EXTEMPORANEOUS DISPENSING – COMPARATIVE ANALYSIS BETWEEN GREECE AND BULGARIA

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ABSTRACT

The pharmacist is responsible for compounding preparations of acceptable strength, quality, and purity with appropriate packaging and labeling in accordance with good pharmacy practices, official standards and relevant scientific data and information. These drugs are widely used by specific groups of patients such as elderly patients, children, etc. That is why the aim of this study is to compare the most prescribed extemporaneous preparations and to outline the disease for which they are prescribed in Greece and Bulgaria.

KEYWORDS: Extemporaneous medications, Greece, Bulgaria.

INTRODUCTION

USP Chapter 795 states that “The pharmacist is responsible for compounding preparations of acceptable strength, quality, and purity with appropriate packaging and labeling in accordance with good pharmacy practices, official standards, and relevant scientific data and information.” The compounding of quality preparations must involve the use of high-quality chemicals.

Compounding standards

Patients are entitled to expect that products extemporaneously compounded in a pharmacy are prepared accurately and are appropriate for use. A few rules should be followed when getting involved in extemporaneous preparation.

- A product can be extemporaneously prepared only when there is no product with a marketing authorization available and that the facilities used to prepare the product complies with the accepted standards.
- The pharmacist and any other members of the staff involved should be capable and experienced to embark on the tasks.
• The required facilities and equipment are available. Equipment must be maintained in good state to guarantee that performance is not diminished in any respect, and must be fit for the intended purpose.

• The pharmacist has to be satisfied as to the safety and appropriateness of the formula of the product not including cases where methadone mixture is prepared extemporaneously.

• It has to be made sure that all the ingredients used, are sourced from recognized pharmaceutical manufacturers and are of a quality accepted for use in the preparation and manufacture of pharmaceutical products. Relevant legislation must be complied with, where appropriate.

• Particular consideration and care should be paid to substances which may be hazardous and special handling techniques are required.

• The product should be labeled with the necessary particulars, including an expiry date and any special requirements for the safe handling or storage of the product.

• If undertaking large scale preparation of medicinal products, all relevant standards and guidance are adhered to.

• Records should be kept for a minimum of two years.

Most commonly prepared extemporaneous preparations
1. Mixtures eg cough mixtures, laxative mixtures etc
2. Gargles and Mouthwashes.
3. Lotions, Calamine, Formaldehyde, Potassium Permanganate, Sodium Bicarbonate, Sodium Chloride and Eye Lotions.
4. Ointments, Creams and Pastes.
5. Preparations for corn and wart treatments.

Ointments are semisolid dosage forms intended for external application either to the skin or mucous membrane. They can be medicated (dissolved or dispersed in vehicles. For example steroids or non medicated used for physical effects as protectants or lubricants. There are four groups of ointment bases: those are oleaginous, absorption, water removable and lastly water soluble bases. Two methods are used to prepare ointments depending on the nature of and the properties of the constituents of base, incorporation of solids liquids and the other method used is fusion. In spite the fact that topical preparations are not required to be sterile they should be free of certain microorganisms such as staphylococcus aureus and pseudomonas aeruginosa, for this microbial preservatives are used to inhibit any growth. As far as filling
concerns it can either be done by hand filling or mechanical filling and packed in such way that there are no air spaces in the jar, to avoid contamination, stored at a cooled place and of course labeled as for external use only.

**Creams** are viscous liquid or semisolid emulsions for application on skin and mucous membrane. They may be medicated, for example to be applied on burns and non medicated, emollients. There are two types of creams, water in oil creams or oily cream containing w/o emulsifier eg. cold cream and oil in water also known as aqueous creams containing o/w emulsifier, eg. hydrocortisone cream. Creams are prepared by dispersing or dissolving medicinal agents in emulsion. Pestle and mortal are used to blend the ingredients and prepare the emulsion. As far as their packaging concerns, it is the same as ointments, so again no air spaces should be in the jar and well tightly closed in their container to avoid risk of contamination. To inhibit microbial growth preservatives along with methylparaben, propylparaben, benzoic acid, phenols and sorbic acid are used.

**Pastes** are semisolid preparations intended for external application to the skin. They generally contain large amount of finely powdered solids such as starch, zinc oxide, calcium carbonate etc. They provide a protective coating over the areas to which they are applied. The base may be anhydrous: liquid or soft paraffin or water-soluble: glycerol or mucilage. Their stiffness makes them useful as protective coatings. For instance magnesium sulfate paste, zinc and coal tar paste.

**Liquid** or viscous preparations are intended for application to the skin. typically, they are suspensions or emulsions. Most of the official preparations contain paraciticicides and are intended for only a small number of applications. Liquids should be dispensed in colored fluted bottles to be able to distinguish them from any other liquid preparations that are meant for internal use. The container should be labeled as ‘for external use only’. Examples of applications are calamine application compound B.P.C., dicophane application B.P.C.

Monophasic liquid dosage forms
They are represented by true or colloidal solutions. The component of the solution which is present in a larger quantity is known as solvent, whereas the component present in a smaller quantity is termed as solute.
They can be classified as
1. Liquid for internal use e.g. syrups, elixirs, linctus, drops and draughts.
2. Liquids for external use which are of two types.

(a) Liquids to be applied to the skin e.g. liniments and lotions etc.
(b) Liquids meant for body cavities e.g. gargles, throat paints, mouth washes, eye drops, eye lotions, ear drops, nasal drops, sprays and inhalation.

**Aromatic waters**

Aromatic waters are also known as medicated waters. They are dilute, usually saturated, aqueous solutions of volatile oils (e.g. peppermint oil, cinnamon oil) or volatile substances (e.g. camphor).

Uses

(i) Some of them have a mild therapeutic action but
(ii) Mainly they are used as flavouring agents in preparations meant for internal use.

**Syrups** are liquid oral preparations in which the vehicle is a concentrated aqueous solution of sucrose or other sugar.

**MATERIALS AND METHODS**

The aim of the study is to compare the most prescribed extemporaneous preparations and to outline the disease for which they are prescribed.

**Methods** Comparative analysis is performed together with statistical processing of the data. The questionnaire was applied in Bulgaria and Greece for 6 months during the period March – September 2014. Statistical processing was performed through SPS ver. 22.

The language of the questionnaire was Bulgarian and English. The tests took place in Sofia, Bulgaria and Thessalonki, Greece. The test subjects were recruited from the pharmacies in the two cities.

Male and female volunteers of different ages were invited to take part in the test. Test subjects could be included in the test if they fulfilled all inclusion criteria and none of the exclusion criteria.

Inclusion criteria

Subjects had to meet the following criteria to be included in the test.

- Persons who are capable to read and speak Bulgarian/ English;
• Persons who are prescribed with extemporaneous preparations;
• Persons that understand the aim of the study.

Exclusion criteria
If subjects met one of the following criteria, they could not be included in the test.
• Persons who belong to medical personnel (like physicians or pharmacists)
• Persons with communication problems.

Data management and quality control
The findings are documented on a standardized questionnaire. Data from the questionnaires are entered on an ongoing basis into a database (SPSS ver. 22.0) after each interview in order to perform the interim analyses.

Pilot Testing
In a pilot test with 2 test subjects, the questionnaire was checked for the right wording/phrasing of the questions and for possible answers that could be given. The questions were selected in consideration of their significance for the patient. A pharmacist checked the priority concerning the significance for the patient. For this test, a total of 30 patients were recruited. After the start of the project one of the patients gave up the program.

RESULTS
Table 1: The ANOVA analysis for comparison between Greece and Bulgaria.

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There is significant difference between Greece and Bulgaria only in regards to the application of extemporaneous medication – the Greek patients are applying it more often in comparison to the Bulgarian patients.

The most common applied extemporaneous drug forms in Greece are cold cream (USP) – soothing ointment or rose water ointment as an inflammatory product and as vehicle of various topical medications; antiseptic lotion applied in cases of acne; peeling lotion applied in cases of acne; salicylic cream for treatment of acne; solution de Milian – great source for oral mucosa and in cases of stomatitis; lotion Andrews – for treatment of onychomycosis; Eau de Cologne for hyperhidrosis of hands and feet; vanishing cream – for hydration of the body; beauty masks and colle a lïcthyol.

CONCLUSIONS
The analysis of the results gathered show that there is no difference between the main problems for which extemporaneous preparations are prescribed. The main diseases are dermatological such as acne, dermatitis, etc. The main population that applies extemporaneous medication includes infants, elderly patients and patients with dermatologic chronic disorders.

Despite the great number of commercially manufactured medications extemporaneous preparations are still prescribed and dispensed both in Greece and Bulgaria.

REFERENCES


