

医療用医薬品添付文書に記載の「社内資料」 情報提供体制に関する検討

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Provision of “Data on File” Described in the Labeling of Prescription Drugs

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Summary

The labels of some prescription drugs refer to “data on file” (internal company data). In this study, we investigated if pharmaceutical companies appropriately provide “data on file” to medical staff upon request. We examined how many prescription drug labels refer to “data on file” by searching the website of the Pharmaceuticals and Medical Devices Agency (PMDA), Japan.

“Data on file” were provided within 2 weeks in 32 cases, and one more was sent after a second request; two could not be obtained. Among the 33 “data on file” provided, 42.4% was provided through medical representatives in pharmaceutical companies (MR) visit, 48.5% by mailing and 9.1% by fax. It took an average of 1.8 days for “data on file” to be provided.

Among prescription drugs, the number of labels referring to “data on file” was 7,389 out of 11,853 total prescription drugs. The number of brand-name drug labels referring to “data on file” was 651 out of 1,597. As regards drug categories the labels of “drugs for various other organ systems” and “drugs for public health” most frequently referred to “data on file” (100%), followed by “drugs for allergy” (60.7%), “drugs for skin” (59.6%), and “drugs for cancer” (57.4%).

“Data on file” is a part of the evidence for the drug description on the label, and therefore should be provided immediately by pharmaceutical companies on request. It is important to establish a system to ensure that all “data on file” is made available to medical staff in a timely manner by pharmaceutical companies when it is requested.

Key words

“Data on file”, Prescription drug label, Brand-name drug, Provision