



23rd May 2016

BSE Limited
Phiroze Jeejeebhoy Towers
Dalal Street
Mumbai 400001

National Stock Exchange of India Limited
Exchange Plaza, 5th Floor,
Plot No.C/1, G Block,
Bandra Kurla Complex
Bandra (East), Mumbai 400051

Scrip Code: 500674

Scrip Code: SANOFI

Dear Sirs,

Re: Company statement on the recall of Combiflam® batches

We enclose herewith the Company's statement on the recall of Combiflam® batches, the contents of which are self-explanatory.

Thanking you,

Yours faithfully,
SANOFI INDIA LIMITED

A handwritten signature in blue ink, appearing to read "K. Subramani", is written over the typed name.

K.SUBRAMANI
COMPANY SECRETARY

Encl:a/a



Company statement on the recall of Combiflam® batches

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 3 batches, is not likely to cause any adverse health consequences, the drug regulator initiated a Class 3 recall.
- 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.