Errata: Amendments to the Combined Executive Summary and the main report for the Evidence Review

This attachment contains information on minor changes to the content of the Combined Executive Summary and the Renewal Evidence Review report.

These changes do NOT influence any of the reports conclusions.

In summary, the amendments remove information regarding the Australian Register of Therapeutic Goods (ARTG) status of HPV tests available in Australia, as at November 2013, when the reports were finalised. The information presented in the original reports was not the latest information available in November 2013. Interested parties are advised to check the ARTG for the registration status of any HPV tests available in Australia.

The following changes are included:

1. Page 6 of the *National Cervical Screening Program Renewal: Executive Summary Report, November 2013*, states as follows:

A number of HPV tests are currently being used in Australia, but there is only one entry in the Australian Register of Therapeutic Goods (ARTG). This is the cobas® 4800 Human Papillomavirus (HPV) Test, sponsored by Roche Diagnostics Australia Pty Limited. Other HPV tests currently used in Australia without ARTG listing (i.e. under TGA transitional arrangements), include: Hybrid Capture II test (Digene) and Cervista (Hologic). All in-vitro diagnostic medical devices (IVDs) supplied prior to 1 July 2010 are provided with a four year transition period (i.e. until 30 June 2014) to be brought into the regulatory framework. It would be expected that all products assessed and used as part of the NCSP would comply with the new regulatory framework.

The above statement should read as follows:

A number of HPV tests are currently being used in Australia. All in-vitro diagnostic medical devices (IVDs) supplied prior to 1 July 2010 are provided with a four year transition period (i.e. until 30 June 2014) to be brought into the Therapeutic Goods Administration regulatory framework for IVDs. It would be expected that all products assessed and used as part of the NCSP would comply with the new regulatory framework.

2. Page 19 of the *National Cervical Screening Program Renewal: Evidence Review, November 2013*, states as follows:

A number of HPV tests are currently being used in Australia, but there is only one entry in the Australian Register of Therapeutic Goods (ARTG); this is the cobas® 4800 Human Papillomavirus (HPV) Test, sponsored by Roche Diagnostics Australia Pty Limited. The test specifically identifies HPV types 16 and 18 while concurrently detecting the rest of the high-risk types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68) at clinically relevant infection levels. Specimens are limited to cervical cells

collected in cobas® PCR Cell Collection Media (Roche Molecular Systems, Inc.), PreservCyt® Solution (Cytyc Corp.) and SurePath® Preservative Fluid (BD Diagnostics-TriPath) (ARTG entry 187190).

Other HPV tests currently used in Australia without ARTG listing (ie under TGA transitional arrangements, as outlined above) include: HC2 test (Digene) and Cervista (Hologic). Older tests (such as Amplicor and Linear Array) are also used, although predominantly in a research setting, and the manufacturer (Roche) has no plans to submit a TGA application.

The above statement should read:

A number of HPV tests are currently being used in Australia. All in-vitro diagnostic medical devices (IVDs) supplied prior to 1 July 2010 are provided with a four year transition period (i.e. until 30 June 2014) to be brought into the Therapeutic Goods Administration regulatory framework for IVDs. It would be expected that all products assessed and used as part of the NCSP would comply with the new regulatory framework.