96076 New Drug Report

(a)

For each new prescription drug for which a notice was filed with the Department under Section 96075, a manufacturer shall file a report with the Department.

(b)

The report shall include the following information: (1) A narrative description of the marketing and pricing plans used in the launch of the new prescription drug in the United States and internationally. (2) The estimated annual number of patients in the United States with a condition for which the new prescription drug may be prescribed. This estimated number shall account for the total number of patients with a condition for which the new prescription drug may be prescribed and shall not be limited to or based on the quantity of the particular new prescription drug introduced to market, anticipated to be introduced to market, or anticipated to be prescribed. (3) Indicate whether the drug was granted breakthrough therapy designation or priority review by the federal Food and Drug Administration prior to approval. (4) If the drug was not developed by the manufacturer:(A) The date the manufacturer acquired the drug; and (B) The price of acquisition.

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(2)

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(3)

Indicate whether the drug was granted breakthrough therapy designation or priority review by the federal Food and Drug Administration prior to approval.

(4)

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(c)

A manufacturer may limit the information reported pursuant to subdivision (b) to that which is otherwise in the public domain or publicly available.

(d)

A manufacturer may append comments to any information described in subdivision (b).