Scientific Centre of Drug and Medical Technology
Expertise after academician E. Gabrielyan
Director -Hakob Topchyan

Dear Mr. Topchyan,

Subject: Notification of Out of Specification (OOS) results for TAMC (total aerobic microbial count) and TYMC (total combined yeasts/ moulds count) for one lot of Atorvastatin 80 mg Film Coated Tablets and potential impact to other Atorvastatin lots manufactured by Pfizer.

Testing of lot T29168 for Atorvastatin film-coated tablets (FCT) resulted in out of specification (OOS) results for TAMC and TYMC at time zero stability testing. Tests detected the presence of *Enterobacter cloacae* in the analysed samples. This lot was packaged from bulk batch # S53283 which was partly distributed in the United Kingdom (lot T43157) with remaining quantities under Pfizer control. No materials from this bulk batch were distributed to other countries. Out of an abundance of caution, even though no further OOS results have been obtained for any additional lots within the scope of the investigation, Pfizer proposes to initiate a recall at the pharmacy retail level for all in-scope lots that have been distributed to different markets due to medium risk associated with this issue for immunocompromised patients.

Test	Specification	Results
Total Aerobic Microbial Count (TAMC)	10^3 CFU/g (CFU: maximum acceptable count = 2000)	2750
Total Yeast Mould Count (TYMC)	10^2 CFU/g (CFU: maximum acceptable count = 200)	2950*
Absence of *E. coli*	Absent in 1g of product	Conforms

* This is likely the same organism growing on the yeast/mould medium

An investigation was performed in Pfizer Manufacturing Deutschland GmbH (Freiburg, Germany) and Pfizer Pharmaceuticals LLC (Vega Baja, Puerto Rico) sites. The probable root cause was identified as a drain cleaning event in the blending room during the manufacture of the Atorvastatin tablets at the Vega Baja site. It was concluded that all lots manufactured after this event and before major cleaning of this room were potentially impacted by the event.

The following lot was distributed to Armenia : S91274, expiry date 31.01.2020.

To prevent recurrence, enhanced procedural and system controls have implemented at the Pfizer, Vega Baja site.

The event is limited to the above mentioned lot and does not impact the quality, safety, or efficacy of other Pfizer-manufactured atorvastatin products in Armenia.

Pfizer's Health Hazard Assessment (HHA) conducted to assess the potential risk to patients due to this event concluded that the potential risk is considered to be low in immunocompetent patients and medium in immunocompromised patients. There have been no reports of adverse events associated with the atorvastatin lots considered in scope for this issue.

As a precautionary measure and based on the investigation findings and medical assessment, Pfizer proposes to voluntarily recall the impacted lots to retail/pharmacy level.

It is anticipated that this action may result in a temporary interruption of supply for Liprimar (atorvastatin) **20mg** tablets for the Armenian market starting from Nov 2017 through end of Feb 2018. Pfizer is working diligently to minimize the duration of this interruption of supply.

If you require any additional information or wish to discuss this further, please contact David Palyan, Pfizer Agent in Armenia.

Sincerely,

Hanna Miadzvedzeva
Head of Regulatory Affairs PEH-CauCAR

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