

***Extract from the Minutes of the 942<sup>nd</sup> Licensing Meeting of the Agency was held on 13 November 2018 in EPA Headquarters, Johnstown Castle Estate, County Wexford***

1. The 942<sup>nd</sup> Licensing Meeting of the Agency was held on 13 November 2018, in EPA Headquarters, Johnstown Castle Estate, County Wexford.

Directors Present: L Burke (Chair);  
G O'Leary, M Crowe, M Lehane, E Cotter & T Ryan.

7. **Notification for the first time use and subsequent contained use of Genetically Modified Organisms (GMOs)**

*Applicant:* uniQure Biopharma BV  
Paasheuvelweg 25A  
1105 BP Amsterdam  
The Netherlands

*GMO Reg Entry No:* G0667-01

The Directors considered a recommendation from the Office of Environmental Sustainability that the Agency approve the proposed consent conditions. The following documentation was submitted: proposed consent conditions and report of the Inspector dated 7 November 2018.

Bernie Murray and David Flynn gave verbal presentations.

**Recommended Decision**

***Consent Conditions for GMO Register Entry No: G0667-01***

***Condition 4 Management of the clinical trial***

- 4.6 Amend the condition to read as follows: 'All communications with the Agency in relation to this trial shall be through the person identified to the Agency under Condition-4.3 4.4.'

The Directors noted the Inspector's report, detailing the background to the application and the reasons for the recommendation.

Following discussion, the Directors approved the consent conditions, as modified, for the deliberate release of Genetically Modified Organisms (GMOs), to uniQure Biopharma BV, Paasheuvelweg 25A, 1105 BP Amsterdam, The Netherlands, GMO Register Entry No. G0667-01.