To be completed by the applicant / holder of certificate of registration[[1]](#footnote-1) / principal from whom the document was purchased for submission in South Africa, based on which party submitted the dossier to the RRA:

|  |  |
| --- | --- |
| **Details of foreign registration** | |
| Recognised Regulatory Authority(ies) (RRAs) | {Insert name of recognised regulatory authority(ies) here} |
| Proprietary name(s) of reference product(s) registered with RRA(s) | {Insert the proprietary name(s) of the associated product(s) which has been registered with the RRA(s) listed above} |
| Active Pharmaceutical Ingredient(s) (APIs) |  |
| Registration date |  |
| Date(s) of approval of post-registration variation(s) if applicable |  |
| **Details of SAHPRA application** | |
| SAHPRA application number |  |
| Product / proprietary name proposed to SAHPRA |  |

I hereby authorise SAHPRA to contact the above-specified regulatory authority or authorities to obtain reliance documentation for registered products. Reliance documentation includes, but is not limited to:

* The full, unredacted assessment / evaluation reports and inspection outcomes / reports
* Results of laboratory testing
* Assessment and inspection reports of other regulatory authorities, provided that these authorities gave their written consent to the use of such reports

Full name of Responsible pharmacist / Person authorised to communicate with the authority: Job title, company:

Email address: Telephone number:

Signature:

Date: Place:

1. Also referred to as marketing authorisation holder [↑](#footnote-ref-1)