Register of Genetically Modified Organisms (GMOs)
Users in Ireland

The name and address of the notifier	The Center for Cellular and Molecular Therapeutics at the Children's Hospital of Philadelphia, 5th Floor Colket Translational Research Building, 3501 Civic Center Boulevard, Philadelphia, PA 19104-4319 USA
The location (including, where necessary, the name of townland or townlands) of a deliberate release proposed under, or granted consent in accordance with, Part II of the GMO (Deliberate Release) Regulations 2003, S.I. No. 500 of 2003	St James's Hospital James's Street Dublin
GMO Register No.	G0498-01
SNIF No.	B/IE/13/01
The date or dates of a Deliberate Release	May 2013 – September 2015
The description and intended uses of each GMO involved	The GMO (called AAV8-hFIX19) is a single stranded Adeno-associated pseudotype 8 viral vector (AAV8) which has been engineered to express the gene for human coagulation factor IX (hFIX) for the treatment of patients with severe Haemophilia B (Factor IX deficiency).
The purpose of the deliberate release or placing on the market	The GMO will be administered to clinical trial patients. The purpose of this Phase 1 trial is to test whether a single administration of AAV8-hFIX19 to patients: • is safe and effective; • can increase the amount of human coagulation factor IX (hFIX) in the blood of patients with severe Haemophilia B (Factor IX deficiency).
The date of receipt of a notification or amended notification	12th February 2013
The date of publication of a notice under article 15(1) or 29(3)	21st February 2013

The number of representations, if any, received under article 16(1)	0
The date of any request by the Agency for further information	17th April 2013 6th June 2013
The date of receipt by the Agency of any further information	30th May 2013 17th June 2013
The date of receipt, or the date on which the Agency otherwise became aware, of any information or any other matter referred to in article 22(1)	
The date of any exercise by the Agency of its powers under article 22(1)	
The date and nature of any decision by the Commission of the European Communities under Article 18 (1) or 23(2) of the Directive	25 June 2013 – Consent granted with conditions. Consent Conditions issued 3 July 2013
The date of withdrawal of a notification or an amended notification	