

The Cold Chain and Vaccine storage

Cliona Kiersey
Chief Pharmacist
National Immunisation Office



www.immunisation.ie

Reliability of Cold Chain

Cold Chain relies on 3 main elements
in each of the 3 areas

- manufacturing site
- distribution site
- Provider facility

- Well trained personnel
- Reliable storage equipment & transportation
- Efficient management procedures



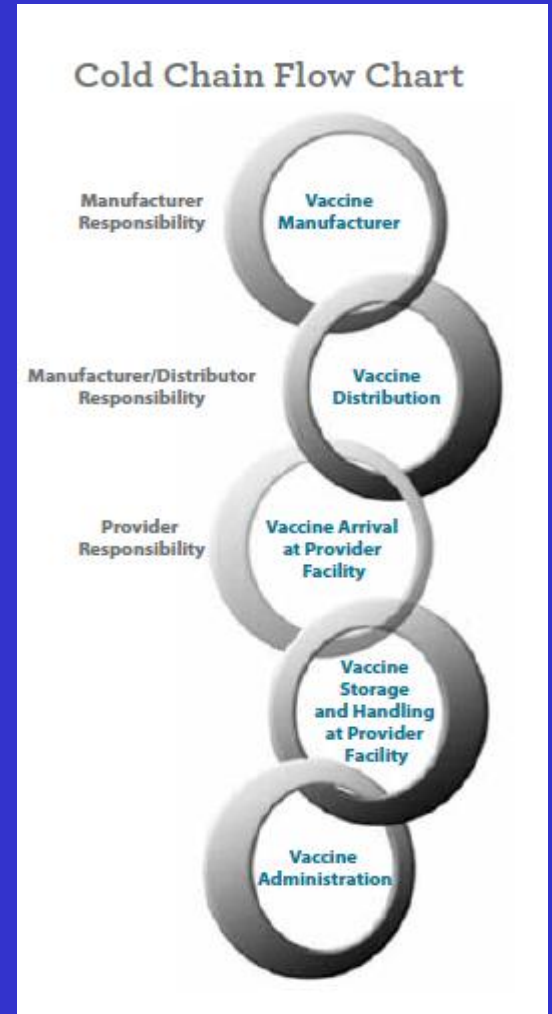
www.immunisation.ie

Who's Responsible for Cold Chain

Temperature records are available for every vaccine from point of manufacturing to delivery at GP surgery.

Storage fridges and transport vehicles are all equipped with heat / cooling devices and alarms/alert systems which are monitored 24/7

The last 3 links refer to time in the Surgery or HSE site.



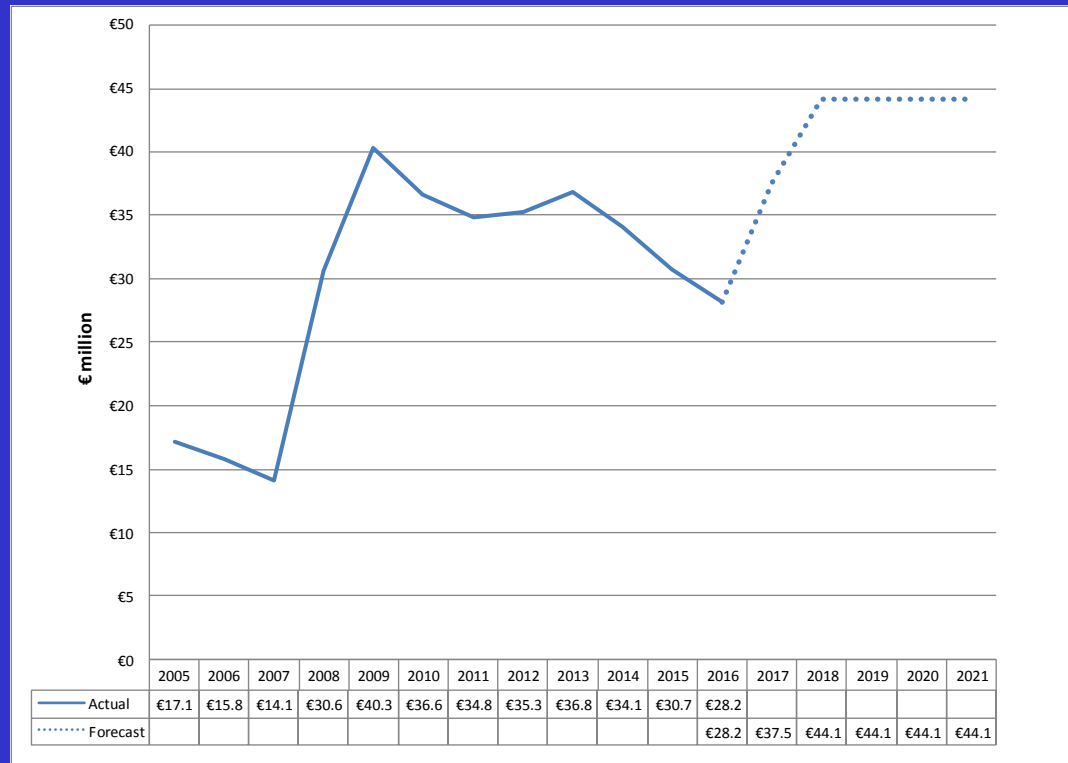
Vaccine Deliveries

- Contract is for 14 scheduled deliveries to each site, however in 2016 there will be extra deliveries from beginning of September to December (16 scheduled deliveries to each site)
- Flu vaccine will be available from September 2016 which should be administered by November creating space in the fridge for new vaccines.
- New vaccines will be available from November for administration from December 1st 2016. There will be 2 deliveries in November facilitating smaller order sizes.



www.immunisation.ie

Actual and forecasted vaccine expenditure 2005 - 2021



www.immunisation.ie

Current Schedule Value of Vaccines per Child

PCI: 6in1, Men C, PCV, MMR, Hib

Junior School: 4in1 and MMR

Secondary School Tdap, MenC and HPV

Indicative price €1,030



www.immunisation.ie

New Schedule Value of Vaccines per Child

- PCI: 6in1, MenB, Rotarix, Men C, PCV, MMR, Hib/MenC
- Junior School: 4in1 and MMR
- Secondary School Tdap, MenC and HPV
- Indicative price €1,350

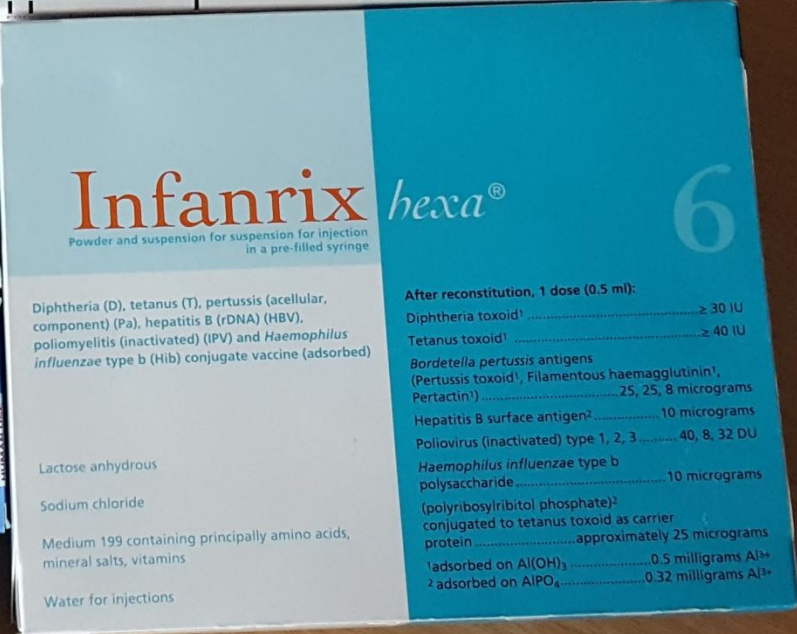
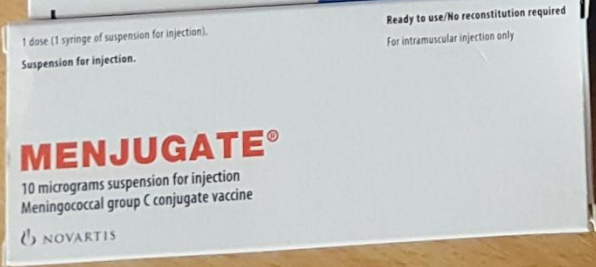
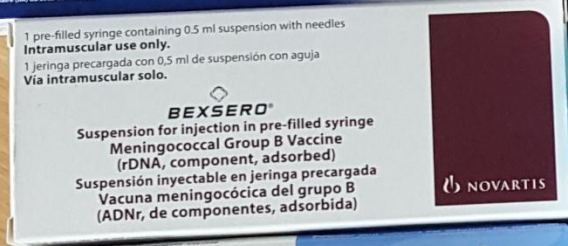
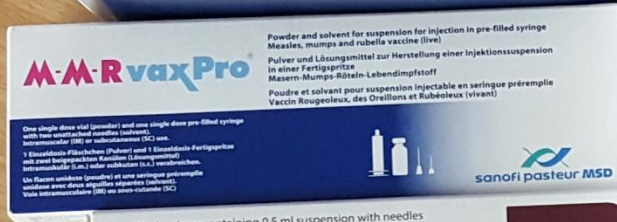
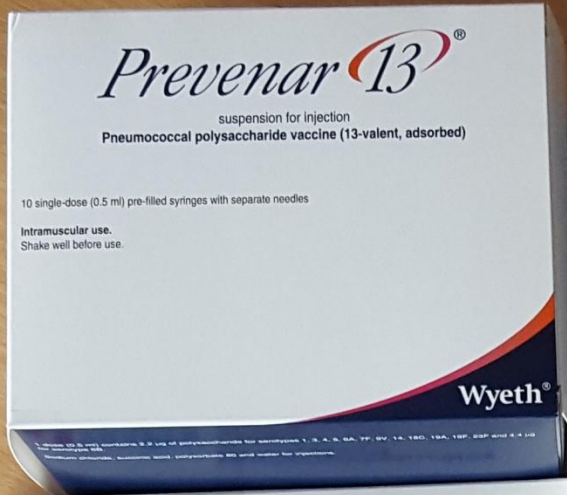


www.immunisation.ie

Current PCI Schedule



www.immunisation.ie



Bexsero – Men B

Bexsero suspension for injection in pre-filled syringe

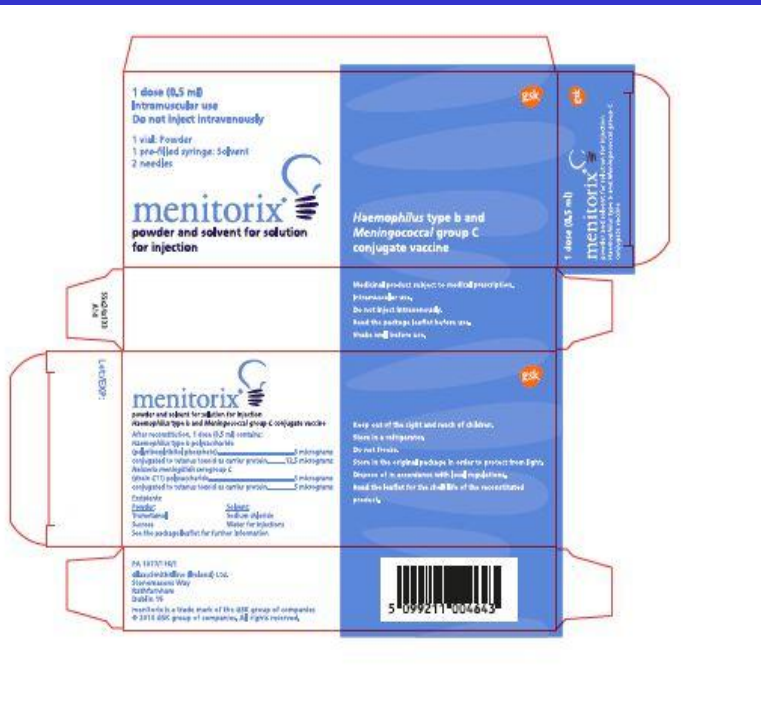
2 needles- 23G x 25mm & 25G x 16mm

Meningococcal group B Vaccine (rDNA, component, adsorbed)



Menitorix (Hib-MenC)

Powder and solvent for solution for injection
White powder and a clear colourless solvent
2 Needles 23G x 25mm & 21G x 40mm



www.immunisation.ie

Förvaras i originalförpackningen. Ljuskänsligt = Förvaras i kylskåp = Får ej frysas
Sållityä alkuperäispakkauksessa. Herkkä valolle = Säilytä jääkaapissa = Ei saa jäätyä
Oppbevares i originalpakningen for å beskytte mot lys = Oppbevares i kjøleskap =
Må ikke fryses

10 x 1 dos/annosta/dose
(1.5 ml)

10 förfyllda orala
applikatorer

10 esitetyttyä oraalista
annostelulaitetta

10 ferdigfylte orale
applikatorer

Färdig att användas/ Ingen beredning krävs
Käyttövalmis/ Sekoittamista ei tarvita
Klar til bruk/ Rekonstituering er ikke nødvendig

Rotarix®

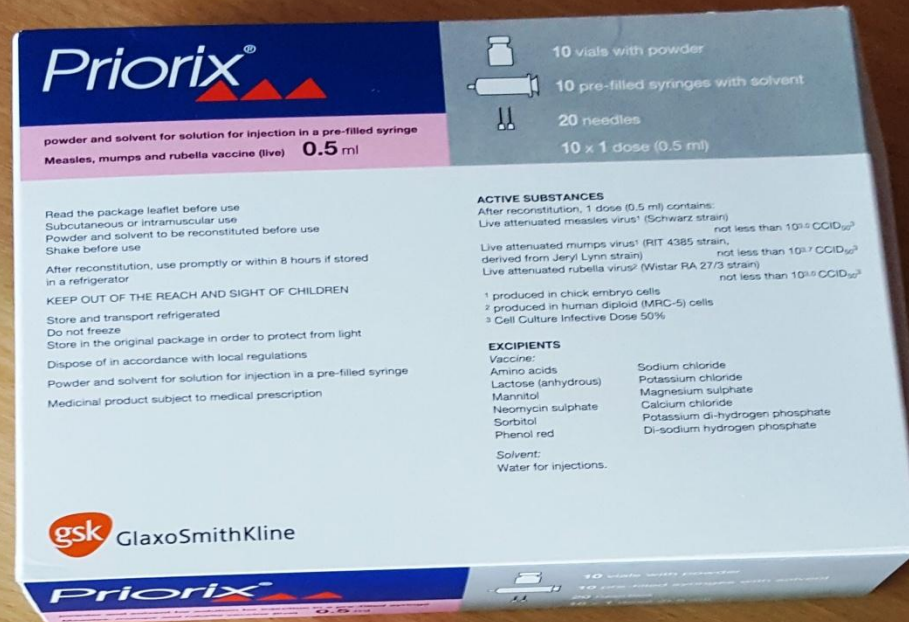
Oral suspension i förfylld oral applikator
Oraalisuspensio esitetyttyä oraalisessa annostelulaitteessa
Mikstur, suspensjon i ferdigfylt oral applikator
Rotavirusvaccin, levande
Rotavirusrokote, elävä
Vaksine mot rotavirus, levende

Oral användning/ Får ej injiceras!
Suun kautta/ Ei saa antaa injektiona!
Oral bruk/ Må ikke injiseres!

gsk GlaxoSmithKline



Current Schools Immunisation Programme (Junior)



Priorix®

powder and solvent for solution for injection in a pre-filled syringe
Measles, mumps and rubella vaccine (live) **0.5 ml**



10 vials with powder
10 pre-filled syringes with solvent
20 needles
10 x 1 dose (0.5 ml)

Read the package leaflet before use
Subcutaneous or intramuscular use
Powder and solvent to be reconstituted before use
Shake before use

After reconstitution, use promptly or within 8 hours if stored in a refrigerator

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

Store and transport refrigerated
Do not freeze
Store in the original package in order to protect from light

Dispose of in accordance with local regulations

Powder and solvent for solution for injection in a pre-filled syringe
Medicinal product subject to medical prescription

ACTIVE SUBSTANCES

After reconstitution, 1 dose (0.5 ml) contains:

Live attenuated measles virus¹ (Schwarz strain) not less than $10^{3.5}$ CCID₅₀²
Live attenuated mumps virus¹ (RIT 4385 strain, derived from Jeryl Lynn strain) not less than $10^{3.7}$ CCID₅₀²
Live attenuated rubella virus¹ (Wistar RA 27/3 strain) not less than $10^{3.5}$ CCID₅₀²

¹ produced in chick embryo cells
² produced in human diploid (MRC-5) cells
³ Cell Culture Infective Dose 50%

EXCIPIENTS

Vaccine:

Amino acids	Sodium chloride
Lactose (anhydrous)	Potassium chloride
Mannitol	Magnesium sulphate
Neomycin sulphate	Calcium chloride
Sorbitol	Potassium di-hydrogen phosphate
Phenol red	Di-sodium hydrogen phosphate

Solvent:
Water for injections.




GlaxoSmithKline

Priorix®

powder and solvent for solution for injection in a pre-filled syringe
Measles, mumps and rubella vaccine (live) **0.5 ml**



10 vials with powder
10 pre-filled syringes with solvent
20 needles
10 x 1 dose (0.5 ml)

10 x 1 dose (0.5 ml) 
10 pre-filled syringes + 10 needles
Suspension for injection
Intramuscular use

Shake well before use

IPV-Boostrix®

suspension for injection in pre-filled syringe

Diphtheria, tetanus, pertussis (acellular component) and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content)



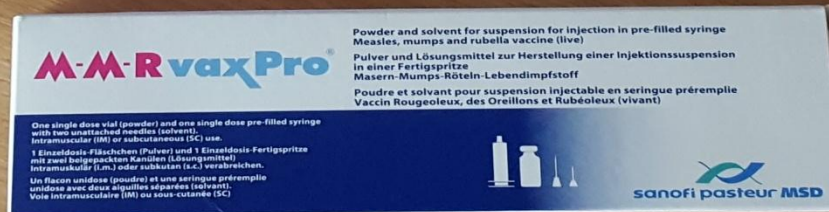
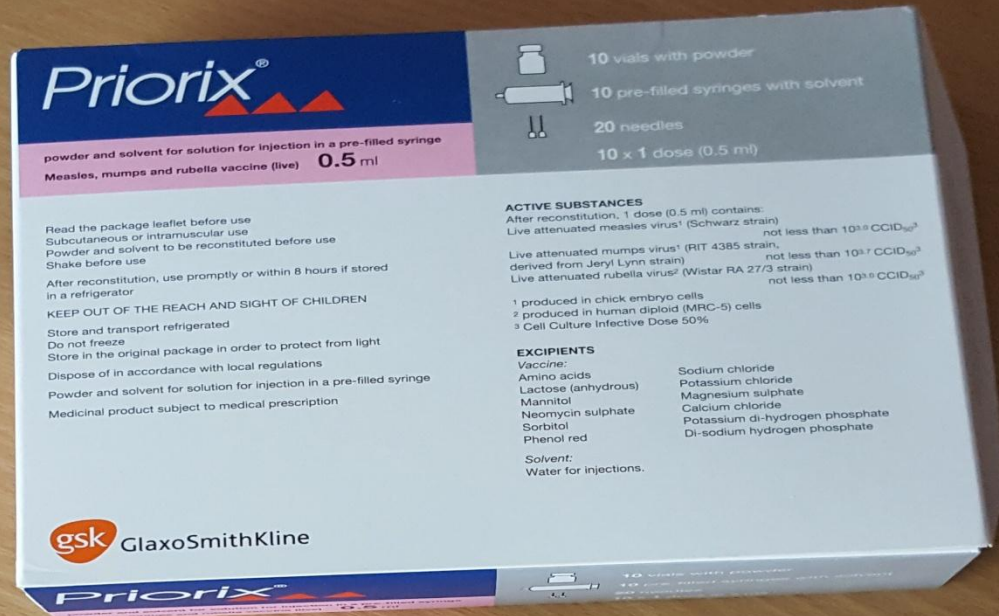
Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

IPV-Boostrix

- Suspension for injection in pre-filled syringe.
- IPV-Boostrix is a turbid white suspension.
- 10 needles 25G x 25mm



MMR Products



Reidhmeannacht na Seirbhíse Sláinte
Health Service Executive

School Immunisation Programme

Second Level.



Needle included with vaccines

- Bexsero 23G 25mm + 25g 16mm
- Boostrix 23G 25mm
- Gardasil 23G 25mm + 25g 16mm
- Hiberix 2 x 25G 25mm
- Infanrix Hexa: (10 pack) 20 x 25G 25mm
- IPV-Infanrix 23G 25mm + 25g 16mm
- IPV Boostrix (10 pack) 20 x 25G 25mm
- Menjugate 23G 25mm + 25g 16mm
- Menitorix 23G 25mm + 21g 40mm
- MMRvaxPro 23G 25mm + 25g 16mm
- Prevenar 13 (10 pack) 10 x 25G 25mm
- Priorix (10 pack) 20 x 25G 25mm



www.immunisation.ie



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Some typical vaccine orders with Costs (current schedule)

Qty	Vaccine
10	INFANRIX HEXA
10	PREVENAR
7	MEN C
4	MMR
4	HIB
5	DITE BOOSTER
	<u>€1,067.80</u>

Qty	Vaccine
30	INFANRIX HEXA
30	PREVENAR
10	IPV-Infanrix
5	Boostrix
20	MEN C
20	MMR
10	HIB
5	DITE BOOSTER
Total	<u>€3,353.72</u>

Qty	Vaccine
60	INFANRIX HEXA
60	PREVENAR
20	IPV-Infanrix
20	Boostrix
40	MEN C
40	MMR
20	HIB
10	DITE BOOSTER
Total	<u>€6,830.93</u>



www.immunisation.ie

New schedule costs

Qty	Vaccine
10	INFANRIX HEXA
10	PREVENAR
10	MenB
10	Rotavirus
4	MEN C
8	MMR
4	MENITORIX
4	IPV BOOSTRIX
5	DITE BOOSTER
3	BOOSTRIX
Total	<u>€1,786.28</u>

Qty	Vaccine
60	INFANRIX HEXA
60	PREVENAR
60	MenB
40	Rotavirus
20	MEN C
40	MMR
20	MENITORIX
20	IPV BOOSTRIX
10	DITE BOOSTER
20	BOOSTRIX
Total	<u>€10,082.25</u>



www.immunisation.ie

Recommended procedure for ordering and accepting vaccines

- Should have a named, trained and designated person and deputy
- Order on-line before closing date
- **Remove expired vaccines from fridge** & prepare for return to UD driver
- Check vaccine deliveries against the order for damage or discrepancies
- Place vaccines in the vaccine refrigerator immediately
- **NEVER leave vaccine delivery at room temperature**
- **Confirm that vaccines are covered by practice/ site insurance**



National Cold Chain Service

Delivered by United Drug in partnership with the HSE

NCC Web Ordering (30030)

Logout

VACCINE ORDER FORM

ORDER HISTORY

DELIVERY SCHEDULE

CHANGE PASSWORD

Welcome to your HSE National Cold Chain Dashboard

Messages

MESSAGE HEADLINE	DATE
STOCKTAKE REQUIRED	19 Nov 2014

[VIEW ALL MESSAGES](#)

Last Order - 19 November 2014

VACCINES	QTY
6 in 1	10
Dta	5
Men C	10
PCV	10

[VIEW YOUR ORDER HISTORY](#)

Delivery Schedule - November

MON	TUE	WED	THU	FRI	SAT	SUN
27	28	29	30	31	1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
1	2	3	4	5	6	7

RED on your Calendar is your **last date** to place order.

GREEN on your Calendar is your **delivery date**.



United Drug Supply Chain Services

We're committed to keeping our simple promise, every day. We work with principals, pharmacies and hospitals to shape our services around their requirements. And we get your products to the people who need them - your patients.

©United Drug Supply Chain Services / All rights reserved.

Useful Links

[HSE Immunisation Website](#)

[United Drug Supply Chain Services](#)



www.immunisation.ie

How much vaccine should be ordered?

- Vaccine stocks should be kept to a minimum by regularly ordering only the quantity of vaccine required until the next delivery. The designated person should know how much vaccine stock they require at any one time, according to the size of the target population.
 - Restrictions placed by online system
 - Maximum of 6 weeks supply at time of delivery
 - During 'flu season this can be reduced to 3 weeks supply as deliveries are fortnightly.



Restrictions on New Vaccines

- Bexsero Schedule Months 2 & 4 & 12
 - Quantity of Bexsero restricted to 1/3 of monthly requirements of Infanrix Hexa for first 2 months, then increase to 2/3 until Sept 2017 when equal quantities of both delivered.
- Rotarix Schedule Months 2 & 4
 - Quantity of Rotarix restricted to 2/3 of monthly requirements of Infanrix Hexa
- **Menitorix Schedule Month 13**
 - Available October 2017



Vaccine Fridge

- **Vaccines must be stored in a fridge to comply with licence**
 - Store within the temperature range of 2-8°C
 - Store in original packaging to protect from light & box contains batch details
- Store on shelves, not touching the sides
- Record fridge temperature **twice** daily
- Set fridge to alarm at +3°C or +7°C to allow time to react before +2°C or +8°C is reached
- Wire fridge directly to power without use of a plug and have a dedicated circuit. **Never unplug the fridge**
- **Never store out of date vaccines in the fridge**



Max/Min Thermometers

- Maximum / Minimum temperatures should be recorded twice daily.
- ENSURE the memory is erased twice daily, in the morning and just before closing surgery, i.e. the maximum, minimum and current temperatures should be checked again and if the thermometer has been correctly reset these three readings should all show the same temperature (i.e. current temperature)
- Recording only shows the highest temperature registered but not the duration.
- Usually the highest recorded temperature is while the door is open.



Data Loggers

- USB temperature data logger for use with pharmacy fridges independent of fridge power supply
- Measurement range from -35°C to +80°C
- Can store up to a year's worth of data (16,382 readings)
- Flashing LED status indicators mean user can see the status of the logger without having to download data
- They do not replace recording Max/ Min readings twice daily.



Break in the Cold Chain

- Can occur due to a problem with the vaccine fridge. E.g.
 - Electricity power cut
 - Switch turned off
 - Fridge door left open.
 - Fridge malfunctions

Vaccines should be transferred immediately to a working fridge or power restored.

Never leave vaccines at room temperature or **do not** remove them from the fridge unless instructed to do so by the Chief Pharmacist or Medical officer in NIO



Recommended procedure following a break in the Cold Chain (1)

Make sure that the fridge is now working properly or transfer to a working fridge.

- Check the temperature and find out how long the fridge breakdown has been
- Send the following to ***Cliona.Kiersey@hse.ie***
 - Name of practice
 - Account number
 - Current fridge temperature
 - Duration of temperature breach
 - Maximum temperature reached
 - Name, quantity and batch numbers of vaccines in the fridge.

Ring for further advice. (087 9915452 or 01 8676108)



www.immunisation.ie

Recommended procedure following a break in the Cold Chain (2)

- Any vaccine not stored between 2⁰-8⁰C is no longer a licensed product
- Company data show that vaccines can be used if exposed to short deviations. Each temperature deviation must be judged on a case by case scenario. Each vaccine has specific criteria and will remain stable for different lengths of time.
- Expired and damaged unopened vaccines must not be used and should be removed from the fridge and returned to the NCCS deliveryman with a completed vaccine return form. Vaccine return forms are available to download from <http://www.immunisation.ie/en/VaccineOrderingandStorage/>.
- Expired and damaged unopened vaccines must not put into a sharps bin.



REMEMBER THE 4Rs

- **Read:** Twice daily readings of the fridge thermometer's maximum, minimum and current temperatures at the same time morning and evening daily during the working week.
-
- **Record:** record fridge temperatures in a standard fashion and on a standard form stating date and time of reading and sign/initial and download data logger regularly.
-
- **Reset:** reset the max/min thermometer (i.e. clear the thermometer memory) after each reading and after a period of high activity once temperatures have stabilised and also at the end of every day.
-
- **React:** the person making the recordings should take action if the temperature falls outside $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$ and document this action



www.immunisation.ie

Planned power outage

- **Keep the room as cold as possible**
- **Fill your fridge.** Place containers of very cold salty water days before the outage in spaces. Double wrap ice blocks with bubble wrap and place on bottom of fridge
- **Lock the fridge**
- **Record the temperature**
- **Use a Datalogger**



WWW.immunisation.ie

***HSE Guidelines
for maintenance of cold-chain
in vaccine fridges and
management of vaccine stock***

***Recommendations for planned
power cut***



www.immunisation.ie

“Borrowed Vaccines”

If vaccines are required due to stock out or a fridge issue you can get vaccines from another practice.

Please do not return vaccines to this practice as vaccines should be ordered by them and delivered directly to them from HSE National Cold Chain Service.



www.immunisation.ie

Examples of Vaccines returned- Clean your fridges!

- **2012**

44,184 doses - 2TU Mantoux test (expiry 05/2002) was 10 years and two months expired when returned.

- **2013**

16,753 doses - Pneumovax (expiry 03/2007) was 6 years and three months expired when returned.

- **2014**

10,737 doses - Pentavac (expiry 09 /2002) was 11 years and 6 months expired when returned. Removed from schedule in 2009.

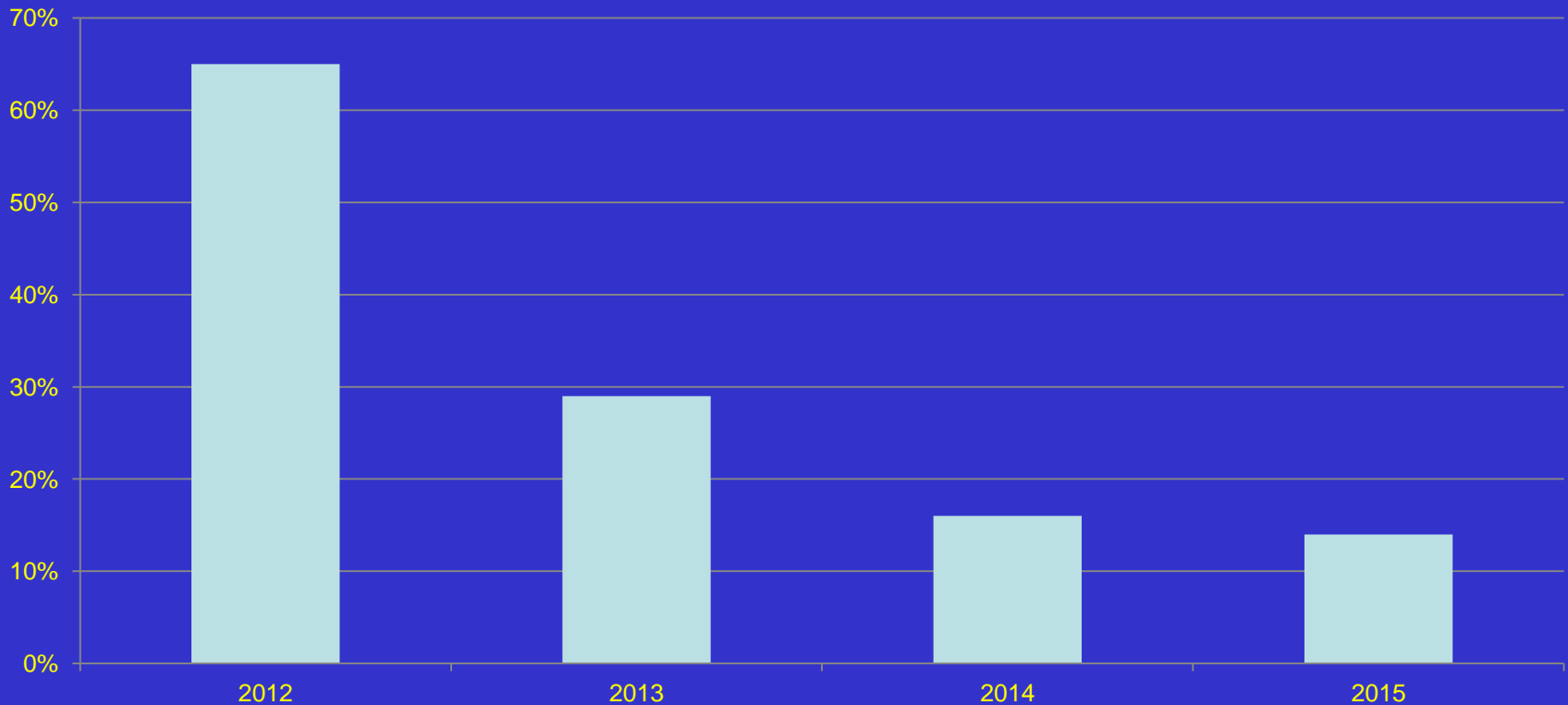
- **2015**

9168 doses- MMR (expiry 03/2004) was 11 years and 6 months expired & Pentavac also returned.

www.immunisation.ie



% Expired Stock Returned with greater than 6 months expiry



www.immunisation.ie

Batch Numbers

- The valid batch number is the number on the box and is the only number to record.
- Please use peel off sticker where available.
- Combination vaccines or vaccines which require reconstitution will have a different batch numbers on each constituent, the number on the box refers to the reconstituted vaccine.
- Only the appropriate batch number can be accepted on the child's record, any other batch number will register as invalid.



Conclusions

- Vaccines are expensive
- Good housekeeping is essential for vaccine management



www.immunisation.ie

Useful resources

- Australian Government Department of Health and Ageing National Vaccine Storage Guidelines 2005, Strive for 5
<http://www.health.gov.au/internet/immunise/publishing.nsf/Content/provider-store>
- Department of Health UK. November 2006. Immunisation against infectious disease.
http://www.dh.gov.uk/en/Policyandguidance/Healthandsocialcaretopics/Greenbook/DH_4097254
- Irish Pharmaceutical Healthcare Association Medical Compendium.
<http://www.medicines.ie>.
- Irish Medicines Board. <http://www.imb.ie>.
- National Immunisation Office Ireland. Health Service Executive.
<http://www.immunisation.ie>.
- Public Health Agency Canada. National Vaccine Storage and Handling Guidelines for immunisation providers 2007. <http://www.phac-aspc.gc.ca/publicat/2007/nvshgpl-ldemv/index-eng.php>.
- Royal College of Physicians of Ireland. Immunisation Guidelines for Ireland. Available at www.rcpi.ie or www.immunisation.ie or www.hpsc.ie



www.immunisation.ie