**APPLICATION TO ACCOMPANY A**

 **Plasma Master File**

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| --- | --- |
| **File No:** TT60-     [ ]  Not allocated yet | **Products in which material derived from the plasma is used:** TT50-      |
|  **PMF Holder Name and Postal Address:**       |
|  **Name and Address of Manufacturing Site(s):**       |

**PMF Holder Contact Details:**

|  |  |  |
| --- | --- | --- |
| **Title:**       | **Name:**       | **Position:**       |
| **Phone:**       | **E-mail:**       |

**This submission relates to:**

[ ]  A new Plasma Master File

[ ]  An updated Plasma Master File (version number/epidemiological year must be clearly identified)

* This PMF has been provided as part of a NMA? Yes / No
* This PMF has been provided as part of a CMN? Yes / No
* A Letter of Access (LoA) is included Yes / No
* A copy of the PMF is included1 Yes / No

1(not required if a LoA to a current PMF already approved by Medsafe is provided).

The following documents are required to be included with all submissions:

* Cover letter (for guidance on content, refer to PMF Checklist overleaf)
* PMF Checklist (see overleaf)
* Electronic copy of the PMF1
* Summary of changes (if an update)
* Letter of Access (if not previously provided)
* Any associated overseas evaluations and approvals, if available  1

1(not required if a LoA to a current PMF already approved by Medsafe is provided).

**Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:**

**Plasma Master File Checklist**

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| --- | --- |
| Y/N | Is the content and format aligned with EMEA/CHMP/BWP/3794/03 Rev.1 and EMA/CHMP/BWP/706271/2010? |
| Y/N | Does the cover letter clearly identify the period of epidemiological data collection? If not, then please provide this information. |
| Y/N | Does the cover letter include a list confirming which of the countries described in the PMF as containing collection centres are relevant to NZ (ie. which countries may be used to source plasma used to manufacture ingredients for products that are distributed in NZ)? If not, then please provide this information. |
| Y/N | Does the above list include countries not previously approved by Medsafe for this purpose?  |
| Y/N | If so, does the cover letter identify these countries? If not, then please provide this information. |
| Y/N | Does the above list include any countries that allow collection from donors that received a blood transfusion in the United Kingdom from 1980 onwards? |
| Y/N | If so, does the cover letter identify these countries, and confirm when their use was previously approved by Medsafe? If not, then please provide this information. |
| Y/N | Does the PMF include dates and outcomes of the most recent GMP audit of each collection and testing facility by an EU or US regulator (or by Medsafe), confirming that a suitable audit outcome was achieved within the three years prior to the period during which epidemiological data described in the PMF was collected, or since then? If not, then please provide this information (in a separate document). |
| Y/N | Has use of any of the collection or testing facilities, or storage or transport organisations, been refused by another regulator (EU, US or Australian) during their evaluation of this PMF to date? If so, please provide details in the cover letter. |
| Y/N | Is the CE-mark/FDA approval status of each test kit and blood collection bag/bottle clearly described in the PMF? Information justifying the use of kits or bags/bottles that lack CE-mark/FDA approval should be present in the PMF. |