11th May, 2016

Company statement on the three batches of Combiflam® recalled in 2016

About Combiflam®

- Combiflam® is a safe, trusted and amongst the most widely prescribed analgesic used for relieving pain, and has been in the Indian market for over three decades.

About the recent recall of Combiflam®

- Routinely, drug regulators collect market samples and check these samples for parameters like Hardness, Disintegration, Assay, Uniformity, etc. in a government laboratory. One such parameter, technically referred to as the Disintegration Test, assesses the ability of the tablet to break down into smaller particles in a stipulated period of time.

- Three batches of Combiflam® tablets experienced a delay in the disintegration time as they took longer than the stipulated time of 15 minutes to disintegrate completely. Since the consumption of Combiflam® from these three batches, is not likely to cause any adverse health consequences, the drug regulator initiated a Class 3 recall.

- Please note that in 2016, three batches of Combiflam® have been recalled. The details of these three batches are below:

Batch no.#	Manufacturing Date	Expiry Date
A150045	January 2015	December 2017
A150825	July 2015	June 2018
A150682	June 2015	May 2018

- Tablets from these recalled Combiflam® batches passed other technical parameters tested by the government analyst including Assay, which is an important laboratory test to quantify the amount of active ingredients in the tablet. We would like to reiterate that the recalled batches passed the Assay test and hence, contained the labelled amount of drug for therapeutic action.

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 as safe and trusted a brand, as before. The Company has taken all suitable measures and acted in compliance with the regulatory directives.