**Changing the Status of a Presentation or Pack Size form**

Use this form to request a change in status for a product presentation or pack size.
Please email the completed form to Medsafeapplications@health.govt.nz

|  |  |
| --- | --- |
| **Medicine:** **Trade name:** **Dose form:** **Strength(s):** **Sponsor:** | **File No:**TT50-      |

**Affected presentations and/or pack sizes:**

Please provide sufficient description of the affected presentation to allow accurate changes to the TPDR or an annotated TPDR.

|  |  |  |  |
| --- | --- | --- | --- |
| **Pack Type:** | **Description:** | **Current status\*:** | **Proposed status\*:** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**\*Status options: marketed, not marketed, withdrawn**

**The status of withdrawn pack sizes can only be changed via CMN/SACN.**

Please note, updating the status will be reflected on the TPDR and the Medsafe website.

 **The presentation/pack size was last distributed in New Zealand on**

|  |
| --- |
| **Submitted by:** |
|  |

|  |  |
| --- | --- |
| **Name:** | **E-mail:** |
|       |       |

**Please tick the appropriate boxes, enter any required dates and sign declaration.**

 **To update the status to not marketed/withdrawn I declare that:**

 All stock of the pack size has been depleted from the NZ market: Yes [ ]

 **I declare that:**

[ ]  There is no data sheet for this general sale / pharmacy only product

**OR**

[ ]  A SACN / CMN has been submitted to update data sheet:

      (insert App ID No.)

**OR**

[ ]  The data sheet is not published because the product is not available. The sponsor commits to submitting an updated datasheet under Datasheet - G1 before a request to change the registration situation from not available to consent given is submitted.

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

(Sponsor or authorised agent)