



27 August 2017

Company Statement - Combiflam®

About Combiflam®

- Combiflam® is the most widely prescribed analgesic used for relieving pain, and has been in the Indian market for over thirty years.

About the recall of Combiflam®

- Some batches of Combiflam® tablets manufactured between 2015 and the first half of 2016 were found to have a 'delayed disintegration' time, as they took longer than the stipulated time of 15 minutes to disintegrate completely. This was qualified as a Class III recall, wherein consumption of the product is not likely to cause adverse health consequences.

Combiflam® continues to be safe

- In the case of Combiflam®, though the disintegration time was delayed, doctors and patients who have prescribed or consumed Combiflam® can be assured that ***there is no impact on the safety and efficacy of the product.***

Corrective Measures

- We have been working closely with CDSCO and have taken necessary action as required. As a result of the technical actions taken to resolve this issue, there have been no deviations in the samples of the subsequent batches.

Message for doctors and patients

- Sanofi India is an ethical and patient-centric company, and we assure all our consumers that Combiflam® continues to remain a safe and efficacious analgesic. The Company has taken all suitable measures and acted in compliance with the regulatory directives.