PHARMACEUTICAL CARE NETWORK EUROPE

Working Conference 2011 – Abstract

Does pharmaceutical care impact on the safety of individual patients?

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The above mentioned participant in the PCNE WC 2009 wishes to submit following abstract for a poster or short oral communication (please type & then fax the form to the secretariat). Max. 350 words.

Title: **Readability levels of patient package inserts for biopharmaceuticals**

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Type of abstract

x Research ☐ Practice development ☐ Practice implementation

Aim of project/study: The term “health literacy” refers to the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions. Biopharmaceutical based products represent a greater and greater proportion of the total pharmaceutical market. The aim of this study was to evaluate the readability levels of the patient package insert for biopharmaceuticals.

Method: The sample of study included the authorized biopharmaceuticals by European Medicines Agency until February of 2007. They were classified in five groups: Monoclonal antibody based products, cytokines, therapeutic enzymes, recombinant blood factors/blood related products, and recombinant hormones. Vaccines and insulins were excluded from the study. The sections of the package insert evaluated were: (1) What is it and why is it used, (2) Before using, (3) How to use, (4) Possible adverse effects, and (5) Storage. The SMOG formula was used to assess the readability level of the package inserts. The Flesch readability formula was applied to a representative medicine of each group selected randomly, in order to verify the results of SMOG formula.

Results: The total number of package inserts assessed was 40 (13 cytokines, 10 recombinant blood factors/blood related products, 7 monoclonal antibody-based products, 6 recombinant hormones and 4 therapeutic enzymes). The SMOG median scores of each of the sections of the package inserts were: (1) 18.7±2.6, (2) 17.4±1.8, (3) 16.8±1.6, (4) 21.4±3.4 and (5) 13.8±1.1. The median scores of Flesh formula were (1) -1.2±7.2, (2) 6.6±4.5, (3) 4.2±9.7, (4) -8.2±11.8 and (5) 16.5±0.8. In general all the

sections had a very low degree of readability (moderate reading difficulty: 14<SMOG<16, difficult: 16<SMOG<18 and very difficult: SMOG>18) and the two formulas applied coincided from a qualitative point of view (optimum readability level in Flesh > of 10). The section of greater difficulty was (4) Possible adverse effects, and the least difficult was (5) Storage. Efforts to improve readability of patient package inserts of biopharmaceuticals must be done to contribute to health literacy and to promote medicines safety and adherence in the context of pharmaceutical care.

+++ NB: PhD students get 50 Pound reduction on the conference fee if their abstract is accepted ++++