

The Cold Chain and Vaccine storage

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Chief Pharmacist
National Immunisation Office

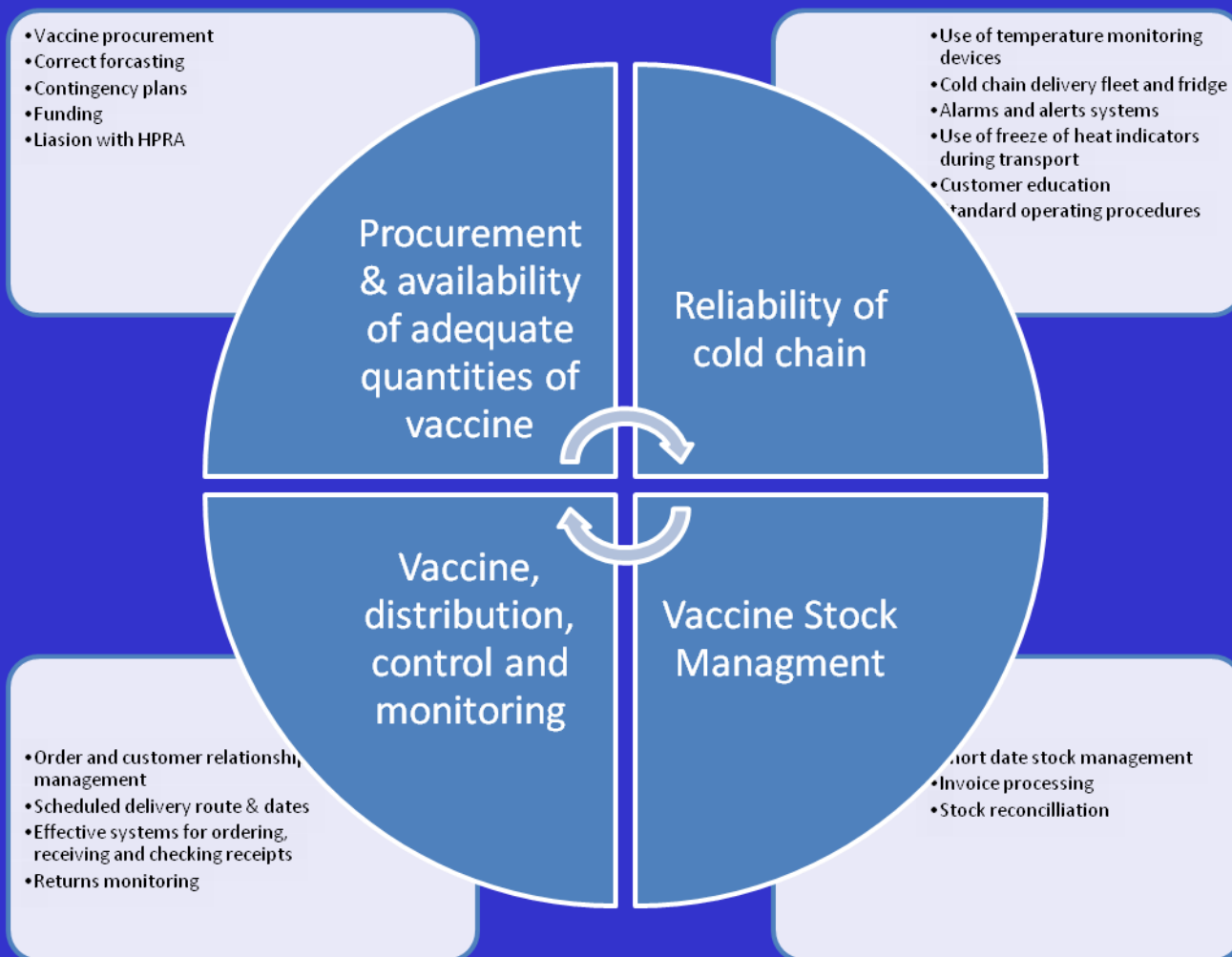


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Objectives

- To explain the cold chain and vaccine delivery service including use of vaccine returns service
- To understand the importance of monitoring the cold chain within your own practice
- To understand the correct procedures for handling and storage of vaccines
- To recommend procedures following cold chain breach





Relevant sections

- Use of temperature monitoring devices
- Cold chain delivery fleet and fridge
- Alarms and alerts systems
- Use of freeze or heat indicators during transport
- Customer education
- Standard Operating Procedures

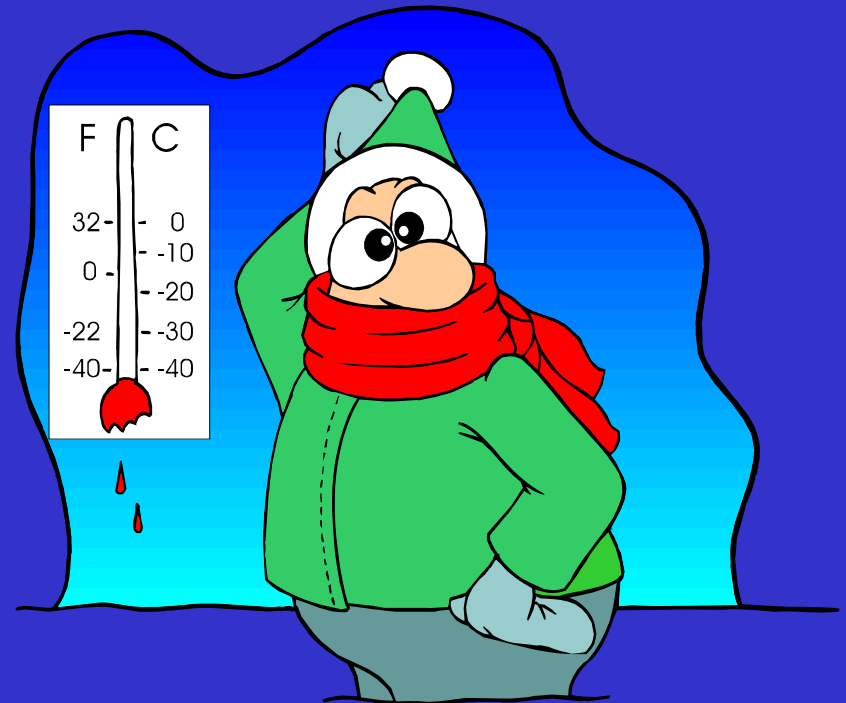
Reliability
of cold chain

Vaccine
distribution, control
and monitoring

- Order and customer relationship management
- Scheduled delivery route & dates
- Effective systems for ordering, receiving & checking receipts
- Returns monitoring

Why is the cold chain important?

- Vaccines must be stored within a specific temperature range between $+2$ and $+8^{\circ}\text{C}$ to ensure their potency and to comply with regulations (PA/EU licence)
- Vaccines are sensitive biological products that may become less effective or even destroyed when exposed to less than $+2$ and greater than $+8^{\circ}\text{C}$ and/or to direct sunlight or fluorescent light
- Assurance in product potency ensures maximum benefit from immunisation



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

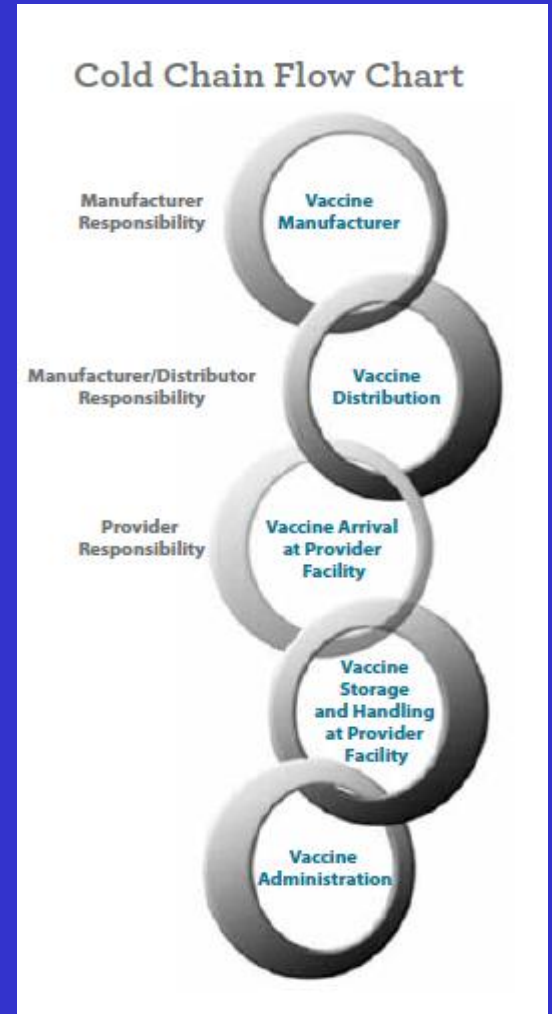


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Who's Responsible for Cold Chain

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



National Cold Chain Delivery Service

- Commenced 1st January 2005, delivering to ~1650 sites annually now has increased to 2,594 sites receiving 2.1 million doses annually
- responsible for ~€37 million annually.
- United Drug Distributors based in Citywest with satellite sites in Limerick and Ballina



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11 Delivery Vans

- Van fridges are equipped with alarms (auditory in cab& text message sent to driver & UD staff) and heating/cooling systems, navigation & location tracking systems.
- Each van has been mapped and 4 temperature probes positioned to record appropriate temperatures
 - Product probe
 - Right side probe
 - Left side probe
 - Air return probeAlarm activated once temperature of +3°C or +7°C registered
- Robust contingency plans in case of power failure or breakdowns. 2 fridge units (1 Backup fridge unit) and battery as back up.
- Standard operating procedures govern all processes.



100 Routes

- Dublin (72% of orders)
 - 60 Routes
 - 3 Vans & 3 drivers
- Limerick (17% of orders)
 - 20 Routes
 - 1 Van & 1 driver
- Ballina (11% of orders)
 - 20 Routes
 - 1 Van & 1 driver

Double deliveries from mid September to mid November



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Vaccine Deliveries

- 2594 sites are entitled to 12 scheduled (monthly) plus 2 extra deliveries during the “flu season”.
- The 12 deliveries are based on 4 weekly cycles (and there are 4 “down” weeks). Between September – November (“flu season”) there are fortnightly deliveries.
- There are an extra ~1000 sites who get only flu / PPV deliveries in flu season.
- Unscheduled
- Emergency



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Unscheduled / Emergency 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)
- Each non scheduled / emergency delivery is an extra charge and cause a disruption to routine deliveries



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Vaccine distribution, Control & Monitoring

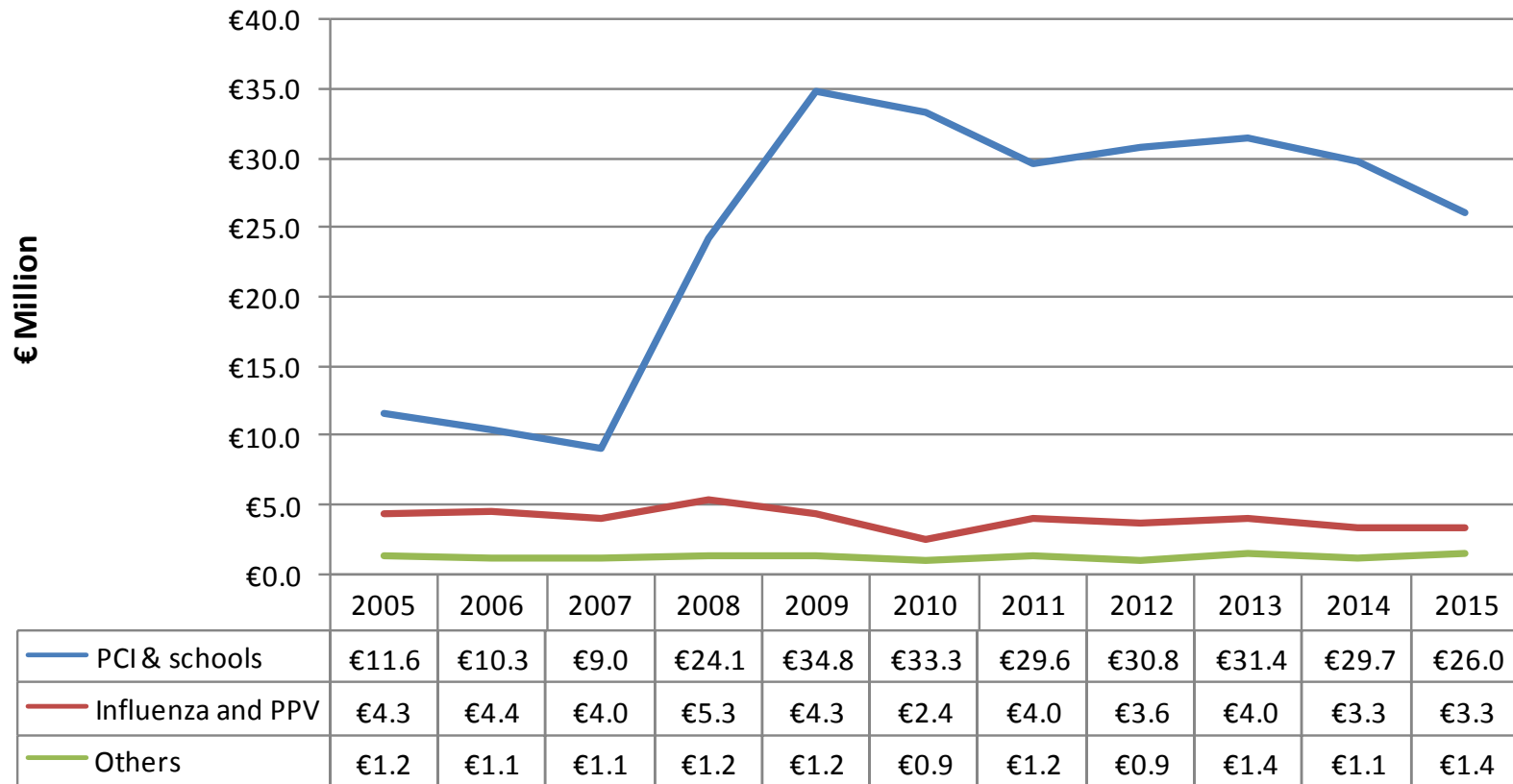
Vaccine distribution is monitored to ensure it is consistent with target cohort requirements as significant deviations may indicate over or under stocking.

Each site should order monthly to facilitate proper stock levels.



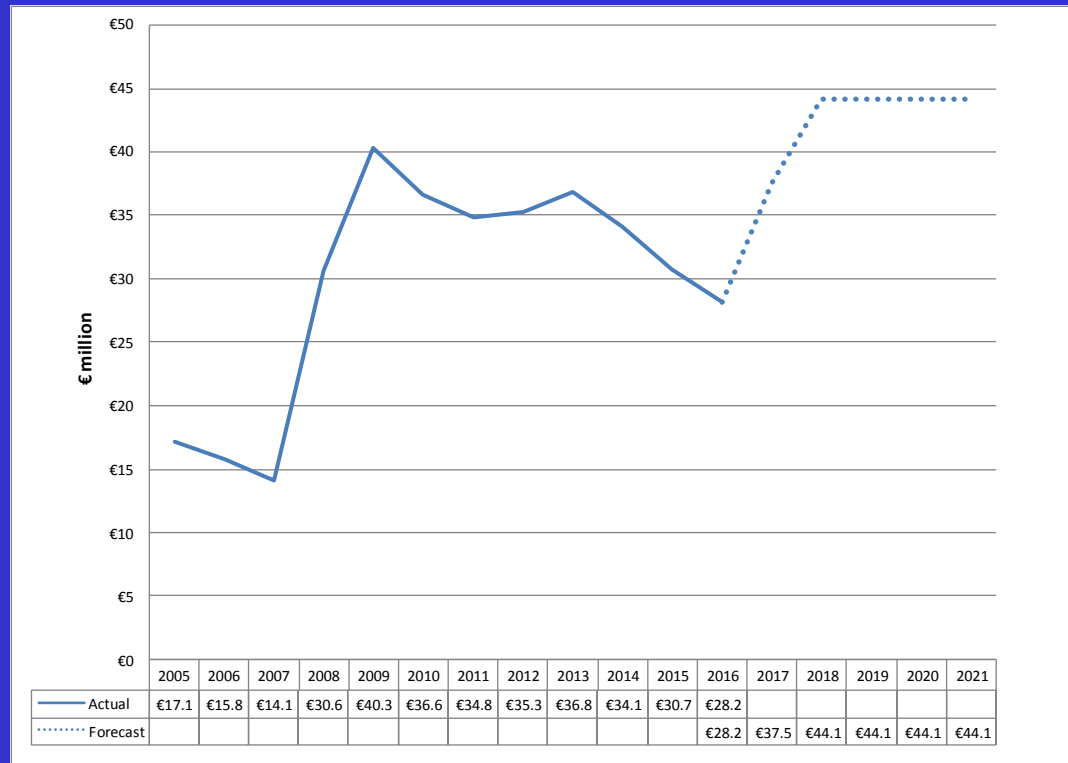
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Cost of Vaccines Purchased



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Actual and forecasted vaccine expenditure 2005 - 2021



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Who can order vaccines?

- GPs who hold an immunisation contract
- Community Health Doctors who run the school immunisation service, BCG clinics
- Hospitals who require vaccines
- Authorised Flu Sites (Retail Pharmacies and Nursing homes)
- Vaccines are delivered monthly directly to these sites.



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Vaccines supplied

	Vaccines
Primary Childhood vaccines	6 in 1, Men C, PCV, MMR, Hib, 4 in 1
Adult vaccines	Td, Tdap Influenza, Pneumococcal polysaccharide vaccine
HSE vaccines	BCG, Tuberculin , 4 in 1, MMR, Tdap, HPV
Restricted vaccines	Hepatitis A, Hepatitis B, Hepatitis A +B Td/IPV, Tdap/IPV, MenACW ₁₃₅ Y, MenB

Current list of available vaccines

- from United drug
- in newsletter
- on immunisation website

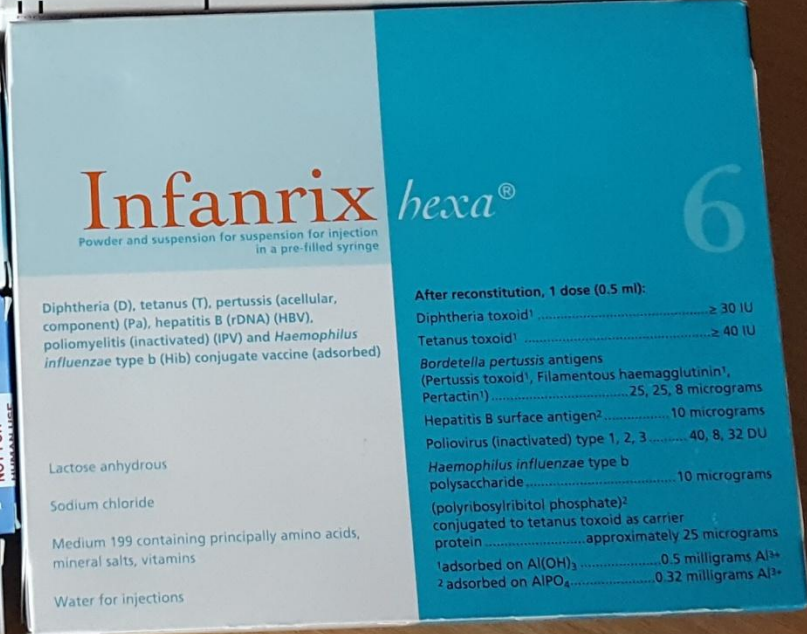
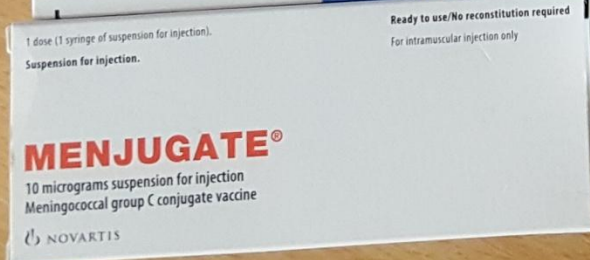
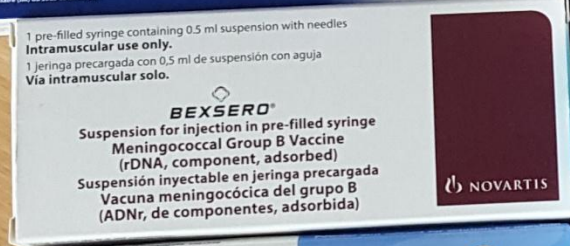
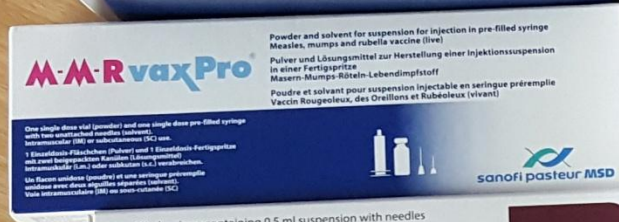
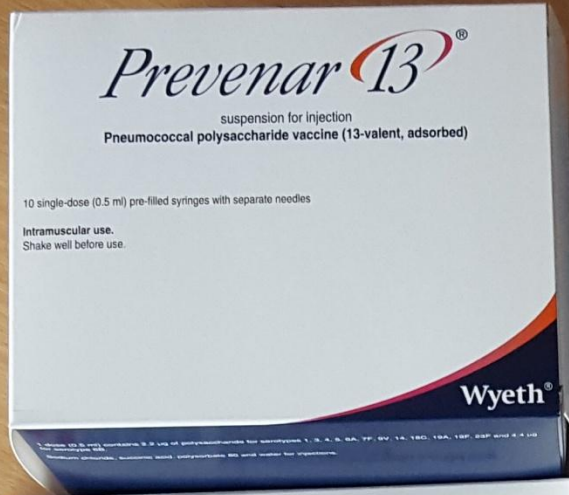
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Current PCI Schedule



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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)

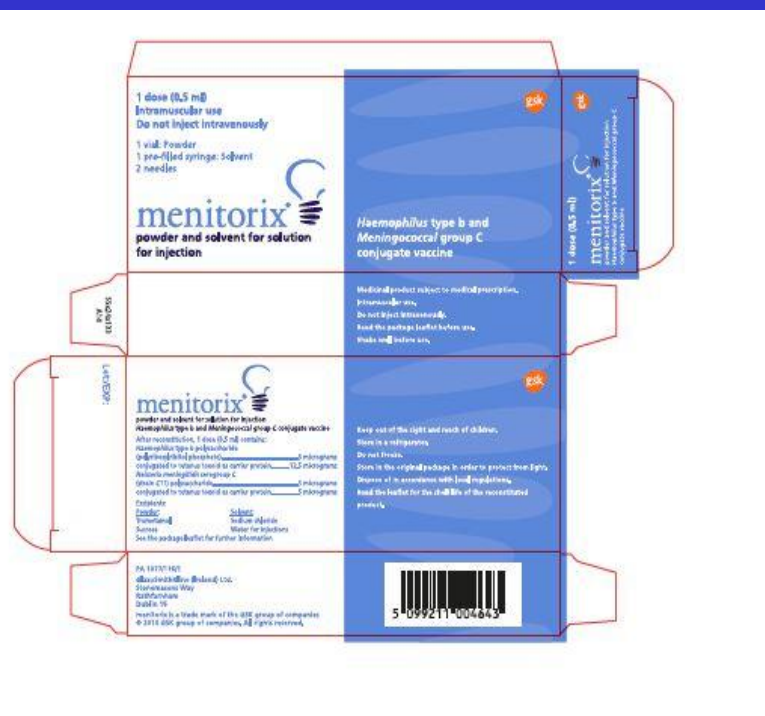


Menitorix (Hib-MenC)

Powder and solvent for solution for injection

White powder and a clear colourless solvent

2 Needles 23G x 25mm & 21G x 40mm



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Förvaras i originalförpackningen. Ljuskänsligt = Förvaras i kylskåp = Får ej frysas
Sållityä alkuperäispakkauksessa. Herkkä valolle = Säilytä jääkaapissa = Ei saa jättää
Oppbevares i originalpackningen 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®

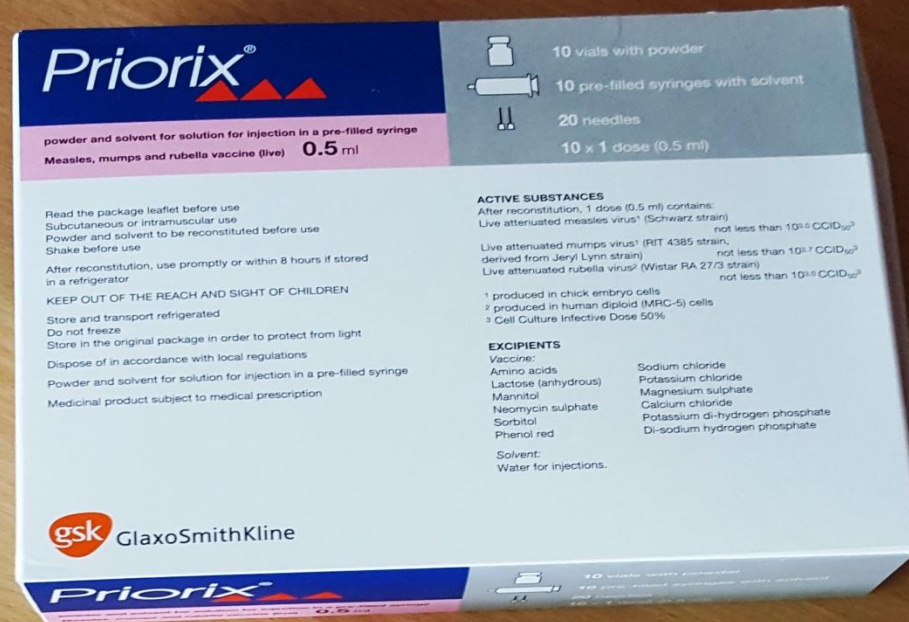
Oral suspension i förfylld oral applikator
Oraalisuspensio esitetyttyä oraalisessa annostelulaitteessa
Mikstur, suspensjon i ferdigfylt oral applikator
Rotavirusvaccin, levande
Rotavirusrokote, elävä
Vaksine mot rotavirus, levende

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 $10^{3.5}$ CCID₅₀

Live attenuated mumps virus¹ (RIT 4385 strain,

derived from Jeryl Lynn strain)

not less than $10^{3.7}$ CCID₅₀

Live attenuated rubella virus² (Wistar RA 27/3 strain)

not less than $10^{3.5}$ CCID₅₀

¹ produced in chick embryo cells

² produced in human diploid (MRC-5) cells

³ Cell Culture Infective Dose 50%

EXCIPIENTS

Vaccine:

Amino acids

Lactose (anhydrous)

Mannitol

Neomycin sulphate

Sorbitol

Phenol red

Sodium chloride

Potassium chloride

Magnesium sulphate

Calcium chloride

Potassium di-hydrogen phosphate

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)



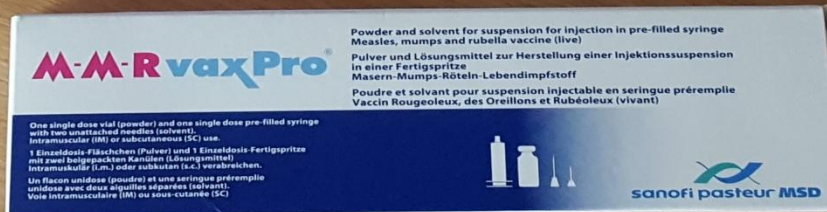
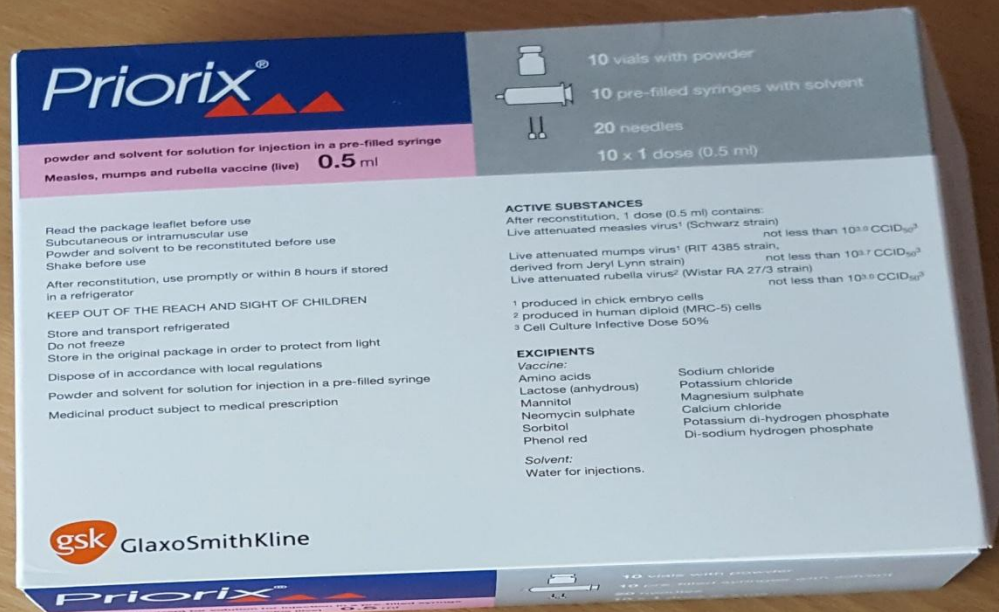
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IPV-Boostrix

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



MMR Products



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School Immunisation Programme

Second Level.



Some typical vaccine orders with Costs

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>



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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>



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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** and prepare for return.
- Give vaccine returns 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**



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 as fortnightly deliveries.



National Cold Chain Service

Delivered by United Drug in partnership with the HSE

Login

Username/Email:

customer@ncc.com

Account ID:

30030

Password:

LOGIN

[Forgotten your Password?](#)

Vaccine Ordering

Welcome to www.ordervaccines.ie. This is the online vaccine ordering page from the National Cold Chain Delivery Service. We provide vaccines for publicly funded immunisation programmes to healthcare settings in Ireland.

If you have an account for ordering vaccines but you have not registered for online vaccine ordering please click "Forgotten your Password?" on the left to begin the registration process. If you would prefer to contact customer services we will set you up with an online username and password.

Once you have your username, account number and password please login using the panel on the left.

If you need any help? - Please contact United Drug customer service on 01 463 7770 or vaccines@udd.ie



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.

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Useful Links

[HSE Immunisation Website](#)

[United Drug Supply Chain Services](#)



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National Cold Chain Service

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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.



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Useful Links

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[United Drug Supply Chain Services](#)



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Vaccine Order Form

VACCINE	PACK SIZE	INDICATIVE PRICE	QTY
6 in 1	10	90.13	<input type="text" value="10"/>
Men C	1	43.05	<input type="text" value="10"/>
PCV	10	73.80	<input type="text" value="10"/>

These vaccines must be ordered together in defined ratios.
If you only need quantities of individual vaccines please contact customer service.

4 in 1	1	24.60	<input type="text" value="3"/>
Boosterix (Tdap)	1	25.76	<input type="text" value="2"/>
Dite	5	12.63	<input type="text" value="5"/>
Hep B (ENGRIX PAED)	1	15.40	<input type="text"/>
Hep B (HBVAXPRO5)	1	15.40	<input type="text"/>
HepB (ENGRIX ADULT)	1	20.81	<input type="text"/>
HepB (HBVAXPRO10)	1	20.81	<input type="text"/>
Hib	1	30.69	<input type="text"/>
Influenza	10	7.38	<input type="text"/>
MMR	1	20.17	<input type="text"/>
Pneumococcal	1	21.05	<input type="text"/>

[CONTINUE TO REVIEW ORDER PAGE](#)

Requested Vaccines

VACCINE	QTY	PRICE
6 in 1	10	901.30
4 in 1	3	73.80
Boosterix (Tdap)	2	51.52
Dite	5	63.15
Men C	10	430.50
PCV	10	738.00
TOTAL		2,258.27

National Cold Chain Service

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NORTH WEST DUBLIN LOCAL HEALTH OFFICE **

(39510)

Logout

VACCINE ORDER FORM

ORDER HISTORY

DELIVERY SCHEDULE

CHANGE PASSWORD

Vaccine Order Form

VACCINE	PACK SIZE	INDICATIVE PRICE	QTY
2TU	10	23.70	<input type="text"/> + -
4 in 1	1	24.60	<input type="text"/>
BCG	5	17.45	<input type="text"/> + -
Boostrix (Tdap)	1	25.76	<input type="text"/>
HepB (ENGRIX ADULT)	1	20.81	<input type="text"/>
HepB (HBVAXPRO10)	1	20.81	<input type="text"/>
HPV	1	141.45	<input type="text"/>
Influenza	10	7.38	<input type="text"/> + -
Men C	1	43.05	<input type="text"/>
MMR	10	20.17	<input type="text"/> + -
Pneumococcal	1	21.05	<input type="text"/>

Requested Vaccines

You have requested no vaccines, please enter your desired quantities in doses using the vaccine order form on the left.

CONTINUE TO REVIEW ORDER PAGE

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Useful Links

HSE Immunisation Website

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Delivery Schedule

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

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

April 2015

MON	TUE	WED	THU	FRI	SAT	SUN
		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			

May 2015

MON	TUE	WED	THU	FRI	SAT	SUN
				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	31

June 2015

MON	TUE	WED	THU	FRI	SAT	SUN
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					

July 2015

MON	TUE	WED	THU	FRI	SAT	SUN
		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	31		

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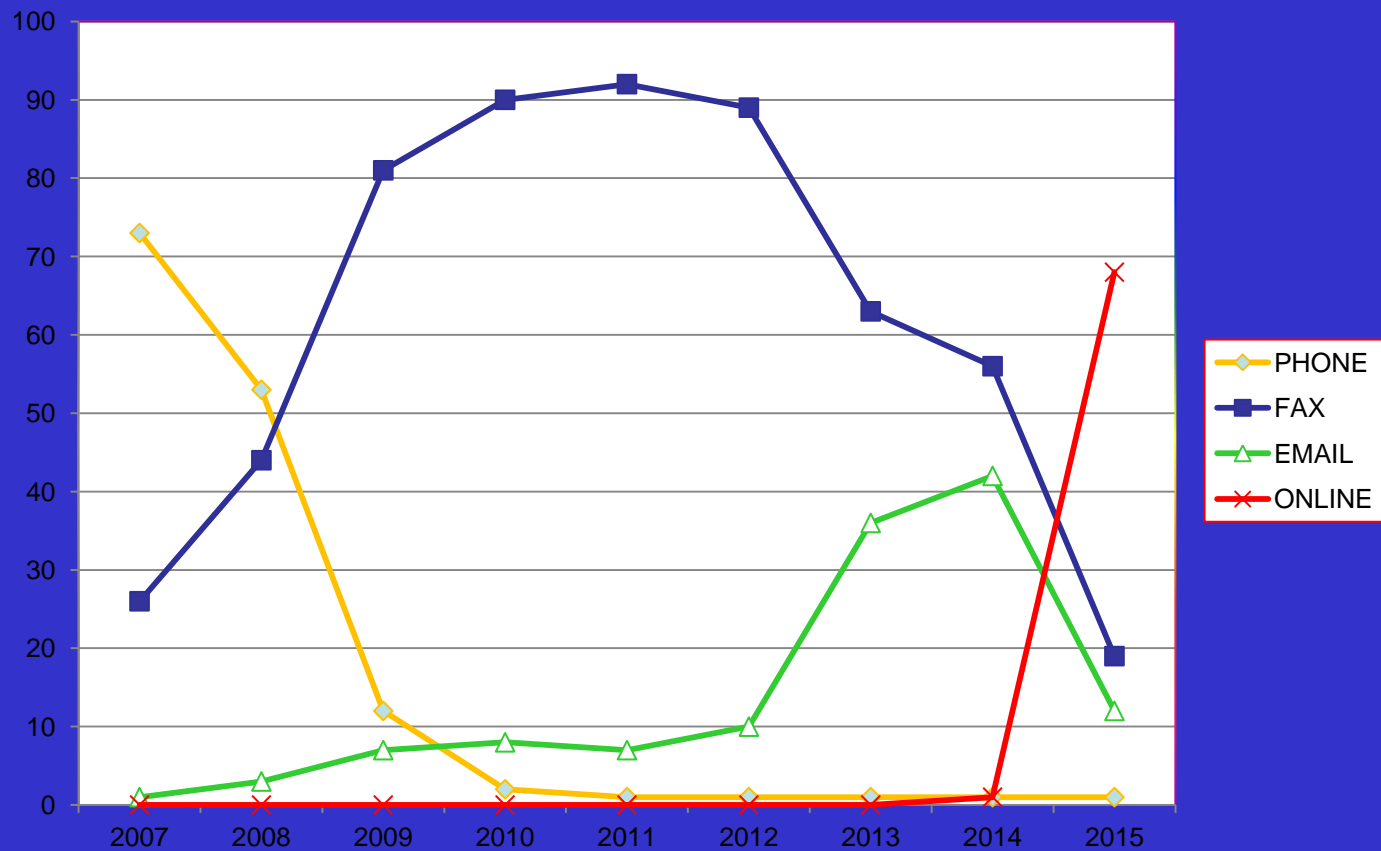
Useful Links

HSE Immunisation Website

United Drug Supply Chain Services



Order Source %



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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 use out of date vaccines**



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.



Recommended procedure following a 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
- *If this happens*
 - 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
 - Contact the Chief Pharmacist, National Immunisation Office for further advice. (087 9915452 or 01 8676108)



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.



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Details Required after Cold Chain Issue

- 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.

Send to Cliona.Kiersey@hse.ie



www.immunisation.ie

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 (Appendix 1) and down load 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 (Appendix 3).



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WWW.immunisation.ie

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



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“Borrowed Vaccines”

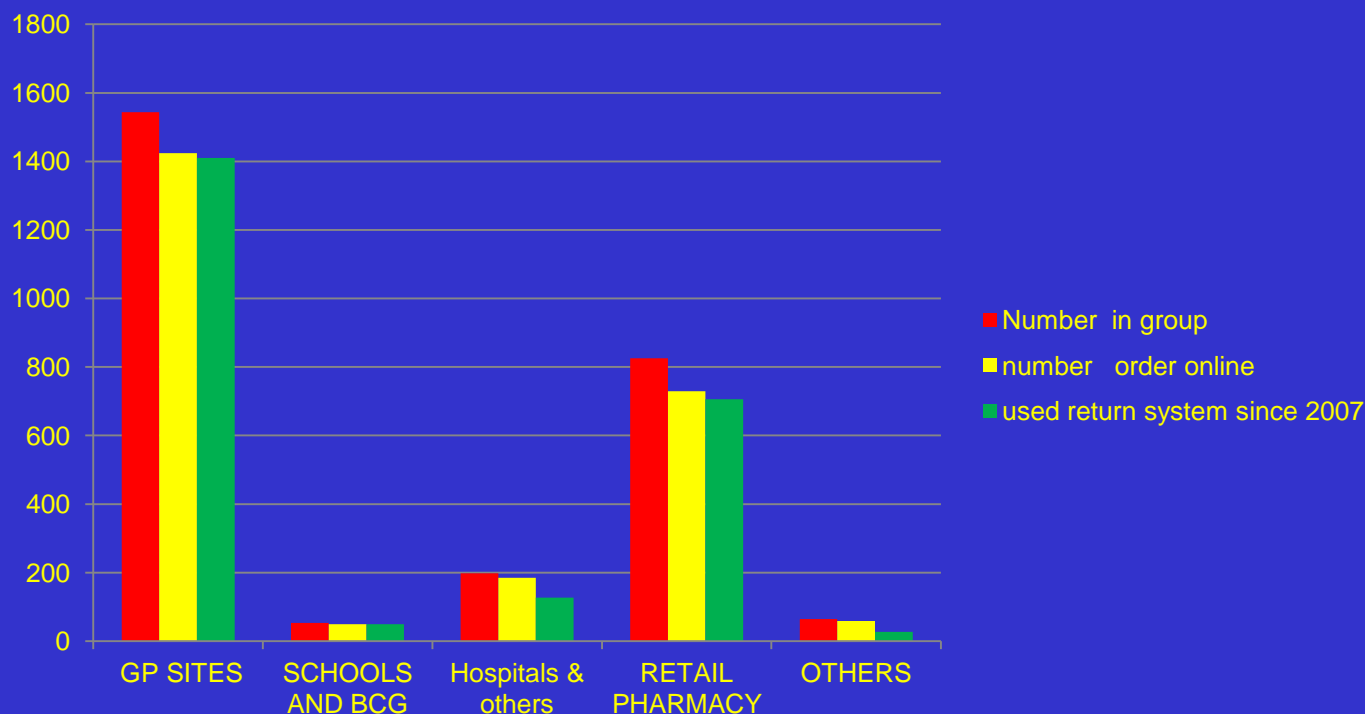
If vaccines are required due to stock out or a fridge issue you can get vaccines from another practice.

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.



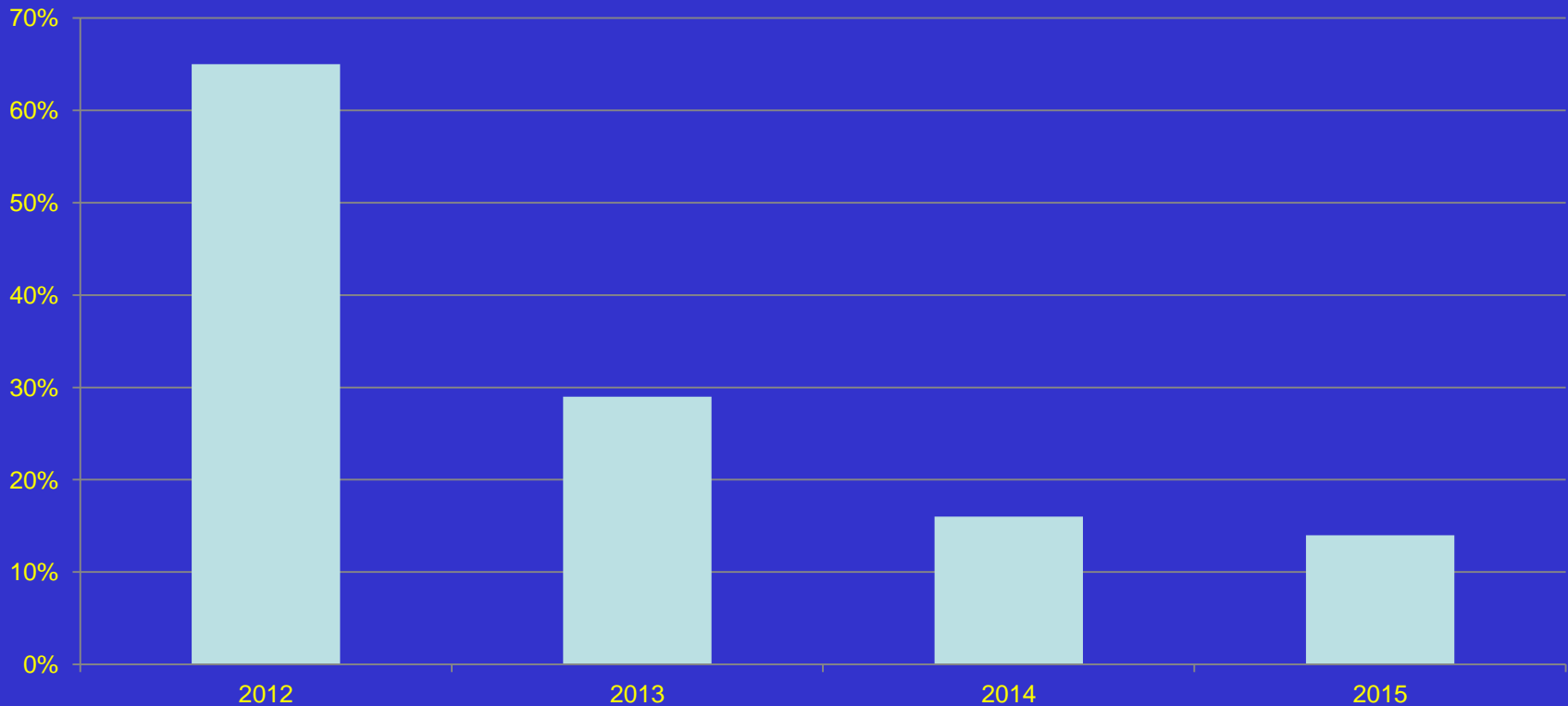
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Sites using online & the returns service



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% Expired Stock Returned with greater than 6 months expiry



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Vaccine expired more than 6 months

- **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**

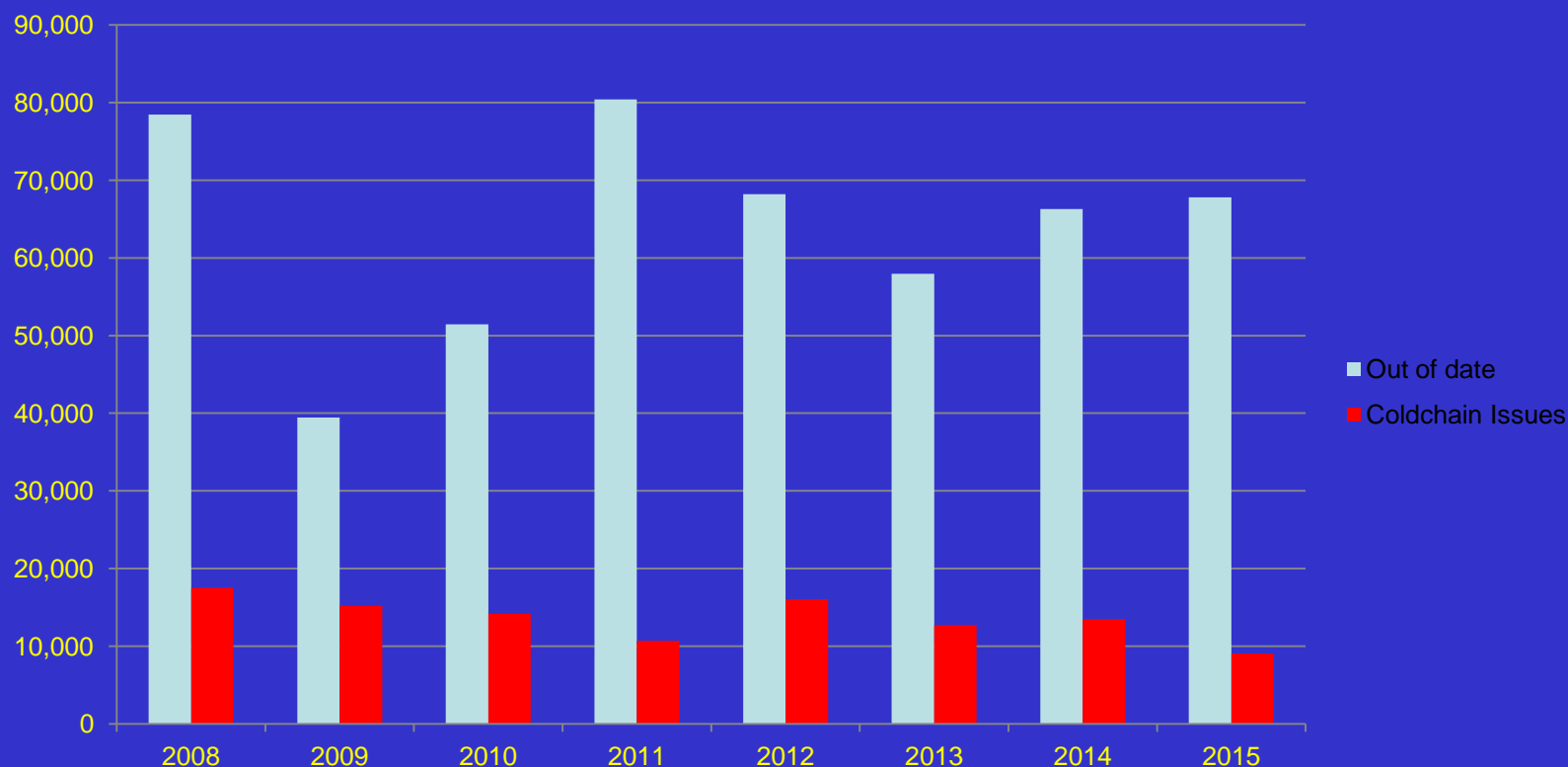
10,737 doses - Pentavac (expiry 09 /2002) was 11 years and 6 months expired when returned. Removed from schedule in 2009.

- **2015**

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

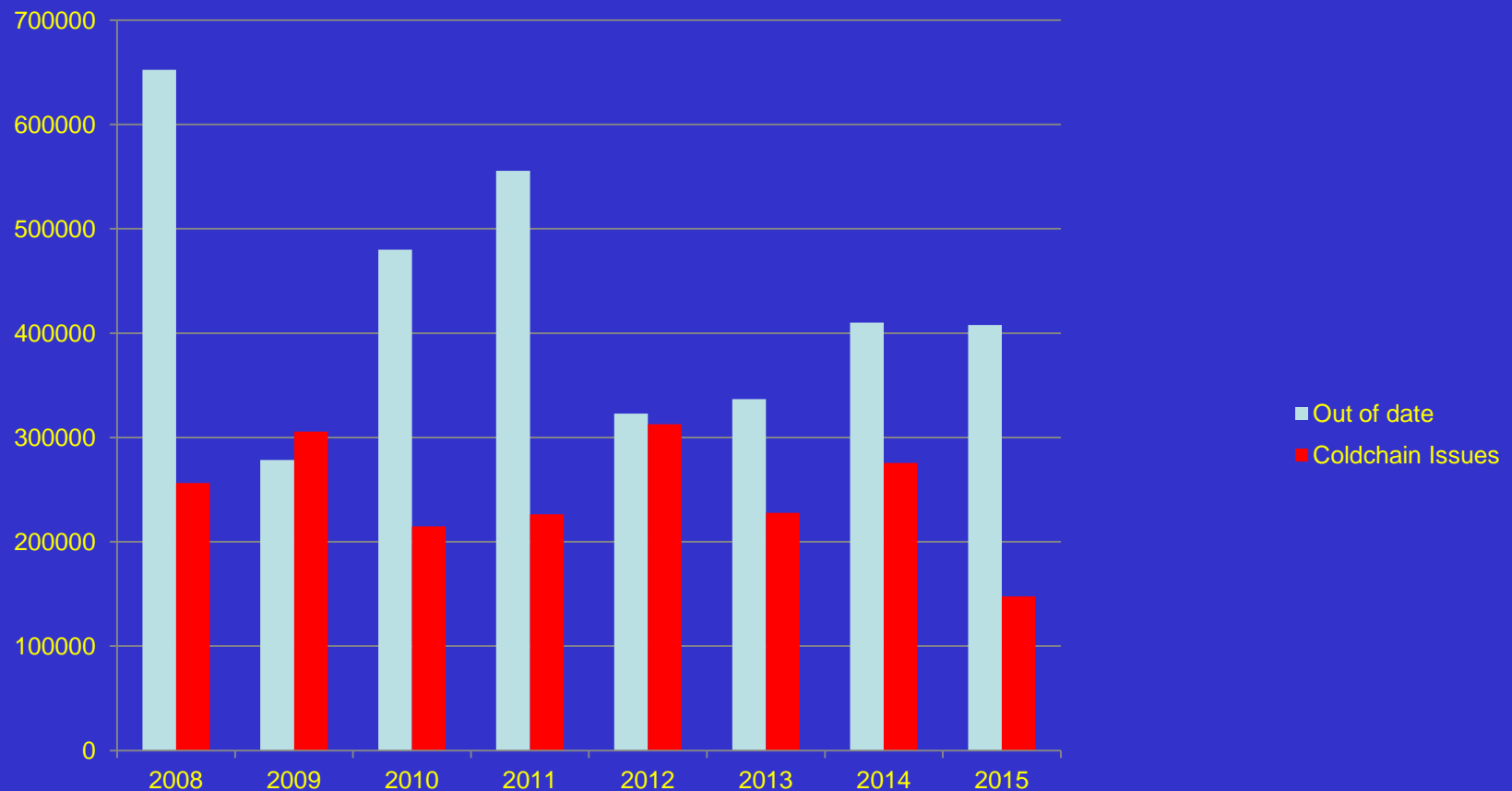


Number of Doses of returned vaccines Expired compared to Coldchain issues



www.immunisation.ie

Value of vaccines Expired compared to Coldchain issues



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



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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/nvshqlp-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



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