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Biocon gets nod to sell first generic in EU

BS REPORTER
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Biopharma major Biocon has received its first generic formulations approval in the regulated markets for a drug to reduce cholesterol. The company will begin selling its rosuvastatin calcium tablets indicated for hyperlipidemia or mixed dyslipidemia in 15 European countries starting from FY17.

"This is indeed a proud moment for Biocon's small molecules business," said Kiran Mazumdar-Shaw, chairman and managing director of Biocon. "This approval paves the way for Biocon to launch rosuvastatin calcium tablets in several European countries."

Biocon was the first generic company to receive the Certificate of Suitability for the formulation from the European Directorate for the Quality of Medicines. The move will allow the company to address a $1.2 billion opportunity that exists in Europe. It will collaborate with regional partners to market the drug.

The approval will also make it easier for Biocon to get regulatory clearance to sell its drugs in emerging markets, which follow what US and European regulators say. It will also boost Biocon's generic formulations business, which is targeting 20-25 filings over the next few years.

"This approval paves the way for Biocon to launch rosuvastatin calcium tablets in several European countries"

KIRAN MAZUMDAR-SHAW
Chairman & MD, Biocon

"The European approval for Biocon's generic version of rosuvastatin calcium underscores Biocon's unique strengths in the chronic therapies space," said Arun Chandavarkar, chief executive officer and joint managing director of Biocon. "It augurs well for this nascent business, which will be one of our growth drivers in the coming years." The firm is also setting up a new facility in Bengaluru for developing and manufacturing new potent oral solid dosage formulations, which will help it grow in the generics space. The Biocon stock rose 4.49 per cent to ₹463.95 soon after the announcement was made.

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Biocon gets foot in EU door with generic okay

BIOTECH company Biocon has received its first generic formulation approval in Europe, paving the way for the company to launch rosuvastatin calcium tablets in several European countries, reports PTI.

Biocon has received European approvals for rosuvastatin calcium 5 mg, 10 mg, 20 mg and 40 mg tablets, a generic equivalent of Crestor tablets, indicated for hyperlipidemia or mixed dyslipidemia, the company said.

The generic formulations approval in the regulated markets is an important milestone in Biocon's small molecules strategy of forward integration from APIs (active pharmaceutical ingredient) to finished dosages, it said on Monday.

Biocon said the approval for rosuvastatin calcium through decentralised procedure will open the door for Biocon to over 15 European countries and will enable the company to address a $1.2 billion opportunity, starting FY17.

The form said it was the first generic company to receive a Certificate of Suitability for rosuvastatin calcium API from the European Directorate for the Quality of Medicines.

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Biocon gets foot in EU door with generic okay

CEP certification indicates that an API is suitable for use in medicinal products in the EU.

"This approval paves the way for Biocon to launch rosuvastatin calcium tablets in several European countries. We plan to collaborate with regional partners in the near term to provide access to this affordable generic and thus help patients and governments to bring down their healthcare spends," Biocon CMD Kiran Mazumdar-Shaw said.

Biocon in a statement said it aims to rev up its generic formulations business with a target of 20-25 filings over the next few years. Its new potent oral solid dosage formulations facility coming up in Bengaluru will enable this business expansion.

It is also working on dossiers to introduce these formulations in emerging markets where regulatory clearances are primarily based on approvals given by regulators in the US/EU, the statement added.

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EU nod for cholesterol drug to help Biocon move up value curve

An indication of US ANDA approval in near future, says CMD Kiran Mazumdar Shaw

SUNANDA JAYASEELAN / HIRAL DESAI

Biocon has received approval from the European Directorate for the Quality of Medicines for cholesterol-controlling drug Rosuvastatin Calcium, opening the doors to over 15 European countries and will enable the company to address a $1.2-billion opportunity starting FY17. Speaking to *Bloomberg TV India*, Biocon Chairperson and Managing Director Kiran Mazumdar Shaw says the approval is an indication of US ANDA approval in the near future.

What is the size of the addressable market for which you got the cholesterol-control drug approval?
The size of the generic market is obviously a fraction of what the current size of Rosuvastatin's market. But I think, more than anything else, this is about our business strategy of moving up the value curve. We have been a very large player in this statin business, and Rosuvastatin off course has been in the API market all these years. I think this enables us to move up the value change and create far creative value. The EU approval is an indication of a US ANDA approval in the near future.

Talking about the USA API market, can you clarify if there was an import ban in the USA as far as your API business goes?
Completely wrong. We have had no ban on any of our plants. I don't know where you got that wrong information. But, I would like to vehemently correct that perception. We have passed all our US audit to date, we have absolutely no ban on any of our manufacturing sites.

The EU approval offers you opportunities of close to $1.2 billion. So what is the kind of incremental revenue gain that you are looking at?
Obviously, it is about the number of players in the market and the way we basically strategise to get good market share. So, obviously there is no such optics I can provide you with at this stage, but I think the important message that we are giving is that we have arrived on the generic stage.

You have mentioned that you would be looking to collaborate with regional partners. What kind of collaboration are you looking at?
Europe is not a homogenous market. And in certain key markets, we will also look at regional partners. And, this also enables us to get into other regions of the world – in Middle East and South East Asia – because European approvals enable us to get into certain markets and register in an expeditious manner.

Europe is not a homogenous market. In certain key markets, we will look at partners.

KIRAN MAZUMDAR SHAW
CMD, Biocon