a monetary value exceeding 2.5% of the minimum monthly wage in force."

ARTICLE 7 – The phrase "on the condition that", which is in the first sentence of clause one in article 9 in the same regulation has been changed to "only if" and subclause (f) of the same clause has been changed as follows.

"f) For each human pharmaceutical product, free samples of a value not to exceed 5% of the yearly total sales calculated by means of monitoring monthly sales as of the date that the product is released to the market within the first calendar year; not to exceed 5% of the sales in the previous year within the second calendar year; not to exceed 3 % of the previous years during the third, fourth and fifth calendar year; and not to exceed 1% of the previous year's sales in the years following the fifth calendar year, may be distributed
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ARTICLE 8 – Article 10 of the same Regulation has been changed as follows.

"ARTICLE 10 – (1) The Product promotion employees;

a) Must be equipped with complete and sufficient required scientific data and information about the products they are promoting.

b) They must be given by the companies they work for or by means of the company they work for purchasing services, in service training which contains basic and required information, includes legal and ethical context and has been approved by the Ministry and be in possession of a certificate which has been issued after such a course. The sufficiency certificate in valid until the end of the fourth year and a new certificate is required to be obtained before the current certificate of the product promotion becomes expired. The sufficiency certificates that are issued for the graduates of University "Medical Promotion and Marketing Programs" are not required to be renewed within this scope.

c) Those that have started working in companies under the title of product promotion employees after 1/1/2015may apply for a sufficiency certificate on the condition that they are at least a high school graduate and can show documentation that they have been successful in the exam which is held.

ç) If the diplomas of graduates from the Medical Promotion and Marketing Programs of Universities are presented a sufficiency certificate may be issued without any other requirements.

d) They are entered into the Ministry electronic registration system by the companies they work for. Product promotion employees who possess a sufficiency certificate and are registered in the system will be issued a Product Promotion Employee Identification Card by their employer in a format that is determined by the Ministry.

e) If the individual does not have a Product Promotion Employee Identification Card they may not be allowed to work for companies as a product promoter.

f) Regardless of the reason the Ministry must be notified by the companies within 20 days when an employee has left or started working.

g) Can provide services for more than one license/permit holder. Liability belongs to the license/permit holder and the rights of the license/permit holder generated by contracts are reserved.

ğ) They may not promote a product or the like to any other health professional other than physicians, dentists and pharmacists; however, on the condition that the relevant department authority/responsible physician is notified and their approval is obtained, they may give information to health professionals other than physicians, dentists and pharmacists on such subjects as product applications and side effects.

h) The information that is used during the promotion of the products in the presence of physicians, dentists and pharmacists supported with promotional materials when necessary, must convey all negative and positive information about the product in accurate form.

ı) They forward any adverse effect/incidents that are reported to them during product promotion, to the relevant services in their company.

i) The promotional materials concerning the product being promoted may not be given to anyone other than physicians, dentists and pharmacists.

(2) The product promotion employee and license/permit holder company are jointly liable for the promotions of products made by the product promotion employee.

(3) Product promotion employees introducing human medical products to public health organizations during work hours is subject to the following rules:

a) The product promotion employee will disclose which license/permit holder they are representing at the beginning of the visit and show their product promotion employee identification card.

b)In every health institution where public services are provided the concerned administrative authority will assign the most suitable time taking into account their working schedules, for product promotion employees to be able to conduct meetings with the health professionals about the products being promoted. This assignment of time may not disrupt training services and the health services being provided to patients.

c) Product promotions may not be conducted in emergency rooms and in polyclinics during patient acceptance hours.

(4) No manner of money or other similar material fees may be demanded from product promotion employees entering a health institution to promote products, even if they are under the name of donations or the like.

(5) No posters or similar promotional material that may be construed as product promotion may be placed, hung and/or adhered to surfaces in public health institutions. However posters and similar promotional materials used in Ministry campaigns to promote healthy living, on subjects such as immunization campaigns, infectious diseases, smoking or obesity are not subject to this provision.”

ARTICLE 9 – Clause three of article 11 in the same Regulation has been changed as follows.

"(3) Conferences, seminars, symposiums and similar meetings to be organized or contributed to by the license/permit holder will be notified to the Ministry. It is required that at least fifteen business days before each meeting, the content of the meeting, probable participants list, items of expenditure and activities are notified to the Ministry; notifications for which a document entry record has been created will be responded to within ten business days and if no response is sent the application shall be considered approved."

ARTICLE 10 – Clauses three and four of article 13 in the same regulation have been changed as follows.

"(3) In the event that human medical products promotions are done in violation of this Regulation, the license/permit holder shall be warned, if repeated operations will be suspended for three months and if violation continues operation will be suspended for a year."

"(4) In the event of any violations by product promotion employees within the period of validity of their certificates which are issued by the Ministry, first the employee will be warned by the Ministry, if repeated their sufficiency certificate will be suspended for three months and if violation continues their sufficiency certificate will be suspended for a year. A product promotion employee may not work during this period of suspension and their Product Promotion Employee Card will be retracted by their employer."

ARTICLE 11 – The below temporary article has been added to the same Regulation.

"Application calendar

TEMPORARY ARTICLE 1 – (1) The principles and procedures and application calendar concerning the application of the 10th article are prepared by the Ministry by 30/6/2013 and announced on the Ministry's internet site."

ARTICLE 12 – Article 16 of the Same Regulation has been changed as follows.

"ARTICLE 16 – (1) In this Regulation;

a) subclause (b) of the second clause in article 7 goes into force on 1/1/2013, the third clause goes into force on 1/1/2012,

b) subclause (e) and (f) of the first clause in article 9 goes into force on 1/1/2013,

c) subclause (b), (e) and (f) of the first clause in article 10 and subclause (a) of the third clause goes into force on 1/1/2015,

ç) Other provisions go into force on 31/12/2011."

ARTICLE 13 – Article 17 of the same Regulation has been changed in the following way.

"ARTICLE 17 – (1) The provisions of this Regulation are executed by the Pharmaceuticals and Medical Devices Institution of Turkey Chairman."

ARTICLE 14 – This Regulation goes into force as of the date that it is published.

ARTICLE 15 – provisions of this Regulation are executed by the Pharmaceuticals and Medical Devices Institution of Turkey Chairman.

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