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Debates intensify over one-year ban on licenses to Toll manufacturers

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In the lead-up to March economic convention, the Egyptian Ministry of Health decided a one-year suspension of licenses to new companies operating in Toll manufacturing contracts of pharmaceutical products. Ministry officials said the moratorium would enable the government to review registration requirements for Toll manufacturing operators, which were last updated in 2011.

The MoH says that Toll manufacturing operators are simply bureaus that seek licenses as companies to register certain pharmaceutical products in Egypt and outsource manufacturing of these products to local laboratories. The

latest data from the MoH estimate the number of such bureaus at 943 and the number of local laboratories for pharmaceutical production at 137 labs, at a ratio of 6.8 bureaus per a lab. "This means that the number of Toll operators is disproportionately large compared to available manufacturing capacity," the MoH argues.

Argument is intensifying over the impacts of the MoH decision on the local pharmaceuticals market. Toll operators view the suspension of new registrations as an obstacle to free and full competition, empowering the few companies which monopolize the market. The MoH contends that its decision will improve the investment climate by creating an opportunity for setting up new labs for manufacturing pharmaceuticals rather than overreliance on existing

labs for Toll contracts.

"The one-year suspension of licenses for new Toll operators is unfair and can only serve the aims of large pharma companies for monopolizing the drug market," argues Mahmoud Fattouh, spokesman of Toll manufacturing operators.

Toll operations are in fact actual producers of pharmaceuticals, he contends, producing drugs through renting production lines from a third party for a contractual amount of money. "They sell their products at appropriate prices, and strongly increase market competition with large pharma."

He estimates local investments in manufacturing drugs at around EGP27.5bn in 137 laboratories. "But only 25 labs have a monopoly position in the market," Fattouh remarks.

"Representatives from these large labs are also members of the advisors committee of the Minister of Health, which took the decision to suspend Toll operators' registration so that they can exercise full control over prices," he notes.

Toll manufacturing operators have already filed a lawsuit against the MoH decision, claiming that the move is unfounded as drug manufacturing labs are raring to more orders from Toll operators. "Increased manufacturing of medicine is eventually in the interest of consumers as they will be able to buy at lower prices," says Fattouh.

Meanwhile, the MoH claims that the one-year suspension of new licenses to Toll operations aims at regulating the local pharmaceuticals market. "The number of Toll operations is dis-

proportionately large compared to drug manufacturing labs," argues Hosam Abdel Ghaffar, spokesman of the Ministry of Health. "The decision will open up new opportunities for investment in this vital industry, taking into account the advent of Egypt's economic summit due this March," he predicts.

The decision will not affect the operation of previously licensed Toll manufacturing companies, he argues, but local labs have limited capacity, production lines, and human resources. "In addition, several applicants for Toll manufacturing licenses are motivated by attempts at securing a status as producers of specific generic products without actually starting to produce them," Abdel Ghaffar claims. "This practice eventually leads to shortages in the market."