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ジェネリックを考える

添付文書からみた先発医薬品と後発医薬品

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Abstract：
Original products and Generics studied through package inserts

In April of 2001, we surveyed the package inserts of both original products and generic products. In the survey, the package inserts from 152 pharmaceutical products of 10 specific drug substances were investigated for both the items listed and their descriptions.

The results of this survey indicated that the package inserts of original products were, in general, better than those of their generic counterparts in terms of the amount of information provided. In particular, the information describing the drugs performance in clinical trials, pharmacokinetics, pharmacology, as well as cited literature were better.

On the other hand, the information provided under the item "Precautions" did not differ significantly between original products and generics with the overall content and description being almost the same, comparatively.

In April, 2003, two years after the original survey, we again surveyed pharmaceutical products to determine whether or not the indications provided in the package inserts had been improved. In particular, we examined whether any attempts were made to revise the "Precautions" as per our instructions, or in accordance with the voluntary agreement to provide indications regarding the use of additives, etc. during the last two years. This survey focused particularly on 3 of the 10 drugs targeted in the previous study. Ticlopidine hydrochloride tablets (14 different pharmaceutical products), ceflacor capsules (7 products) and loxoprofen sodium tablets (24 products) were investigated.

The results of this survey showed that package inserts for cefaclor capsules had been improved modestly, having at least one item added in the information given. The added information was "Precautions regarding dosage and administration" and "Adverse effects". In contrast, the number of items provided for ticlopidine hydrochloride tablets and loxoprofen sodium tablets was generally the same as before.

However, all package inserts of cefaclor capsules and ticlopidine hydrochloride tablets had been duly revised according to the instructions on revision of "Precautions" that had been issued during the last two years.

As for loxoprofen sodium tablets, the package inserts of only the original products and two generic products had been revised in accordance with our instructions issued on March 19, 2003. Prior to that, all package inserts of this drug, original and generic, had been written in accordance to issued instructions. In terms of the other information provided, little improvement could be noted.

In conclusion, package inserts of generics were generally improved with due attention given regarding information provided for "Precautions". However, descriptions of items in package inserts of generics differed from product to product. Accordingly, it is anticipated that since the amount of information will be a key factor in the decision on the use of generics in the future, it is essential that the quantity and quality of provided information be improved.