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Dear Healthcare Professional Communication

15 August 2019

Clarification of *Priorix* vaccine expiry dates

Summary

- The expiry date for *Priorix* vaccine is provided on the outer packaging of the product and also on the tear-off label on the vial

Dear Healthcare Professional,

GlaxoSmithKline Australia (GSK), in consultation with the Therapeutic Goods Administration, would like to provide the following information to ensure that there is no confusion in relation to the expiration date of measles, mumps and rubella vaccine (MMR), *Priorix*.

A dose of *Priorix* vaccine distributed in Australia consists of a glass vial (containing the freeze-dried MMR antigens) and a glass pre-filled syringe (containing sterile water as diluent), that once reconstituted, provides a single dose of vaccine.

Several expiry labels appear on the different components of the vaccine:

1. Glass syringe that contains sterile water as diluent: one expiry date denoting expiration of the sterile water;
2. Glass vial that contains antigens: two expiry dates, one denoting the expiry date of the freeze-dried antigens in the vial and one denoting the expiry date of the two components once combined and ready for administration. The expiry date denoting the expiry date of the vaccine once combined is recited on the tear-off portion of the vial label; and
3. The outer packaging containing the vial and the syringe: the expiry date on the box denotes the expiration of the vaccine once combined. The expiry date on the outer packaging will be consistent with the expiry date recited on the tear-off portion of the vial label.

For clarity, the earliest expiry date of the vaccine components sets the expiry date for the whole product **and this expiry date is printed on the outer packaging and also the tear-off portion of the vial label.**

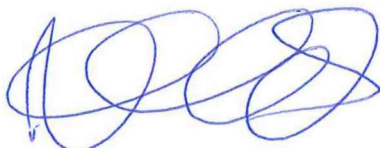
In most circumstances, the labels on *Priorix* vials show the same expiry date for both the contents of the vial and the reconstituted vaccine. A number of batches* of *Priorix* vaccines are currently being distributed in Australia that have a shorter expiry date for the diluent, and therefore results in two different expiry dates on the vial that could

potentially cause confusion. These affected batches will be supplied in ten and single dose packs to the National Immunisation Program and private markets over the next few months only.

GSK has attached a pictogram summary of expiry date coding for *Priorix* with this letter to assist.

For further information on any of these topics please contact GSK Medical Information on 1800 033 109.

Yours sincerely,

A handwritten signature in blue ink, consisting of several overlapping loops and curves, positioned below the text 'Yours sincerely,'.

Andrew Weekes
GSK Australia Medical Director

Which expiry date to use for Priorix



The expiry date to use is printed on the outer packaging and tear-off label on the vial

	Pre-filled syringe (Diluent)	The vial (Antigen)	Outer packaging	
Label showing batch number and expiry date	<p>LOT: A69DE986A EXP: 10-2020</p> <p>DILUENT for use in the reconstitution of Priorix 1 dose = 0.5 mL Water for injections to 0.5 mL GlaxoSmithKline Biologicals Rixensart, Belgium</p> <p>452895</p>	<p>Tear-off label</p> <p>THIS IS THE EXPIRY DATE TO USE</p>	<p>Located on the end of the box</p> <p>Single Pack:</p> <p>10's Pack:</p>	
Expiry Date	<p>The batch number and expiry date for the Diluent is printed in the black box</p> <p>A69DE986A</p> <p>D= Diluent</p>	<p>The second black box indicates the batch number and expiry date for the vial containing Freeze dried product</p> <p>A69FE986A</p> <p>F= Freeze dried</p>	<p>The expiry date and batch number for the Combined contents of the syringe and the vial is printed in the top black box (tear-off label).</p> <p>A69CE986A</p> <p>C= Combined Contents</p> <p>Note: This is the earlier of the expiry dates of the syringe and vial.</p>	<p>This expiry date is the same as the combined contents expiry date printed on the tear-off label on the vial.</p>