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To: Primary Care Teams, School Immunisation Programmes, Health Professionals, Pharmacies

From: Rayoni Keith, Manager, Immunisation

Subject: **Boostrix vaccine leakage during injection**

The Ministry of Health (the Ministry) has been advised that some vaccinators are experiencing problems with the GSK Boostrix vaccine leaking from the seal between the syringe tip and needle hub during administration. Pending investigation the suspected cause of leakage is a manufacturing issue associated with the connection between the syringe and needle hub seal.

This leakage has been known to occur very occasionally over the last couple of years and GSK have implemented manufacturing changes to rectify the issue. However, recently some vaccinators in school-based programmes have found higher rates of leakage during recent school-based vaccination sessions. The Ministry, PHARMAC, Medsafe, GSK and IMAC are working together to minimise this disruption.

The vaccine and syringe

The issue is only related to the syringe manufacture with a few syringes experiencing a reduced seal between the syringe and needle hub connection during administration. The leakage does not impact the integrity of the syringe before use, and does not pose concern for sterility assurance. Please continue to vaccinate with the Boostrix vaccine.

Reducing leakage

Leakage can be reduced or prevented by firm application of the needle to the syringe with a twisting movement to secure the needle. Ensure you push and twist the needle into place using as much force as practical. Before removing the needle sheath take care to hold the hub of the needle onto the syringe while removing the sheath with your other hand.

As an interim measure remove any air bubbles by pushing the plunger rod (NOTE: this is not usual practice, but may help reduce leakage). Removing air bubbles is not required for clinical safety, but may reduce the leakage currently being experienced with the Boostrix vaccine.

How much vaccine loss is too much?

It is not uncommon to lose a very small amount of vaccine during administration, usually from the injection site. It is unfortunately not possible to provide a clear guideline regarding the need for re-vaccination in this case, where vaccine is lost.

If a small drop or two are seen to appear on the needle hub or on the person's skin, then it would be reasonable to assume that re-vaccination is not required. If more volume of vaccine is observed, then the vaccinator may decide to err on the side of caution and re-vaccinate.

Let us know

Please keep a record of these vaccine administration issues and let us know by calling 0800 IMMUNE (0800 466 863). This will assist the vaccine manufacturer to identify which batches are involved and facilitate resolution.

If you have any queries about anything in this update, please email immunisation@moh.govt.nz