A survey of package inserts use by patients

There are many problems associated with package inserts, according to a new study. As package inserts are one of the most frequently used sources of written information, approaches to optimise them should be explored

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There is an international trend to improve information for patients about drugs and therapy.[1,2] In 1993, at a meeting jointly organised by the WHO and the Council for International Organizations of Medical Sciences (CIOMS), the right of people to be informed about their healthcare was clearly defined.[3] Furthermore, patients are very interested to get more information and a greater say in questions regarding their own health. In 2002, a survey of over 8,000 people in eight European countries showed that 74% of the participants wanted to be more actively involved in treatment decisions.[4]

Both pharmacists and medical doctors can give verbal or written information to patients within or outside the hospital. The problem is that, by direct communication, only those who provide the information can estimate what each patient has understood. Health professionals, however, have limited time to convey comprehensive information. Therefore, there is a need for a combination of verbal and written information to increase knowledge and compliance.[5–7] This is in agreement with regulations issued by the European Parliament and the Council of the European Union Directive 2001/83/EC,[8] which requires that every drug has to have a package insert.[8,9]

So far, assessments of the package inserts of drugs by patients are rare, as are evaluations about their effects on patients' health. The survey described below attempted to assess the importance of different issues of package inserts from the patient's perspective.

Study design

A questionnaire focusing on expectations and preferences of patients regarding package inserts was distributed in November 2001 among 1,500 patients in a community pharmacy in Jena (Germany). Of these, 855 people answered the questionnaire (return rate: 57.0%; age: 13–89 years; average: 50 years; female: 66.2%). The educational training of the participants was as follows:

- Eight years: 18.9% (n=162); 10 years: 24.8% (n=212).
- A-levels: 8.1% (n=69); diploma from university for applied science: 17.8% (n=152); university: 23.5% (n=201); no statement: 6.9% (n=59).

The majority (79.6% of all volunteers) said that they "always" read the package inserts of newly prescribed drugs; 19.3% said that they did so "sometimes"; and only 1.1% said they "never" read them.

On request, participants classified the various subject matters of the package inserts into three out of five categories with regard to the importance for the patients. Information about "therapeutic indications", "dosage instruction", "contraindications" and "side-effects" were seen as "very important", whereas

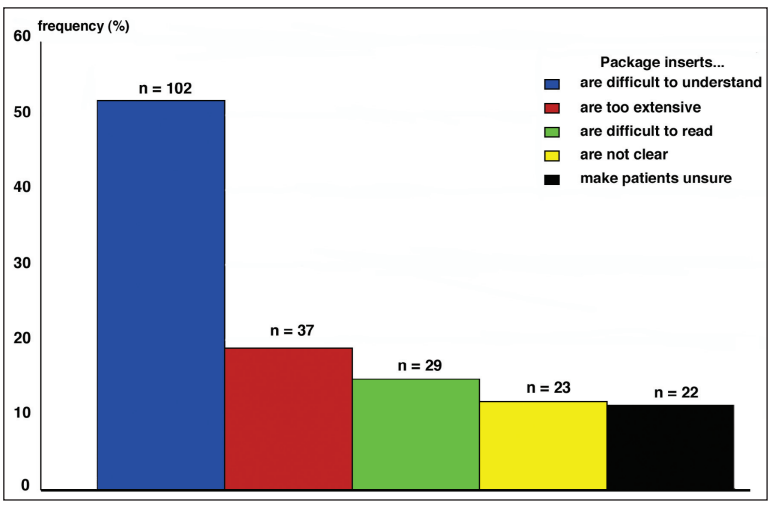

Figure 1. Selected comments about package inserts by 197 participants (multiple answers were possible; 57 comments could not be classified)

Table 1. Classification of the information presented in package inserts

Content category	Assessment by participants	Calculated median	n
Therapeutic indications	Very important	4.09	837
Dosage instruction	Very important	4.07	845
Contraindications	Very important	4.03	846
Appropriate precautions for use and special warning	Very important	4.00	849
Interactions	Very important	3.97	843
Possible adverse drug reactions	Very important	3.80	837
Hints for application errors	Very important	3.63	839
Storage	Important	3.37	844
Therapeutic group	Important	3.37	838
Ingredients	Important	3.33	838
Date of the last update	Important	2.77	846
Application form and quantity of the drug	Important	2.76	845
Manufacturer	Less important	2.22	846

Possible categories for assessment: "most important" – 5; "very important" – 4; "important" – 3; "less important" – 2; "unimportant" – 1

details about the "manufacturer" were considered as "less important" (see Table 1). This ranking is also reflected in the structure that participants suggested for future package inserts (see Table 2). This result was independent from the demographic variables of the survey participants.

The participants were also asked about their wishes regarding the amount of information given and the content for a future package insert. Out of 821 participants, 73.4% said they would prefer "less comprehensive" package inserts, 24.5% agreed with leaving the package insert as it was, and only 2.1%

Table 2. Rank order of content categories in package inserts according to patients and the AMG (German Drug Law),[17] in accordance with the Directive 2001/83/EC of the EU[1]

Calculated median	Content categories	Rank in the order of package inserts	
		Patients	AMG §11
2.71	Therapeutic indications	1	5
3.98	Dosage instruction	2	9
5.12	Ingredients	3	1
5.33	Appropriate precautions for use and special warnings	4	7
5.49	Contraindications	5	6
5.94	Interactions	6	8
6.25	Possible adverse drug reactions	7	11
6.70	Therapeutic group	8	3
7.70	Hints for application errors	9	10
9.56	Application form and quantity of the drugs	10	2
10.12	Storage	11	12
11.89	Manufacturer	12	4
12.30	Date of the last update	13	13

wanted more information. According to 76.3% of 822 participants, a package insert should include "only the most important information"; 8% would have liked additional information; and 15.7% were satisfied with the content of the current package inserts. The size of package inserts was also criticised by 18.8%.

More than 50% of the 197 volunteers who gave comments about package inserts found it difficult to understand the information, and 11.2% felt insecure after reading the inserts (see Figure 1).

Discussion

The results of the survey show many problems associated with package inserts. As package inserts are one of the most frequently used sources of written drug information,[10,11] approaches to optimise them should be explored as soon as possible. This especially refers to difficulties in understanding the extensive information provided, and suggests a more suitable structure for package inserts.[12,13] Other studies confirm the results of this survey on the importance of the content and presentation of package inserts.[11,14,15]

Package inserts should contain only the information that is of importance for the patient, although this is debatable from a legal point of view. Another study, the PAINT survey,[16] showed that patients needed significantly more time to find the information they needed in the original versions of package inserts, compared with shorter versions. The address of the manufacturer for each Member State of the European Union is currently mentioned on package inserts, which can take up to 25% of the space available, and this might have to be reconsidered.[16]

Conclusion

According to the results of different surveys, the structure of package insert should be as follows, in order of importance:

- Name of the medicinal product.
- Ingredients.
- Therapeutic indication and therapeutic group.
- Contraindications.
- Appropriate precautions for use and special warnings.
- Dosage instruction.
- Hints for application errors.
- Interactions.
- Possible adverse drug reactions.
- Application form and quantity of the drug.
- Storage.
- Manufacturer.
- Date of the last update of the package insert.

The European Parliament and the Council of the European Union changed the structure of package insert with the Directive 2004/27/EC. The new rank order is similar to our recommendation, and all Member States of the EU shall have to bring their national regulations into compliance with this Directive by no later than 30 October 2005.[18] ■

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