Package inserts and their comprehensibility for patients

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Background: Content and design of package inserts have an important impact on patient compliance and thus on the effectiveness of drug use. Regardless of all efforts by the supervisory authority and the manufacturers to improve the readability and comprehensiveness they are still under discussion despite the recommendations of the European Commissions for testing the readability of package inserts.
Aims: The survey PAINT (package insert test) examines the comprehensibility and availability of information from five package inserts of different drugs and five in the run-up to this test developed model package inserts of the same drugs.
Methods: A questionnaire with 15 questions to the content of the package inserts was adapted by references from Sless and Wisemann[1], the EMEA and the EFPIA. It was distributed among 1150 patients. In a cross-over procedure every participant got one original and one model package insert within the interval of 4 weeks.
Results: 1105 persons answered the questionnaire in the first round and 1051 in the second (return rate: 95.9 % and 91.2 %). At the time of the study the participants were 10 to 92 years old with a mean age of 38 years. Two third of the interviewees were woman.
There was only a small number of missing values. 92.6 to 94.4 % of all questions were answered completely. For this task the participants needed 10.9 to 13.8 minutes in the calculated median for each model package insert.
In every leaflet the persons asked could find a correct answer significantly better for the questions by the model package inserts compared with the original version. They could also read model leaflets significantly faster. The time which the participants needed to answer the 15 questions for the original package inserts were 14.3 to 19.6 minutes in the calculated median. With regard to the original package inserts participants gave correct answers only in 74.7 to 85.8 % of the cases. In the originals they did not found 3.8 to 6.9 % of the requested information.
For example, regarding the question “What is the maximum dose for a day?” the volunteers reproduced correctly this information in the model package insert in 83.6 to 94.0 % of the cases which was significantly better than compared with the results for the originals (9.4 to 90.2 %). 9.9 % of the participants could not find this important information in the original editions. Most of the mistakes based on instructions of the dosage in milligram instead of “tablet” or volume and the maximal daily dosage was better found in package inserts which presented this information in a table.
Conclusions: It is possible to optimize the package inserts. Therefore we suggest the following recommendations for an instruction of the dosage in the package insert:

1. Every dose must be noticed in number of tablets or capsules and volume respectively.
2. Use a table for a better understanding is recommendable.

[1)] Sless, D.; Wiseman, R.: Writing about medicines for people; Pharmaceutical Benefits Branch Department of Health and Family Services, Canberra (1997)

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