101ST GENERAL ASSEMBLY

State of Illinois

2019 and 2020

HB4771

Introduced 2/18/2020, by Rep. Deanne M. Mazzochi

SYNOPSIS AS INTRODUCED:

410 ILCS 620/3.24 new

Amends the Illinois Food, Drug and Cosmetic Act. Requires a manufacturer of a prescription drug that is sold, offered for sale, or distributed in this State, or placed on a formulary to be eligible for payment, co-payment, or reimbursement in this State, to notify the Department of Public Health of specified information concerning active pharmaceutical ingredients.

LRB101 17711 CPF 69458 b

- HB4771
- AN ACT concerning health.

2 Be it enacted by the People of the State of Illinois, 3 represented in the General Assembly:

4 Section 5. The Illinois Food, Drug and Cosmetic Act is 5 amended by adding Section 3.24 as follows:

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(410 ILCS 620/3.24 new)

Sec. 3.24. Active pharmaceutical ingredients. A manufacturer of a prescription drug that is sold, offered for sale, or distributed in this State, or placed on a formulary to be eligible for payment, co-payment, or reimbursement in this State, must notify the Department of Public Health of the following:

(1) the country of origin for the active pharmaceutical 13 14 ingredient, in a searchable form by proprietary name, such as a brand name, if one is associated with the drug 15 product, and ingredient name, such as a generic chemical 16 name; if the country of origin for a manufacturer varies 17 18 based on dosage or route of administration, each country of 19 origin shall be specified for each such dosage or route of 20 administration;

21 <u>(2) the Drug Master File number for any angiotensin II</u> 22 <u>receptor blocker and certification that the active</u> 23 <u>ingredient specification contains a nitrosamine</u> HB4771 – 2 – LRB101 17711 CPF 69458 b

1	specification of "Not Detected"; and
2	(3) the Drug Master File number and drug name for any
3	active pharmaceutical ingredient that contains a
4	nitrosamine specification control because the process of
5	manufacture for the active pharmaceutical ingredient makes
6	use of recycled solvents or catalysts.