**APPENDIX 1**

**Approved variations/renewal(s)/commitments submitted subsequent to the finalization of the European/National assessment/ the issued Marketing authorization (DCP day 210, MRP day 90, date of issued MA):**

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| **Type no/ Classification category /NCA identification /EU full procedure number**  ( as appropriate) | **Submission date** | **Approval/**  **acceptance date** | **eCTD sequence number**  **(**as appropriate**)** | **Indexation of change** | **Summary of change** |
| IB no xxx |  |  |  | 3.2.P xxx, Vol yy |  |
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**Is further update of the dossier proposed by the Marketing Authorisation Holder before start of MRP/RUP to comply with the current legislation and/or EU Guidelines in place as the application is seen as new for the member states concerned(CMS).**

**Indicate your proposal as appropriate:**

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| **Type of regulatory action** | **Summary of change proposed** | **Indexation of change** |
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