SUBMISSION AND NOTIFICATION OF THE STANDARD FORM REFERRED TO IN ARTICLE 5(2)(B) AND (C) OF REGULATION (EC) 469/2009, AS AMENDED BY REGULATION (EU) 2019/933

Standard form for notification pursuant to points (b) and (c) of Article 5(2)

Tick the appropriate box	☐ New notification ☒ **Update of an existing notification**	
(a) Name and address of the maker	**Lotus Pharma Bulgaria EOOD** Address: 102D CHERNI VRAH BLVD., FLOOR 4, SOFIA 1407, BULGARIA	
(b) Purpose of making	☐ Export ☐ Storing ☒ **Export and storing**	
(c) Member State in which making is to take place and Member State in which first related act (if any) prior to making is to take place	Member State of making	**Ireland**
	(Member State of first related act (if any))	**Bulgaria**
(d) Number of certificate granted in the Member State of making and number of certificate granted in Member State of first related act (if any) prior to making	Certificate of Member State of making	**2012/007**
	(Certificate of Member State of first related act (if any))	**SPC/BG/2012/0002**
(e) For medicinal products to be exported to third countries, reference number of marketing authorisation, or the equivalent of such authorisation, in each third country of export	**New Zealand** MA Number: Medsafe File Ref. TT50-11567 (Application No. 137576) – consent to distribute under section 20 of the Medicines Act 1981, granted on 22 October 2026 (MA holder: Te Arai BioFarma Limited)	