

Register of Genetically Modified Organisms (GMOs) Users in Ireland

The name and address of the notifier	The GUIDE Department (Department of Genito Urinary Medicine and Infectious Diseases) St James's Hospital Dublin 8
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 - Part B release or field trial.	The Wellcome Trust-HRB Clinical Research Facility St James's Hospital Dublin 8
Notification Ref. No.	1. B/IE/14/01 2. B/IE/14/02
GMO Register No.	G0536-01
The date or dates of a deliberate release	From 1 July 2014 to 31 December 2015
The description and intended uses of each GMO involved	<ol style="list-style-type: none"> 1. <u>Chimpanzee Adenovirus 3 NSmut1 (AdCh3NSmut1)</u> AdCh3NSmut1 is a modified recombinant virus vaccine derived from an attenuated replication incompetent chimpanzee adenovirus; 2. <u>Modified Vaccinia Virus Ankara NSmut (MVA-NSmut)</u> <u>MVA-NSmut</u> is a recombinant virus vaccine derived from the attenuated virus, Modified Vaccinia Ankara. <p>Both vectors are genetically modified to promote the expression of the Hepatitis C immunogen, NSmut</p>
The purpose of the deliberate release	The purpose of the trial is to assess the vaccines for safety and immunogenicity in HIV-1 seropositive individuals on antiretroviral therapy (ART).
The date of receipt of a notification or amended notification	14 April 2014

The date of publication of a notice under article 15(1)	16 April 2014
The number of representations, if any, received under article 16(1)	0
The date of any request by the Agency for further information	13 May 2014
The date of receipt by the Agency of any further information	23 May 2014
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	
The date of withdrawal of a notification or an amended notification	
The date and nature of the decision by the Agency on a notification or an amended notification	Approved 8 July 2014. Consent Conditions issued 22 July 2014.