



[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

**MHRA**

10 South Colonnade  
Canary Wharf  
London  
E14 4PU  
United Kingdom

[mhra.gov.uk](https://www.mhra.gov.uk)

E-mail: [REDACTED]

15/12/2021

**Application reference:** [REDACTED]

**Application for an Innovation Passport as part of the Innovative Licensing and Access Pathway (ILAP) for midomafetamine (3,4-methylenedioxymethamphetamine hydrochloride) for the treatment of Post-traumatic Stress Disorder has been approved.**

Dear Ms [REDACTED],

Following the Innovation Passport meeting on 11/10/2021 and after further consideration by the Innovative Licensing and Access Pathway Steering Group (AWTTC, MHRA, NICE, SMC, and representatives from the ILAP Patient and Public Reference Group), the partners are pleased to inform MAPS PBC that the innovative medicine designation, the Innovation Passport, has been awarded for midomafetamine in the treatment of Post-traumatic Stress Disorder.

The Innovation Passport is the entry point to the Innovative Licensing and Access Pathway (ILAP) which aims to accelerate time to market, facilitating patient access. This designation is linked to a portfolio of activities through the product specific creation of the Target Development Profile (TDP). The Innovation Passport Holder is encouraged to submit the completed template for the creation of the TDP at the earliest opportunity for this or subsequent indications. More information can be found here:

<https://www.gov.uk/government/publications/innovative-licensing-and-access-pathway-ilap-for-medicines/target-development-profile-tdp>

The product has been assigned the following ILAP reference number [REDACTED].

Please do not hesitate to contact the ILAP co-ordinator ([innovationpassport@mhra.gov.uk](mailto:innovationpassport@mhra.gov.uk)) should you require further information or advice, quoting your ILAP reference number.

Yours sincerely,

ILAP Steering Group

The ILAP is delivered in partnership by the **All Wales Therapeutics and Toxicology Centre, Medicines and Healthcare products Regulatory Agency, National Institute for Health and Care Excellence** and the **Scottish Medicines Consortium**, part of Healthcare Improvement Scotland.