

**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	<input checked="" type="checkbox"/> New notification <input type="checkbox"/> Update of an existing notification	
(a) Name and address of the maker	EIRGEN PHARMA LIMITED Address: Westside Business Park, Old Kilmeaden Road, Waterford, X91 YV67, Ireland	
(b) Purpose of making	<input type="checkbox"/> Export <input checked="" type="checkbox"/> Storing <input type="checkbox"/> 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	2015/017
	(Certificate of Member State of first related act (if any))	2015000012S
(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		