The template for the **request for a clock stop extension** is to be provided as a signed PDF document. Please note that this letter should be submitted to the CHMP Chairs and the EMA Product Lead either by Wednesday of the week of the LoQ/LoI/RSI adoption, or, latest on Monday of the CHMP week prior to the previously agreed written response submission. The guidance on the duration of clock stops is outlined in: [Time allowed for applicants to respond to questions and issues raised during the assessment of new marketing authorisation applications in the centralised procedure | European Medicines Agency (europa.eu)](https://www.ema.europa.eu/en/time-allowed-applicants-respond-questions-and-issues-raised-during-assessment-new-marketing-authorisation-applications-centralised-procedure)

<Date, Place>

<CHMP Chair, Co-Chair>

Cc: <Rapporteur, Co-Rapporteur, EMA Product Lead>

European Medicines Agency

Domenico Scarlattilaan 6

1083 HS Amsterdam

The Netherlands

Dear <CHMP Chair, Co-Chair>,

**RE: EMEA/H/C/<product number>**

**<Product Name>, <INN>,** **<Applicant/MAH>**

Herewith, the applicant <name> for the <conditional marketing authorisation/marketing authorisation under exceptional circumstances/marketing authorisation> / the Marketing Authorisation Holder (MAH) <name> applying for the <line extension/extension of indication to the marketing authorisation> of <INN/invented name> is seeking a(n) <x month(s)> extension to the clock stop for submission of the responses to the <D120 List of Questions (LoQ)/D180 List of Outstanding Issues (LoI)/Request for Supplementary information (RSI)>. If agreed, the total clock stop duration shall be <xx months> and the written responses shall be submitted by <date (as per the applicable timetable)>. *(Please refer to:* [*Time allowed for applicants to respond to questions and issues raised during the assessment of new marketing authorisation applications in the centralised procedure | European Medicines Agency (europa.eu)*](https://www.ema.europa.eu/en/time-allowed-applicants-respond-questions-and-issues-raised-during-assessment-new-marketing-authorisation-applications-centralised-procedure))

The <applicant/MAH> identifies the below stated issues as reasons for the need of an extended time to prepare the responses to the raised <LoQ/LoI/RSI>, and declares whether these have already been discussed at an earlier stage. The <applicant/MAH> is aware that reasons already identified in the past, but not adequately addressed, are unlikely to support the request sufficiently. *(Please refer to:* [*Time allowed for applicants to respond to questions and issues raised during the assessment of new marketing authorisation applications in the centralised procedure | European Medicines Agency (europa.eu)*](https://www.ema.europa.eu/en/time-allowed-applicants-respond-questions-and-issues-raised-during-assessment-new-marketing-authorisation-applications-centralised-procedure))

|  |  |  |
| --- | --- | --- |
| Category | Reason <delete/duplicate as appropriate> | Description/Justification(s) |
|  | CHMP requested <GMP/GCP/GLP/PhV> inspection | *<please specify MO(s)/OC(s) and provide detailed justification(s)>* |
|  | CHMP requested <Scientific Advisory Group/Ad-hoc Expert Group> meeting | *<please specify MO(s)/OC(s) and provide detailed justification(s)>* |
|  | Time needed to address CHMP’s  Quality <MO(s)/OC(s)>in the <LoQ/LoI/RSI> | *<please specify MO(s)/OC(s) and provide detailed justification(s)>* |
| Previously identified/discussed at <presubmission/validation/LoQ/LoI/RSI> |
|  | Time needed to address CHMP’s  Non-clinical<MO(s)/OC(s)>in the <LoQ/LoI/RSI> | *<please specify MO(s)/OC(s) and provide detailed justification(s)>* |
| Previously identified/discussed at <presubmission/validation/LoQ/LoI/RSI> |
|  | Time needed to address CHMP’s  Clinical <MO(s)/OC(s)>in the <LoQ/LoI/RSI> | *<please specify MO(s)/OC(s) and provide detailed justification(s)>* |
| Previously identified/discussed at <presubmission/validation/LoQ/LoI/RSI> |
|  | Time needed to address CHMP’s  other <over-arching, multidisciplinary, procedural, regulatory> <MO(s)/OC(s)>in the <LoQ/LoI/RSI> | *<please specify MO(s)/OC(s) and provide detailed justification(s)>* |
|  | Previously identified/discussed at <presubmission/validation/LoQ/LoI/RSI> |  |
|  | Other | *<please specify MO(s)/OC(s) and provide detailed justification(s)>* |

Yours sincerely,

<Name and signature of authorised contact person>