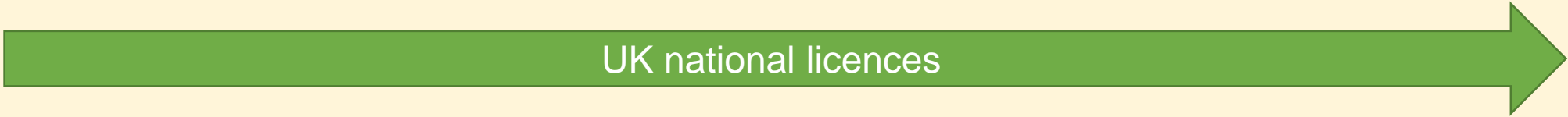


Notification of pharmacovigilance system details to the MHRA from 1 January 2021



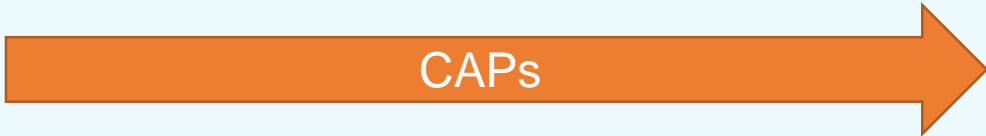
1

2

1 January 2021

31 December 2021

30 June 2022



3



1

2

- 1 If any change to details of UK QPPV from XEVMPD, notify MHRA within 2 weeks. Otherwise, notify MHRA of UK QPPV and UK PSMF details by 30 June 2022.
- 2 Submission of a single change Type 1AIN - C.I.8.a) variation covering all UK MAs under a unique pharmacovigilance system (collections of no more than 25 PLs).
- 3 Submission of initiating eCTD sequence for converted EU MAs (within one year of 1 January 2021). If any changes to details of UK QPPV from XEVMPD, simultaneously submit a Type 1AIN - C.I.8.a) variation.