

Federal State Institution
“State Institute of Drugs and Good Practices”
(FSI “SID & GP”)



**A survey of pharmaceutical
manufacturers on the readiness for
the introduction of a labeling system**



STAGES AND POLLING RESULTS OF RUSSIAN LICENSEES

FIRST STAGE

Last October
we requested data from
493 Russian
license
holders reflecting costs for
re-equipment of packaging
lines for different pharma-
ceutical products .

246 businesses
responded

99 domestic companies
provided calculations
of requested costs

147 companies refrained from
disclosing such calculations



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SECOND STAGE

In November 2017, during the second stage, we requested that companies file in data on the number of lines planned for commissioning within the drugs labeling system. The submission deadline was December 5, 2017. Received detailed reports allowed to present a comprehensive summary in late January 2018. я

539

requested that companies file in data on the number of lines planned for commissioning within the drugs labeling system.

1000 packaging lines will be commissioned individual labeling system

46

manufacturers did not favour our information requests



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THIRD STAGE

During the 3rd stage of these polling activities in February 2018, we asked Russian manufacturers to share their timelines for produced drugs to be entered into the automated monitoring system of INN. Calendars received from the manufacturers with schedules of drugs entered into the INN system, were relayed to the Ministry of Industry and Trade in late 2018.

RECEIVED

225 responses from
manufacturers

out of

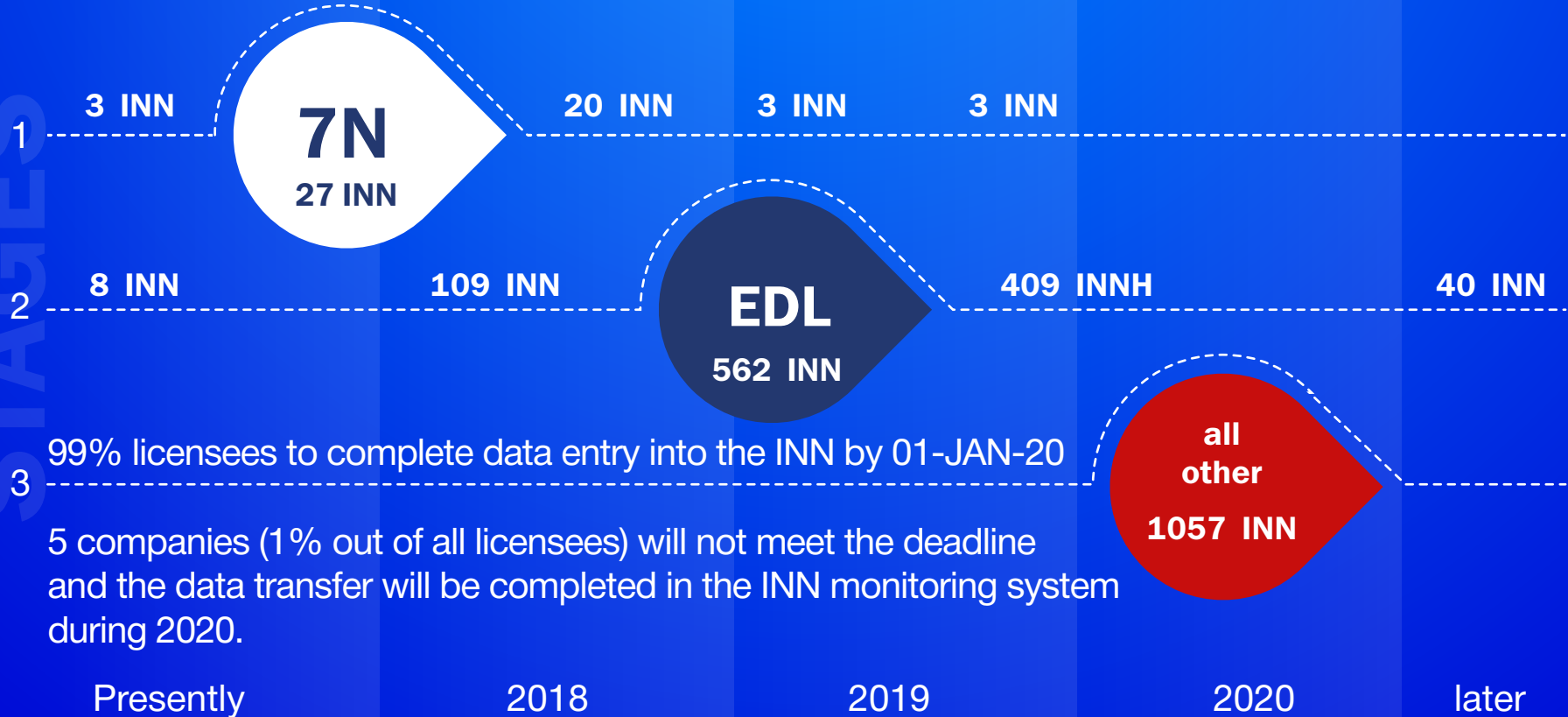
468 contacted
companies.

Total number of license holders
is 539



RESULTS DEMONSTRATED

STAGES





FOREIGN MANUFACTURERS SURVEY

Number of foreign
production sites

1708

as of 20.04.2018 responses were received from
four pharmaceutical manufacturers (17 production sites)

107

INN
ALL

4

INN
7N

55

INN
EDL

In total, as reported by the Russian MoH on 17.01.2018, there are almost two thousand foreign to Russia sites (1708). Starting this April - on a monthly basis - our Institute presents a consolidated report to the Ministry of Industry and Trade based on surveys of foreign manufacturers.

The survey is currently in process, and some pieces of information are still on the way. The latest on that is as follows: on April 20, 2018 we received four pharmaceutical manufacturers (17 production sites, 5 holders of marketing authorizations: KEDRION (Italy), Swedish Orphan Biovibrum International AB (Sweden), Hetero Labs Lt. (India), Gedeon Richter (Hungary). In total it makes 107 INN, 4 of them are 7N и 55 - EDL.



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