Better Health, Brighter Future

Direct Healthcare Professional Communication

FOR INFORMATION ONLY: NO ACTION REQUIRED

HyQvia▼ (human normal immunoglobulin and recombinant human hyaluronidase): crimping defect in hyaluronidase vial

23rd December 2020

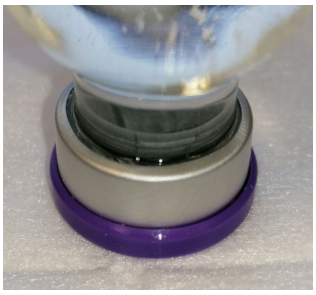
Dear Healthcare professional,

Baxalta Innovations GmbH in agreement with the European Medicines Agency (EMA) and Medicines and Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

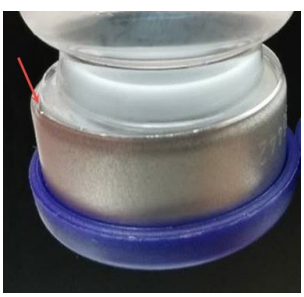
Summary

- Crimping defects that were recently identified on hyaluronidase (HY) vials during packaging of HyQvia
- The company's investigation has shown that a small number of HY vials within several HyQvia batches on the market (*refer to batch list in Attachment 1*) could potentially be impacted by an inefficient crimping of the aluminum cap of the HY vial present in the dual-vial unit – the defect is not associated with the immunoglobulin vial
- The rate of occurrence of the crimping defect is low, and there is not thought to be an impact on the product's usability, safety, and quality – no action is required

Correctly crimped



Insufficiently crimped



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Background on the safety concern

HyQvia▼ is a dual vial unit consisting of one vial of human normal immunoglobulin (Immune Globulin 10% or IG 10%) and one vial of recombinant human hyaluronidase (rHuPH20). HyQvia is indicated as replacement therapy for the treatment of Primary immunodeficiency syndromes with impaired antibody production and secondary immunodeficiencies (SID) in patients who suffer from severe or recurrent infections, ineffective antimicrobial treatment and either proven specific antibody failure (PSAF) or serum IgG level of <4 g/l.

In depth evaluation and testing performed by Takeda, as well as by the manufacturer of the hyaluronidase vial, demonstrates that the integrity of the vial closure is fully maintained. Therefore, product quality and sterility assurance are not compromised and normal administration of the product is supported.

Investigation at the manufacturer of the hyaluronidase vial is ongoing. Corrective actions to prevent recurrence of this defect will be agreed with the European Medicines Agency. As an interim action, both the Hyaluronidase manufacturer and Baxalta Belgium (Takeda) have implemented additional inspection and sampling, to detect and remove any further inefficiently crimped vials.

This letter is sent only for the information. You will not be required to take any action as Takeda's investigation showed that the rate of occurrence of the crimping defect is low, and that there is no impact on the product's usability, safety, and quality.

Call for reporting

HyQvia▼ is subject to additional monitoring. This will allow quick identification of new safety information. Please report ANY suspected adverse drug reactions (ADRs) to new drugs and vaccines identified by the black triangle▼ to the MHRA through the Yellow Card Scheme.

Please note that suspected adverse reactions should be reported to the MHRA electronically via the Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

The non-identical nature of biological medicines and vaccines means it is very important that safety surveillance is carried out on a brand/product-specific basis. When reporting a suspected ADR to a biological medicine (such as blood products, antibodies and advanced therapies [such as gene and tissue therapy]) or vaccine, please ensure that you provide the brand name (or product licence number and manufacturer), and the specific batch-number.

Additionally, when providing patients with details of the vaccine or biological medicine administered, it is good practice to give them details of the brand and batch number. This will

allow patients and carers to more accurately report suspected ADRs to the Yellow Card Scheme

Company contact point

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Should you have any queries, please contact me per details provided below.

Yours sincerely,

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***Annexes** 1* **HyQvia Batch listing**

Batch Size (ea)	Units affected (ea)	Batch Number	Expiry Date	Manufacturing Date(Note1)	Product Distribution	Pack Languages
126	126	LE16W076AD	Nov 2022	05 Dec 2019	UK	English
406	406	LE16W076AH	Nov 2022	05 Dec 2019	UK	English
48	48	LE16WA68AG	Sep 2022	15 Oct 2019	UK	English