

Application for renewal of a Wholesale Dealer's Licence under the Medicines (Jersey) Law 1995

Introduction

An application has been received from Mr Sidharth Mehta on behalf of Genesis Pharmaceuticals Ltd, in accordance with Article 19 of the Medicines (Jersey) Law 1995, for the renewal of a wholesale dealer's licence. The application is for a licence to cover wholesale dealings in medicinal products for human use, relating to the procurement and administration of such products.

Detail

The application includes all the information required by the Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences) (Jersey) Order 1997. The applicant is the current nominated Responsible Person (RP) in relation to activities undertaken in accordance with the licence. As part of the renewal application, the applicant will be stepping down as RP but remaining as Director of the Company. Cherry Sullivan has been nominated to be the RP.

The company procures medicines from the UK, EU, and third countries to supply their sole customer, Genesis Pharmaceuticals Limited (UK), which is part of the same group of companies. All products are licensed UK products when they enter the UK market. Procurement from third countries is considered to be fiscal introduction into the UK market.

The applicant has been wholesale dealing in medicinal products in Jersey since October 2019 and has been subject to a comprehensive inspection by a Senior GDP Inspector from the Medicines & Healthcare Regulatory Agency, as well as the Acting Chief Pharmacist, on 13 April 2023. This was a routine inspection for a licence renewal which assessed compliance with the Guidelines on Good Distribution Practice of Medicinal Products for Human Use and the Medicines (Jersey) Law 1995. There were no critical or major deficiencies observed during the inspection – there were some deficiencies classified as 'other'. Both the MHRA and the Acting Chief Pharmacist are content that the applicant satisfies all legal and pharmaceutical aspects required by the Medicines (Jersey) Law 1995 for the renewal of a wholesale dealer's licence.

Changes required to the current Wholesale Dealer's Licence are:

- Change of RP from Sidharth Mehta to Cherry Sullivan
- Change of site to units 123-124 Regus, Liberation Station, Esplanade, St Helier, Jersey, JE2 3AS
- A condition permitting the licence holder to source medicinal products from third countries by way of fiscal introduction into the UK market.

The applicant also operates in the UK under a Wholesale Dealers Authorisation (WDA) granted by the UK medicines regulator, the Medicines and Healthcare Products Regulatory Agency (MHRA). The applicant continues to operate in the UK under this authorisation.

Recommendation

To approve the application by Sidharth Mehta on behalf of Genesis Pharmaceuticals Ltd for the renewal of a wholesale dealer's licence to be valid until 30 April 2028.