

医療用医薬品添付文書情報に関する検討 (その1) - 錠剤および散剤の包装に関する記載形式について -

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Evaluation of the information on package inserts for medicine (part 1) - Description formats of tablet and powder preparation packages -

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Abstract :

Objective Package inserts for medicine must contain information required for safe treatment and for the preparation and use of medicine. In this study, we investigated the descriptions on package inserts, which is essential information for purchase, and pharmaceutical companies' awareness.

Method We examined the description on the package inserts for tablets, including capsules and powder preparations, from 98 pharmaceutical companies. We also investigated the descriptions of the package section using a questionnaire.

Results According to the descriptions on the package inserts, the package forms could be identified only in 41% of the 2,216 tablet preparations and 13% of the 1,301 powder preparations. The description formats of the package inserts of tablet preparations were standardized only in 26 pharmaceutical companies, and those of powder preparations were standardized only in 19 pharmaceutical companies. However, according to the answers to the questionnaire, most pharmaceutical companies considered that they had standard description formats, and did not need to change the formats. With regard to the items required for identification, many companies answered that no descriptions on the package inserts are necessary.

Conclusion The package forms of many medicines could not be identified based on the descriptions on the package inserts alone, but those pharmaceutical companies were not inclined to improve the descriptions, suggesting that to control medicines appropriately, it is necessary to standardize the description formats of the package inserts.

Keywords : package inserts, tablet, powder, preparation package, pharmaceutical company