Many package leaflets are still difficult to read - Diapharm study reveals only slow improvement

Münster, Oldenburg (Germany) 28 April 2010. Of the 100 most commonly prescribed medicinal products, not even half have a patient information leaflet that is easy to read. Only four of these medicinal products have package leaflets that are very easy to understand. This is the finding of a study by the pharmaceutical service provider Diapharm (www.diapharm.com) under contract from the German Federal Institute for Drugs and Medical Devices (BfArM).

“There is a positive trend towards clearer patient information leaflets, but this trend is still weak”, is how Beate Beime from Diapharm characterises the results of the study. “One reason for this is that it only became necessary to check patient information leaflets for legibility and clarity as recently as 2005”, as Beime says. She also notes that the regulation only applies to newly registered medicinal products - older products are not reviewed retrospectively. Many of the 100 most commonly prescribed medicinal products are long-lasting successes, products which have been on the market for many years.

Beime also points out that the methods which are used to check the package inserts of new medicinal products are not always reliable: “A certification system is needed for institutions which carry out such readability tests on patient information leaflets”, suggests the Diapharm manager.

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Avoidable side-effects of medicinal products mainly occur when the drug is unintentionally or unwittingly used wrongly. “It can easily happen. For example, if the patient misunderstands the guidelines on dosage or overlooks the information about contraindications”, warns Beime. For this reason, the EU Commission has drawn up a 'Guideline on the Readability of the Labelling and Package Leaflet of Medicinal Products for Human Use' and revised it again last year. It regulates how an easily readable and intelligible information leaflet should look. However, not all the EU states are adopting these recommendations: “For example, the German legislature has not made the layout aspect compulsory”, Beime complains. As a result, many German medicinal product manufacturers are hardly interested in the design of the patient information leaflet.

A more serious problem was identified by the Diapharm study: newer medicinal product information leaflets are not getting shorter – as recommended by readability experts – but longer. And this trend could get worse: the legislature requires that in future, more information on use with children should be included in the information leaflets.

(c. 2,540 characters)

Image caption *(Beime_Beate_DIAPHARM.jpg)*
The results of a readability study with 100 medicinal products were presented last Wednesday by Beate Beime from Diapharm at the 'BfArM in Dialogue' event in Bonn.

Background information: Diapharm

Diapharm is a full-service provider to the healthcare industry. Founded in 1988, Diapharm supports pharmaceutical companies in all questions concerning regulatory affairs, medical & clinical development, quality and

business development. Its activities focus on the sectors of medicinal products, food supplements and dietetic food, medical devices and cosmetics. With about 100 employees, Diapharm is at the service of multinational companies as well as of recent start-ups and small to mid-sized businesses.