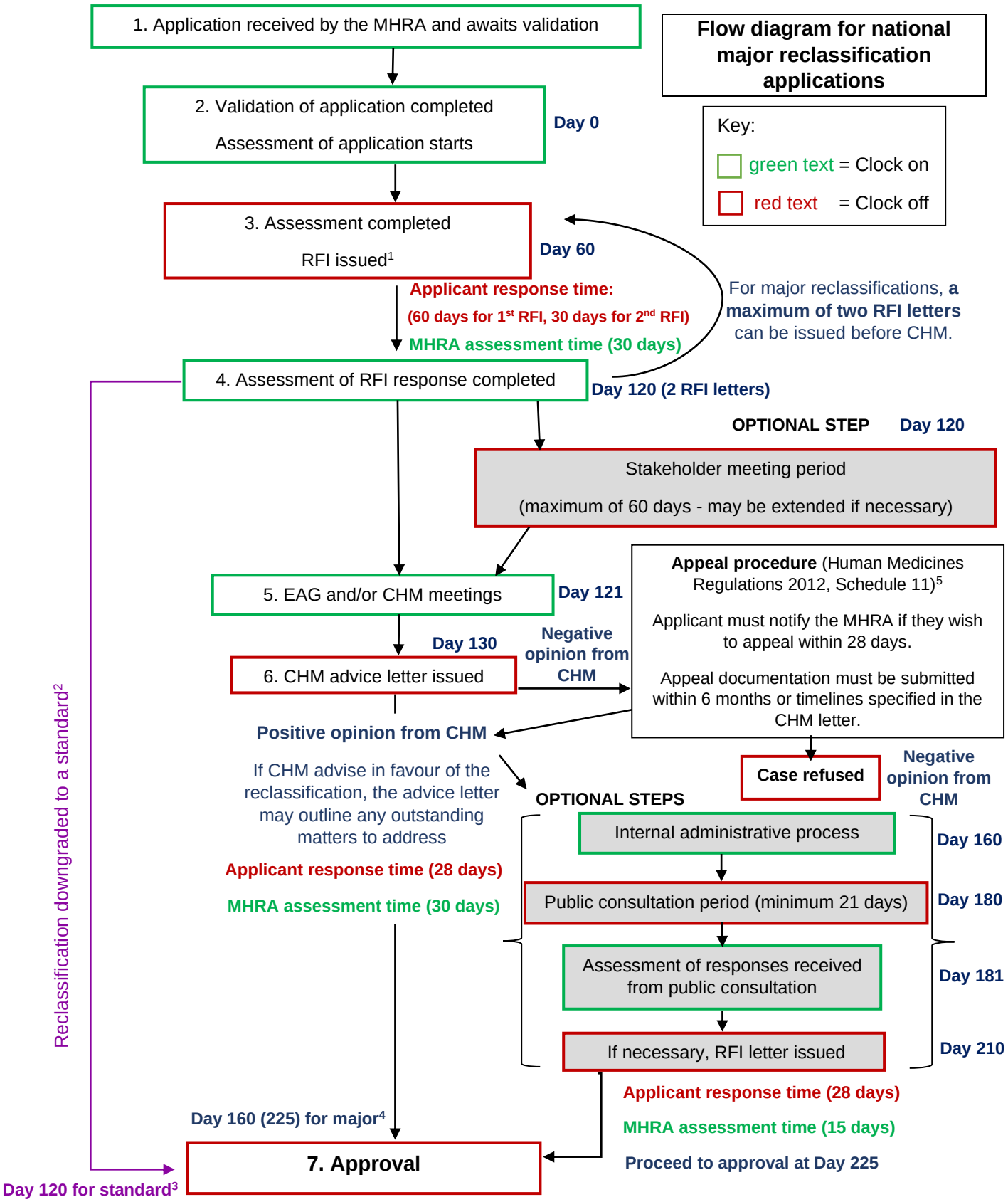

The assessment team will notify the applicant if some or all of the optional steps are likely to be undertaken.
[1]For some major reclassifications, an RFI may not be issued, and the assessment will proceed to step 5.
[2] A major reclassification application will be downgraded to a standard application if no advice is sought from the Commission on Human Medicines (CHM).
[3]120 days based on **two** RFI letters being issued. 90 days with one RFI letter issued.
[4]160 days based on the optional steps **not** being undertaken. 225 days with all of the optional steps included. These timelines are based on **two RFI letters issued at step 3**. If only one RFI letter is issued at step 3, the regulatory clock will be 30 days shorter.
[5]Appeal procedure will proceed in accordance with timelines advised by the CHM secretariat.