Original Article

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Legal analysis of the information contained in dental plaster packs

Mário Marques Fernandes[1,2], Ricardo Mattana[2], Carolina Mattana[2], Ana Paula Reckziegel[2], Rachel Lima Ribeiro Tinoco[3], Rogério Nogueira Oliveira[1]

[1]Department of Community Dentistry, School of Dentistry, University of São Paulo, São Paulo, SP, Brazil
[2]Department of Forensic Dentistry, Brazilian Dental Association, Porto Alegre, RS, Brazil
[3]Department of Community Dentistry, School of Dentistry, University of Campinas, Piracicaba, SP, Brazil

Abstract

Aim: The aims of this study were: a) to verify if the instructions displayed on the packages and labels of dental plaster available for purchase in the city of Porto Alegre are in accordance with the Brazilian laws, and b) to analyze how information is available on packages and labels of dental plaster acquired by dentists. **Methods:** For this study, it was used the method proposed by Silva et al. (2010) modified, according to which the information related to instructions for product use displayed on packages and labels, if present, provided by manufacturers and/or importers from each brand of plaster was reviewed: how to use, composition, price, expiration date, health risks and disposal instructions. The collected information was subsequently confronted with the requirements laid out in national legislation on trade of dental plaster. **Results:** No product showed the price or the instructions for disposal. One brand showed no information of the package and another one showed only the composition of the product; this requirement was present in most products. The mode of use and the expiration date were present in almost all packages, except for two brands. Only two brands presented information on health risks, and yet unsatisfactory. **Conclusions:** The different brands and types of dental plaster analyzed presented some kind of violation of the provisions of the Brazilian legislation, most with missing or unsatisfactory information.

Keywords: calcium sulfate, forensic dentistry, consumer advocacy, product packaging, dental materials.

Introduction

Dental plaster is generally used to make casts for study, prosthetic procedures, and to integrate the patient records. However, although yet little noticed, dental casts play an important role as pieces of evidence for forensic expert exams, either for human identification by comparing information contained in previous examinations, either for its use in civil litigations. For this reason, dental casts should be well archived and kept by dentists[1].

Currently in Brazil, the consumer is supported by the Consumer Defense Code (CDC), approved by Law 8.078/1990, which aims at protecting the public order as well as the social interest in consumption relations in order to preserve the more vulnerable part of this relationship: the consumer. In opposition, there are the suppliers,that develop activities, such as production, assembly, creation, construction, transformation, import, export, distribution or trading of products

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Correspondence to:
Mário Marques Fernandes
Laboratório de Antropologia e Odontologia Forense (OFLab – OFLAB),
Universidade de São Paulo
Avenida Prof. Lineu Prestes 2227,
CEP: 05508-000
Cidade Universitária, São Paulo, SP, Brasil
Phone: +55 11 30917891
FAX: +55 11 30917874
E-mail: mario-mf@live.com

and services. These companies must respect the consumer rights, under penalty of responding to civil and/or criminal lawsuits, for any damage caused. By purchasing products, dental instruments or equipment, dentists begin to act as a consumer, being supported by the CDC. In this sense, the CDC states in its article 6, section III, as a basic right of consumers the access to adequate and clear information about the various products and services, with correct specification of quantity, characteristics, composition, quality and price, as well as potential risks[2-3].

This way, the Brazilian National Agency of Sanitary Surveillance (ANVISA), on standardizing labels of dental plaster, considers dental plaster as exempt from registration at the regulating organ because they are classified as risk level 1, as stated in the user manual contained in Resolution No. 185/ 2001, which provides guidance on registration, modification, revalidation and cancellation of registration of medical products. However, in Annex V (Guide for Risk Assessment), there Rule I states this this applies to: 'product that has no contact with the patient or touches only intact skin[4-5].

It is worth noting that the plaster is found in many countries, particularly in Germany and Scotland. Chemically, the mineral used for dental purposes is almost a pure dihydrate calcium sulfate. The plaster used in dentistry is obtained by the removal of part of the water of crystallization of the dihydrate calcium sulfate by the process of plaster calcination. The criterion for use of a certain type of plaster depends on its use, and consequently, on the physical properties needed for that particular application. The American Dental Association (ADA) specification No. 25 classifies the dental plaster into 5 types: a) Type I – molding plaster, b) type II - ordinary plaster, c) type III – plaster stone, d) Type IV - high strength plaster stone, and type V - extra-hard plaster stone. The ordinary plaster is generally used in prosthetic dentistry to make study and anatomical models, fixing models in articulators, including complete and removable dentures in furnaces, among others. Plaster stone is most commonly used in dentistry for producing various types of prosthetic models, orthodontic models, study models, and others. It is thus up to the dentist choose which type of plaster will be used[6].

The aims of this study were: a) to verify if the instructions displayed on the packages and labels of dental plaster available for purchase in the city of Porto Alegre are in accordance with the Brazilian law, and b) to analyze how information is available on packages and labels of dental plaster acquired by dentists.

Material and methods

In this research, all commercial registered establishments that sale dental products in the district center of Porto Alegre were visited, in the search of different brands and types of dental plaster available. The products were requested to employees, who provided the product for analysis. The sample consisted of nine products (n = 9) from six brands: Yamay® (Atibaia, SP, Brazil) - Y, Asfer® (São Caetano do Sul, SP, Brazil) - A, Vigodent® (Rio de Janeiro, RJ, Brazil) - V, Dam Proben® (Cachoeirinha, RS, Brazil) - DP, Dentsply® (Petrópolis, RJ, Brazil) – Dy, and Polidental® (Cotia, SP, Brazil) - P. All brands are registered belonging to Brazilian companies, and two of them produce more than one type of plaster – Asfer® (three types) and Vigodent® (two types).

For this study, it was used the method proposed by Silva et al. (2010)[7] modified, according to which the information related to instructions for product use displayed on packages and labels, if present, provided by manufacturers and/or importers from each brand of plaster was reviewed: how to use, composition, price, expiration date, health risks and disposal instructions. The collected information was subsequently confronted with the requirements laid out in national legislation on trade of dental plaster. For each data assessed it was associated the letters "S" (satisfactory information), "U" (unsatisfactory information) or "A" (absence of information).

For this analysis, photographs of the package of each brand were taken with a digital camera, with the aid of a dark background and a millimeter scale. The images were made of both the front and the back of the label and/or package.

Results

With respect to how information about the products was available, all of them had information displayed on the package or on the label, in the form adhesives or printed externally. No product showed the price or the instructions for disposal. The brand DamProben® did not show information of the package and the brand Polidental® exhibited only the composition of the product. Composition was present in the majority of products, but it was unsatisfactory in the brands of plaster type IV. The mode of use and the expiration date were shown in almost all packages, except for the brands of plaster type IV. Regarding health risks, only the brands Yamay® and Asfer® presented information, and yet unsatisfactory (Table 1).

Discussion

All commercial establishments that sell dental products in the city of Porto Alegre were contacted. Most dental products stores are located in the district center, according to the list provided by ANVISA. Therefore, for sample collection, were accessed five establishments of a total of nine. Still considering the sample analyzed it must be understood the features of the product, according to the supervisory body. The dental plaster is a product that, although considered not medical, is handled by health professionals, such as dentists, in various fields and specialties – including forensic experts and forensic dentistry specialists –, as well as prosthetic technicians[2,4-5,7-10].

According to the ANVISA's table coding of medical products, the dental plaster is encoded in dental consumer item, number 2101190 (plaster for dentistry). ANVISA classifies dental plaster as exempt from registration at the regulating organ. However, it needs to be enrolled according

Table 1 - Classification of information included on the labels and/or packages of the dental plaster brands analyzed in the study (S = satisfactory information; U = unsatisfactory information; A = absence of information).

Information	Type II plaster			Type III plaster		Type IV plaster			Type V plaster
	Dam Proben®	Vigodent®	Asfer ®	Yamay®	Asfer ®	Asfer ®	Vigodent®	Dentsply®	Polidental®
How to use	A	S	S	S	S	S	S	S	A
Composition	A	S	S	S	S	U	U	U	S
Price	A	A	A	A	A	A	A	A	A
Expiration date	A	S	S	S	S	S	S	S	A
Health risks	A	A	U	U	U	A	A	A	A
Disposal instructions	A	A	A	A	A	A	A	A	A

Asfer® has three different types of plaster and Vigodent® has two different types of plaster

to the Resolution 260/02, art. 2, which states the health products subject to registration. In Annex I of that resolution, obeying certain requirements and conditions, all medical products framed in any risk class, including parts and accessories, must be registered at ANVISA. This way, Figure 1 was elaborated to show clearly, which justifies the no need of registration of dental plaster:

The analysis of variables established in this study showed that instructions for use and expiration date were the most respected requirements and displayed in 78% (n = 7) of the packages, which goes head-on against the CDC guidelines. None of the brands presented price on the label, limiting the access of the consumers to clear information and reducing their ability to make a more consistent choice within their personal budget. The CDC, in Article 6, subsection III, determines as consumer law: "III - adequate and clear information about the various products and services, with correct specification of quantity, characteristics, composition, quality and price, as well as the risks that present"[2-3,7,11-12].

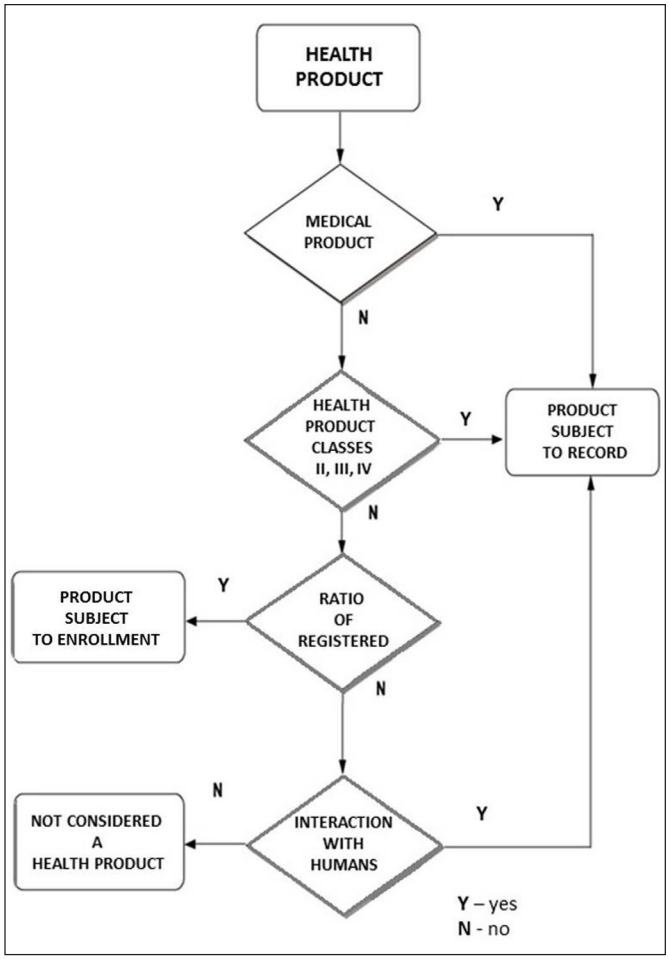

Fig. 1. Flowchart of framework of health products according to registration (ANVISA, 2002[8]).

Expiration date, requirement still respected, being mentioned in 78% (n = 7) of the products. However, this important information was missing in two brands, which may cause serious damage during the clinical work or forensic exam on not taking prey when handling the product, for being out of date or having its hardening time excessively increased. In this sense the Consumer Defense Code also protects consumers, pointing in Article 31, in full: "The supply and presentation of products or services should ensure correct, clear, precise, and in Portuguese on their characteristics, qualities, quantity, composition, price, warranty, expiration date and origin, among other data, as well as the risks posed to the health and safety of consumers"[2-3,10-12].

Another information that missing in 56% (n=5) of brands and unsatisfactory in 34% (n=3) of them was health risks. It is important to highlight that plaster is handled by dental professionals and mainly by dental technicians. So, those professionals are exposed to plaster dust produced mostly during preparation of work or study plaster models. It is known that excessive exposure to plaster powder (silica powder) can cause respiratory diseases to workers not wearing without personal protective equipment. As an example, it can be cited pneumoconiosis, which virtually block the pulmonary alveoli and prevent breathing. The disease starts with silicosis caused by plaster, aluminum oxide and ceramic powders, pumice and Spain white. Still, the major causative agent of this severe disease is silica, which is found on most products like plaster, coating, and ceramic used in dental laboratories[9-11,13-14].

In this regard, the CDC describes on its Article 63 about what is considered violation of the norm: "Omit ostensive signs or sayings about the harmful or hazardous product, on the packaging, wrappers, receptacles or advertisements", and predicts a sentence from six months to two years and fine. It

also clearly states as violation (Article 66): "Making false or misleading statements, or omit relevant information about the nature, characteristics, quality, quantity, safety, performance, durability, price or warranties of products or services," which punishable by detention from three months to one year and a fine[3,11,14]. This information of extreme importance that should be included on labels and packages was simply ignored by a significant number of manufacturers.

Finally, it was analyzed the presence of instructions on product disposal. It must be said that when purchased, the use of the product becomes a responsibility of the consumer, which means, it is not yet considered a residue at this point; it will become later, when the generator of waste will be responsible for managing this waste, as stated in the health legislation[15-16]. Following the Resolution No. 306, which establishes technical standards for waste management for health services, special attention must be given to chapter V, where it is stated that any generator of waste from health service should prepare the plan of waste management from health services, which consists of a document that governs the actions relating to solid waste management, observing the characteristics of the facilities and covering aspects related to the generation, separation, packaging, collection, storage, transportation, treatment and disposal, as well as public health protection. In Chapter IV, there is the classification of waste of health services, which aims at highlighting the composition of the waste according to their biological, physical, chemical, state of matter and origin for their safe handling[15].

In Group "D", called ordinary waste, are all wastes generated in the services covered by this resolution which do not require different processes related to packaging, identification and treatment, and should be considered urban solid waste. Fall into this group: plaster, gloves, adhesive tape, cotton, gauze, bandages, serum catheter and the like, that have not had contact with blood, tissues or body fluids (in case of contamination, they should be classified in Group "A")[15-16].

None of the evaluated packages contained guidance on the disposal of the product. Although it is a manufacturer's obligation, since the product purchased by the dentist is not yet a residue, social responsibility and education on waste disposal belong to everybody, including those who produce the product. Therefore, dental schools should address more deeply themes of biosecurity directed to waste disposal in such a way that future dentists can be aware of their clinical, ethical and legal obligations in order to promote safe and healthy conditions to the patients, workers and environment[17].

Finally, it is noteworthy that most plaster brands did not have some basic information related to the products, probably because the regulating bodies seem to act discreetly in relation to control and supervision. Therefore, the manufacturers do not have a major commitment in guiding the consumer and clearly disobey what the CDC dictates regarding a product that is widely used not only in dental clinics. It is also largely employed in forensic exams, for activities like facial reconstruction and analysis of bite marks, being an important adjunct to unravel crimes, clarify investigations and support dilemmas of processes in civil, criminal, labor, social security, ethical or administrative fields[1-2,7,9-10,18-20].

Given the described survey, it is fair to conclude that the different brands and types of dental plaster analyzed presented some kind of violation of the provisions of the Brazilian legislation, most of them with missing or unsatisfactory information.

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