Drug Alert

CLASS 1 MEDICINES RECALL

Action Now - including out of hours

Date: 23rd October 2019 Our Ref: MDR-16-10/19

Dear Healthcare Professional,

Pharma-MT c/o Biogen Netherlands B.V.

Avonex 30µg/0.5ml solution for injection **EU/1/91/033/005**
Interferon beta 1a

Batch Number	Expiry Date	Pack Size	First Distributed
1423675	31/10/2020	4 pre-filled pen + 4 needles	December 2018

Under the supervision of the Medicines Authority, Pharma-MT in collaboration with Biogen Netherlands B.V. is initiating a recall up to pharmacy level for the listed batch of Avonex 30µg/0.5ml solution for injection.

During the 12 month stability study testing of a batch of Avonex, one of the pre-filled syringes out of 20 samples failed the container closure integrity test. Further examination of the syringe indicated impact damage on its interior surface with the likely root cause being a damaged syringe washing nozzle. As part of the stability program a total of 1240 Avonex pre-filled syringes and 1158 Avonex pens have been successfully tested and following the identification of the defect, 318 retention samples of the syringes were visual checked and found to be without defect.

Biogen considered the potential loss of sterility as having a serious adverse health consequence due to the risk of systemic infections. The company reviewed the reported safety information in their global safety database and found no adverse reaction reports attributable to this quality defect.

Notwithstanding this, due to the potential seriousness of the defect, Biogen initiated a voluntary precautionary recall on 18th October 2019.

Since the defect is related to the medical device, Biogen is recalling all the Avonex batches which were manufactured using this batch of syringes. Only the listed batch was distributed locally and all packets of this batch should already have been placed under quarantine.

Yours faithfully

Janice Cassar Giacomotto
Medicines Inspector

Licensing Authority
Superintendent of Public Health