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Q&A for Halol Facility Post USFDA OAI Classification

1. What does the Official Action Indicated (OAI) status mean?

The OAI status implies that the USFDA expects further corrective actions to be undertaken by the company. Interalia, the OAI status normally implies that the USFDA may put all new approvals from the Halol facility on hold till the outstanding corrective actions are completed. However, we continue to manufacture and supply already approved products from the facility to the US market.

2. Is there a likelihood of Warning Letter being issued to the plant?

This is a process that is governed by the Compliance Office at the USFDA and we would not like to comment on the same.

3. Will supplies from the plant to US be affected?

We do not anticipate any major supply disruption for existing products due to the OAI classification. We will work with the USFDA to ensure that there is no shortage in supplies to the US market.

4. How many ANDAs are pending approval from the Halol site?

19 ANDAs and 2 NDAs are pending approval from Halol for the US market

5. Do you expect ANDA approvals from Halol to continue?

In their communication, the USFDA has mentioned that they may put all new approvals from the Halol facility on hold. As a result, product approvals for the US market may get delayed till the outstanding corrective actions are completed and Halol facility comes back into compliance with USFDA norms.

6. Do you have backup for the injectables and other complex generics filed from Halol?

Although the Baska facility is USFDA approved and can manufacture injectables, it cannot manufacture some of the dosage forms filed from Halol. Hence, a backup of such products may not be possible.

7. How much does US supplies from Halol contribute to overall revenues?

US supplies from Halol, as of now, contribute approximately 3-4% of our consolidated revenues.

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8. Will supply of products from Halol to other countries be affected?

We do not anticipate any major supply disruption for other markets.

9. Do you expect other international regulatory agencies also to review their stance on Halol post this development?

As of now, we do not have any indication on whether any other regulatory agency is going to re-inspect the Halol facility because of OAI status. However, post the USFDA inspection in Dec-2019, Halol has undergone a successful inspection by the European regulatory agency.

10. How much time will be required to get Halol back into compliance?

We are communicating with the USFDA to discuss the next steps. As of now, it is difficult for us to give any timeline for resolution.

11. Will Halol require a re-inspection before it gets USFDA clearance?

Generally, once the facility is classified as OAI, it requires a re-inspection to clear the OAI status. However, the final decision rests with the USFDA.

12. Will the COVID-19 lockdown delay the re-inspection?

We can't comment as it depends on multiple factors like the timeline of lockdown in India and when international travel restrictions are lifted globally.

13. What message would you like to give to your customers in the US?

We would like to assure our customers that supplies of existing products will continue. We are cooperating with the USFDA and taking all necessary steps to resolve the outstanding issues as fast as possible. Sun Pharma is committed to being cGMP compliant and in supplying high-quality products to its customers globally.

14. Will you be appointing an external consultant to help you in Halol remediation?

We have been working with a third party consultant since the conclusion of the inspection in December 2019.

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