

The Cold Chain and Vaccine storage

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Chief Pharmacist
National Immunisation Office



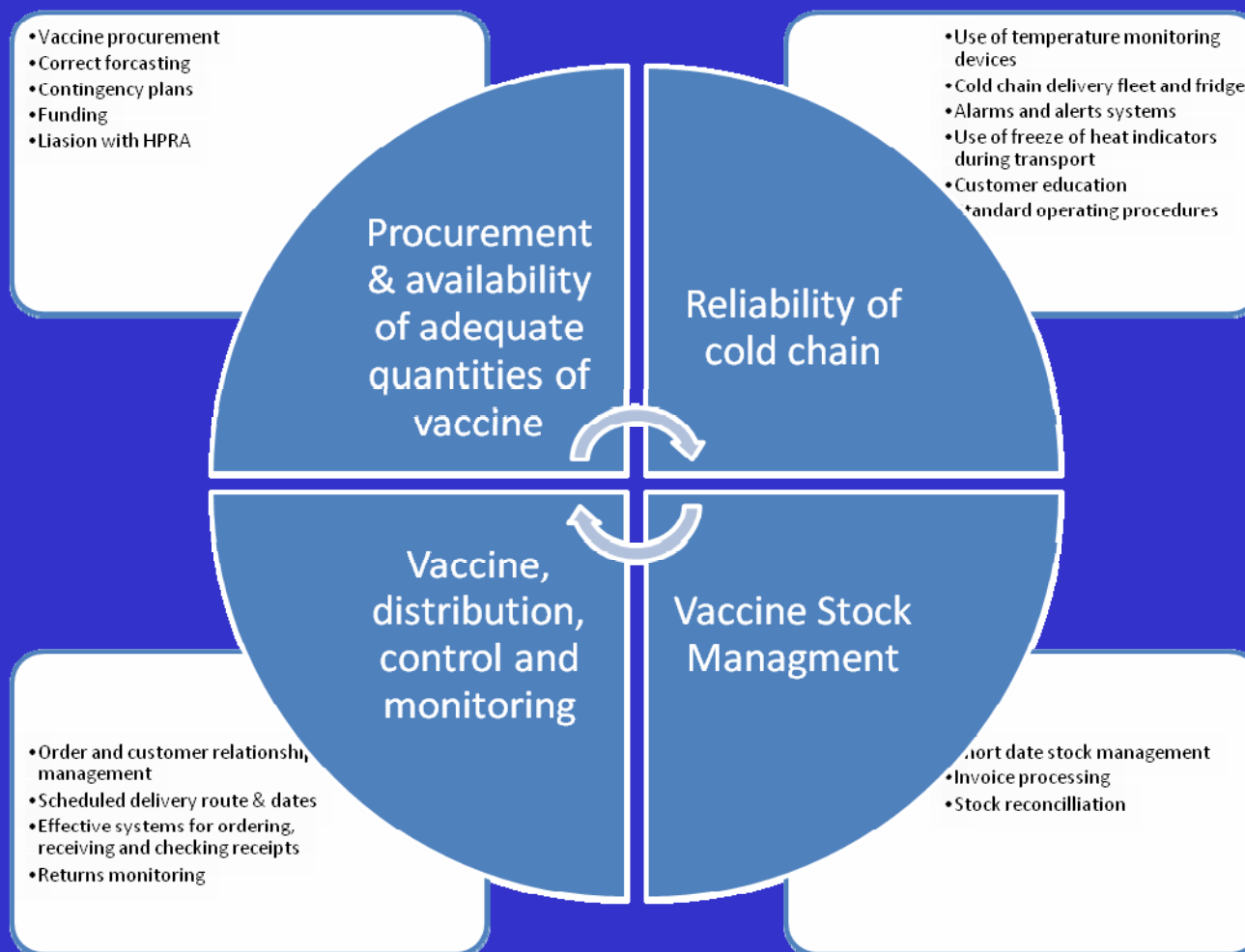
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Objectives

- To outline the complexity of vaccine management, the importance of cold chain and the delivery service
- To understand the importance of ordering appropriately and the roll out of the new vaccines
- To explain the importance of monitoring the cold chain within your own practice, the correct procedures for handling and storage of vaccines including procedure following cold chain breach and returns service



Factors affecting Vaccine Management Performance



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

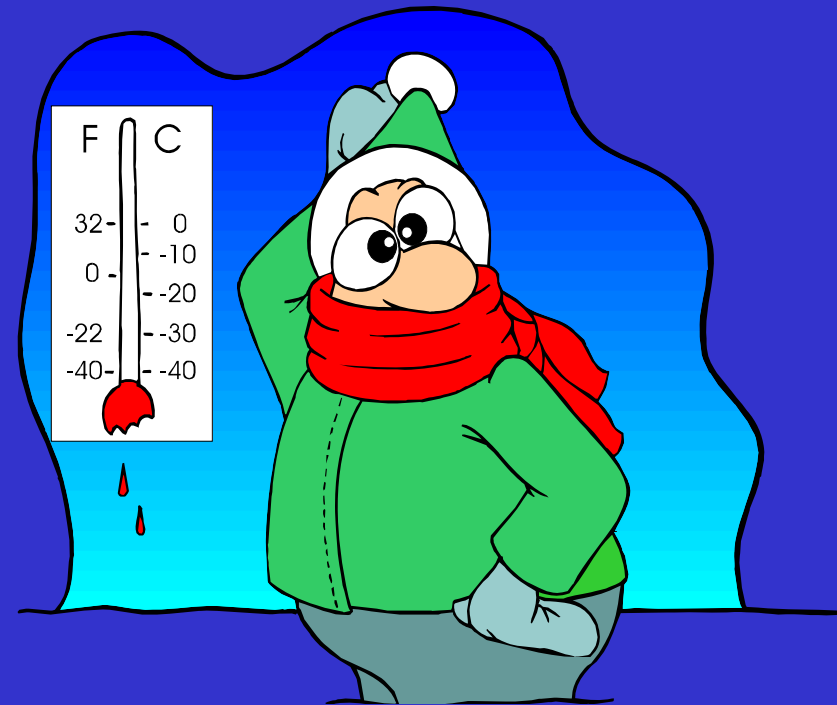
- Order and customer relationship management
- Scheduled delivery route & dates
- Effective systems for ordering, receiving & checking receipts
- Returns monitoring



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Why is the cold chain important?

- Vaccines must be stored within a specific temperature range between +2 and +8°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°C and/or exposed 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

The lower 3 links refer to when the vaccines are your responsibility and they should be covered by the practice insurance



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National Cold Chain Delivery Service (2nd Link)

- 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

Fortnightly deliveries from September to December



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Annual 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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Vaccine Deliveries in 2016

- Contract is for 14 scheduled deliveries to each site, however in 2016 there will be extra deliveries from beginning of September to December (15 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.



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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
- Unscheduled deliveries cannot be accommodated between September and December.



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Importance of Ordering Appropriately

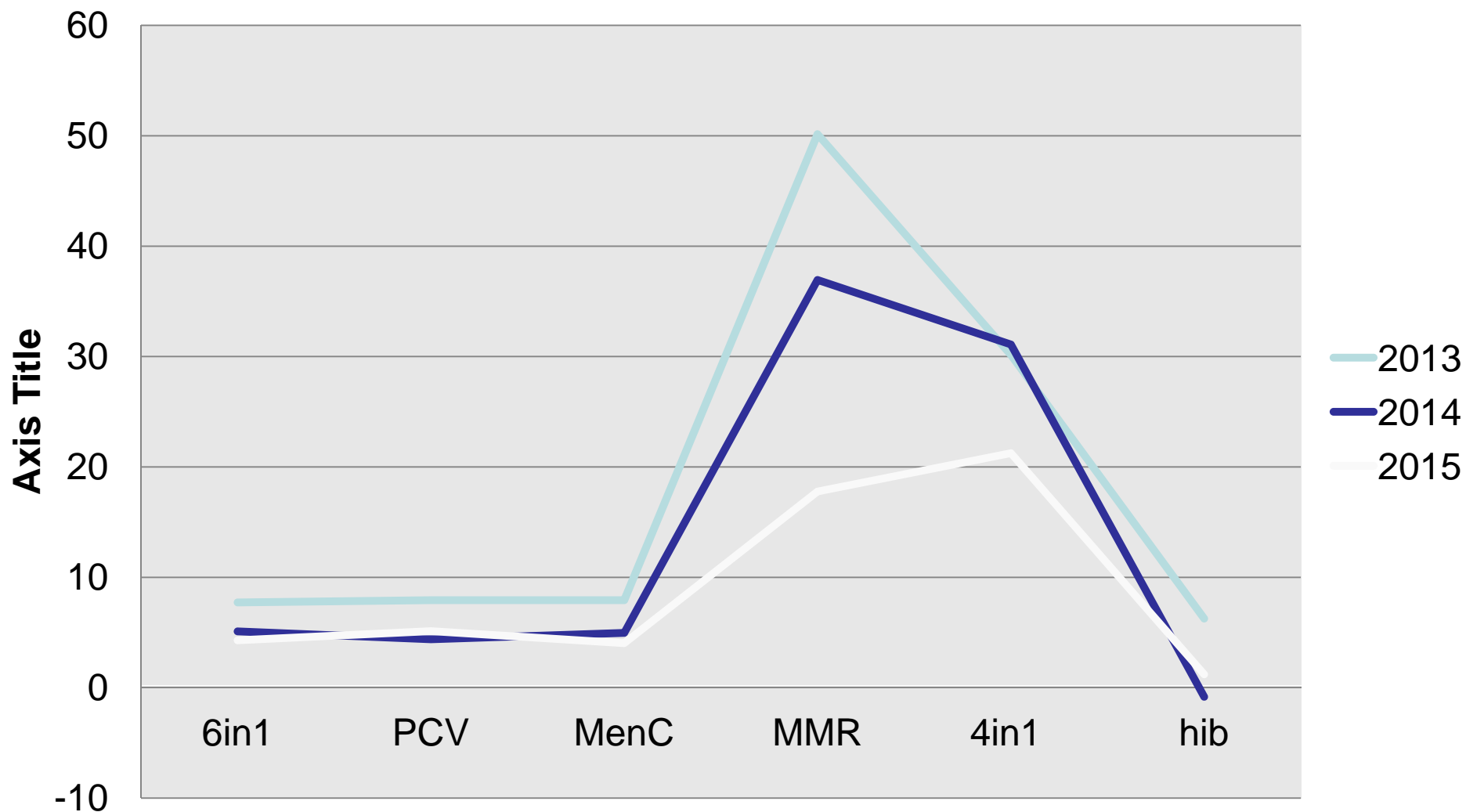
Vaccine orders are monitored to ensure consistency with target cohort requirements. Significant deviations may indicate over or under stocking, leading to vaccine wastage or missed opportunity to vaccinate.

Each site should order monthly to ensure proper stock levels.



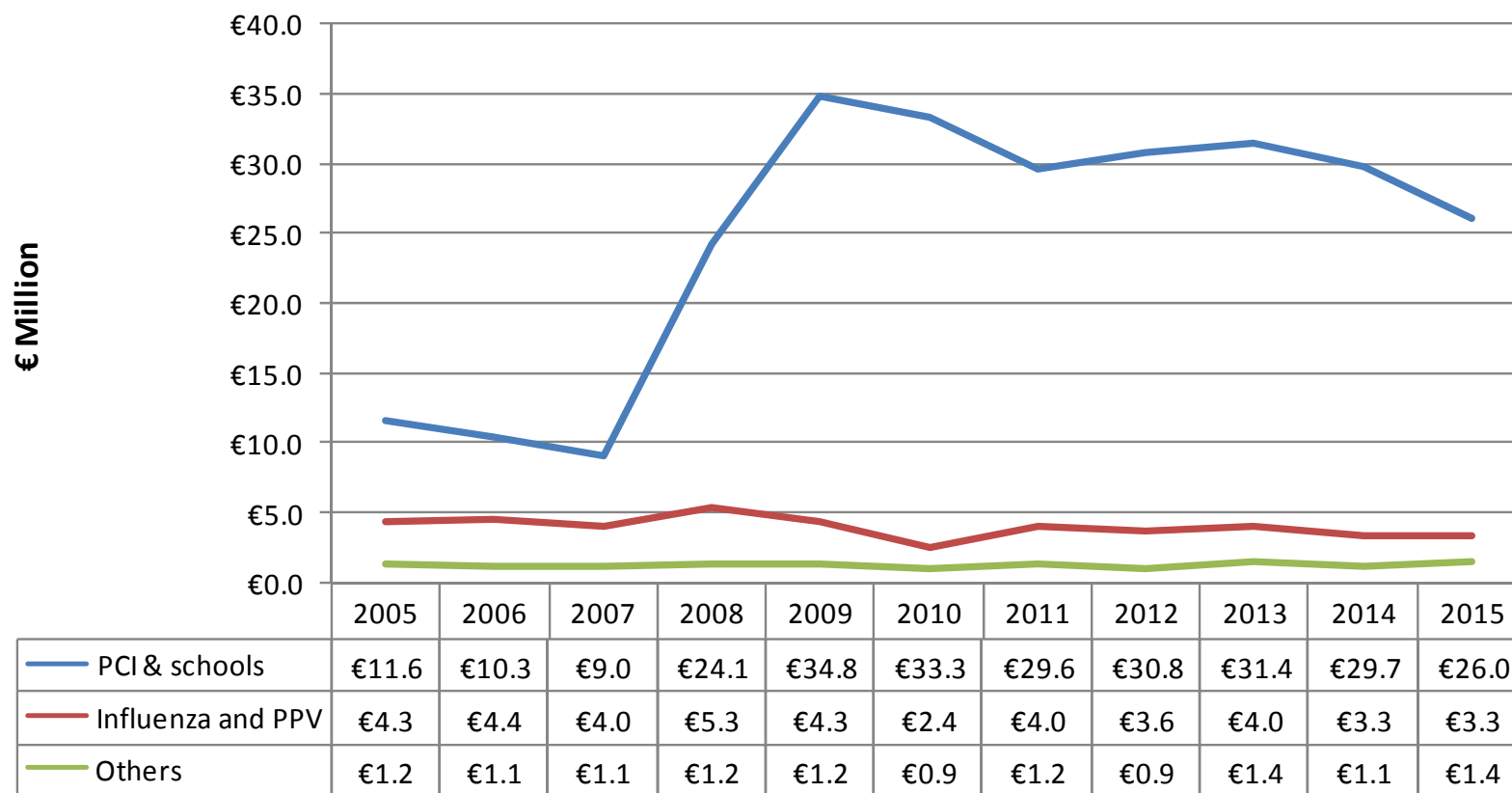
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The Number of Doses Distributed Compared to Target Cohort & Corrected to 95% uptake



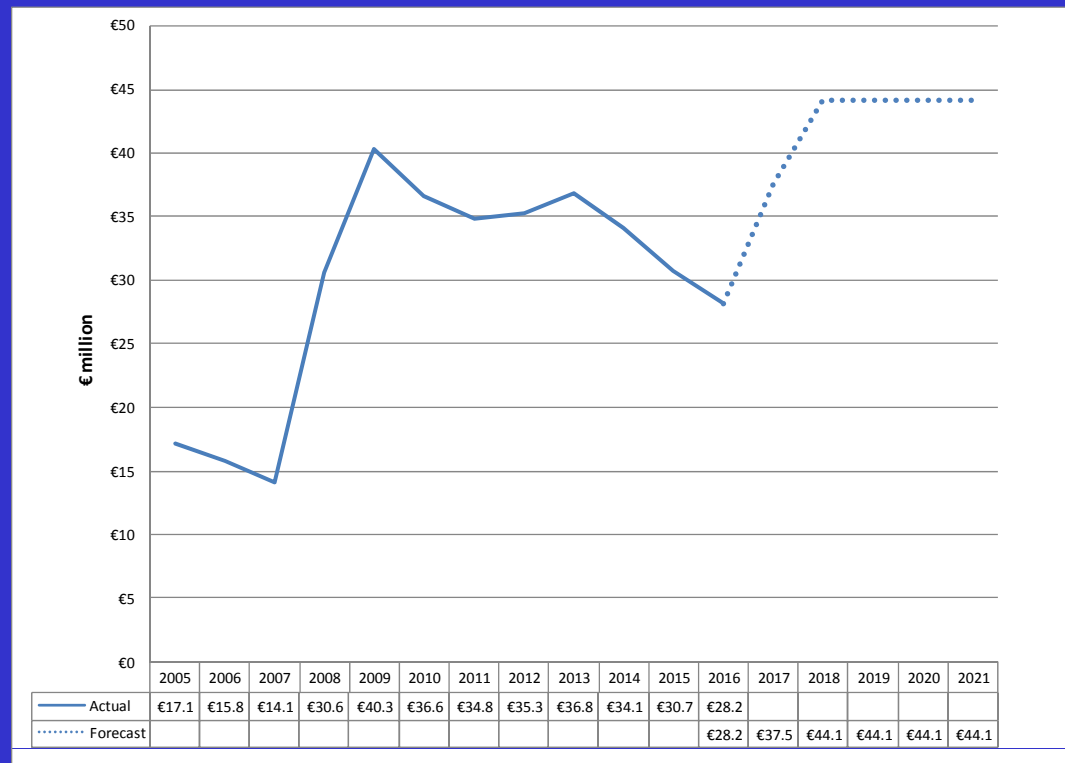
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Cost of Vaccines Purchased



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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 direct to these sites.



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Vaccines supplied

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 , Tdap/IPV, MMR, Tdap, HPV, Men C
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 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



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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

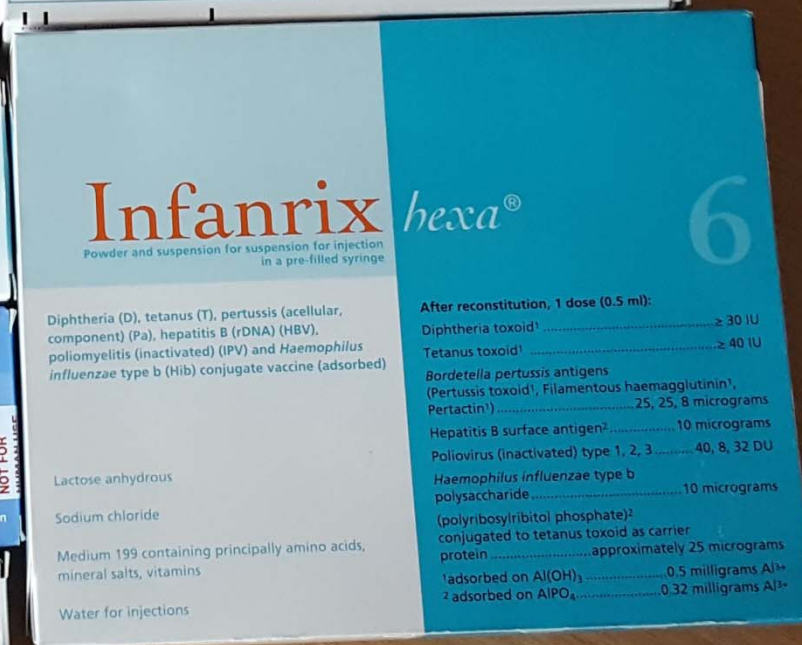
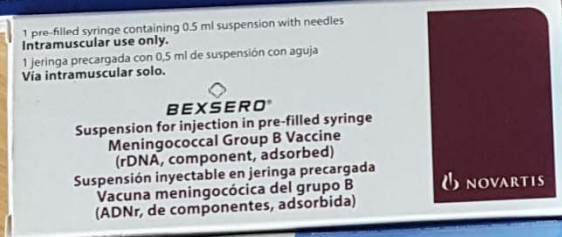
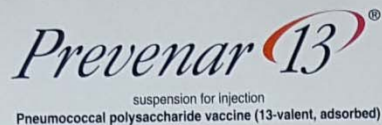


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Current PCI Schedule



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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)



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Menitorix (Hib-MenC)

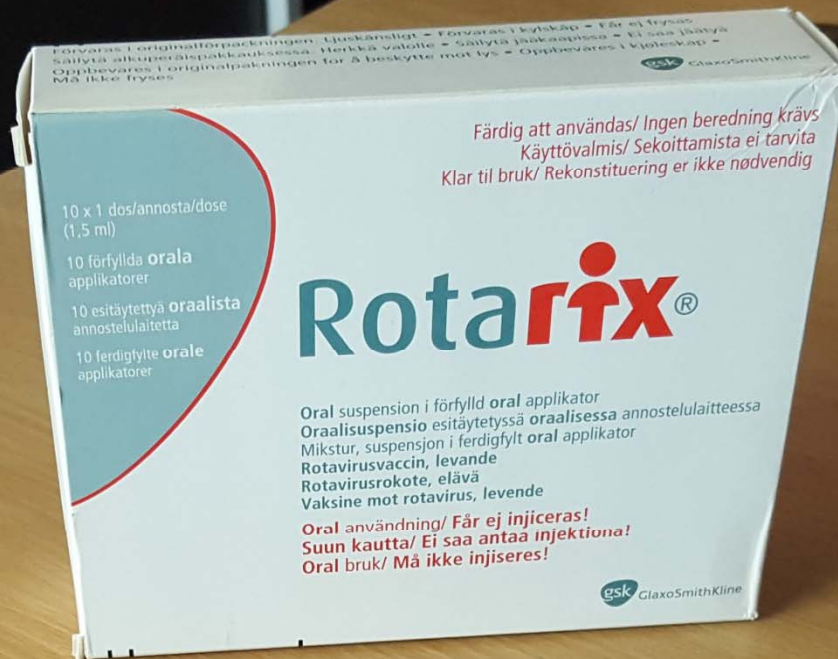
Powder and solvent for solution for injection
White powder and a clear colourless solvent
2 Needles 23G x 25mm & 21G x 40mm



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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)

Live attenuated mumps virus¹ (RIT 4385 strain,
derived from Jeryl Lynn strain) not less than $10^{3.7}$ CCID₅₀³
Live attenuated rubella virus² (Wistar RA 27/3 strain) not less than $10^{3.5}$ CCID₅₀³

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

Solvent:

Water for injections.

Sodium chloride

Potassium chloride

Magnesium sulphate

Calcium chloride

Potassium di-hydrogen phosphate

Di-sodium hydrogen phosphate



GlaxoSmithKline

Priorix®




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



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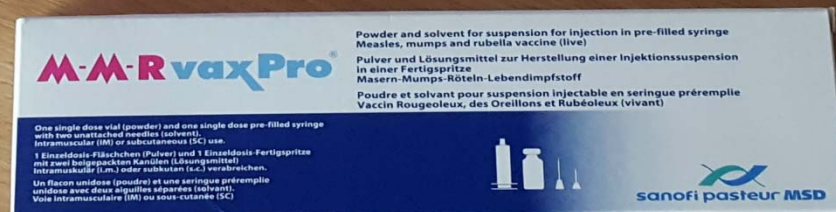
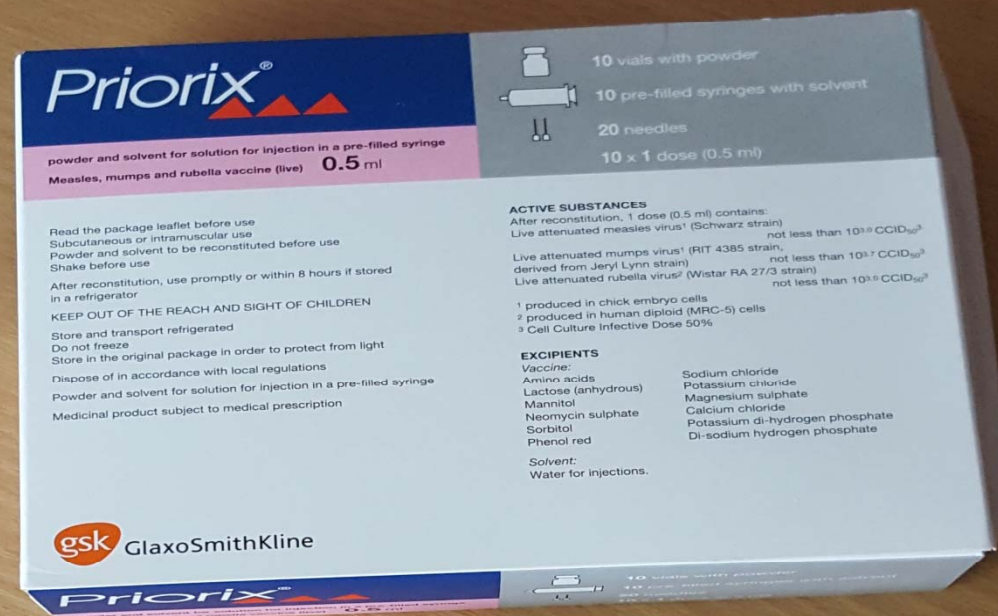
Target cohort for 2016/2017

- Junior Infants should receive IPV- Boostrix
- Older children up to the age of 10 years should receive IPV-Infanrix



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MMR Products



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



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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 to NCCS driver
- Check vaccine deliveries against the order for damage or discrepancies
- Place vaccines in the vaccine fridge immediately, ensuring the shortest dated vaccine is at the front
- NEVER leave vaccine delivery at room temperature
- Confirm vaccines are covered by practice insurance



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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 should be in the fridge at time of delivery
 - During 'flu season this can be reduced to 3 weeks supply as deliveries will be fortnightly



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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



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National Cold Chain Service

Delivered by United Drug in partnership with the HSE

Login

Username/Email:

Account ID:

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](#)

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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	1	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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Vaccine Order Form

VACCINE	PACK SIZE	INDICATIVE PRICE	QTY
6 in 1	10	90.13	10 + -
Men C	1	43.05	10
PCV	10	73.80	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	3
Boosterix (Tdap)	1	25.76	2
Dite	5	12.63	5 + -
Hep B (ENGRIX PAED)	1	15.40	
Hep B (HBVAXPRO5)	1	15.40	
HepB (ENGRIX ADULT)	1	20.81	
HepB (HBVAXPRO10)	1	20.81	
Hib	1	30.69	
Influenza	10	7.38	+ -
MMR	1	20.17	
Pneumococcal	1	21.05	

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



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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

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DR SALEEM SHARIF (34595)

Logout

VACCINE ORDER FORM

ORDER HISTORY

DELIVERY SCHEDULE

CHANGE PASSWORD

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

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Online Results

Online is now used by 95% of sites

Value of vaccine distributed decreased by 2%

Number of doses distributed decreased by 2%

Number of doses returned for destruction decreased by 2%

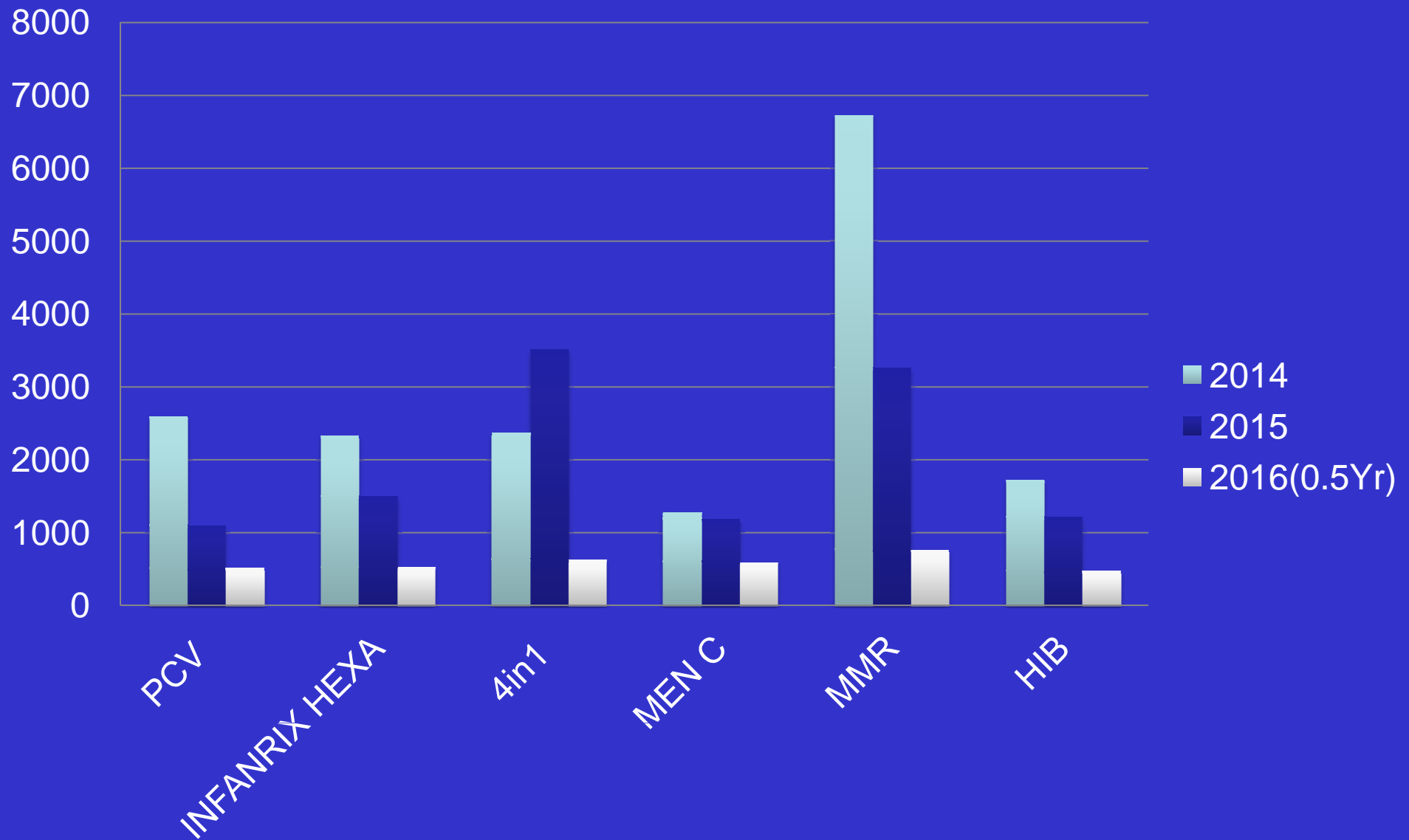
Value of vaccines returned for destruction decreased by 19%



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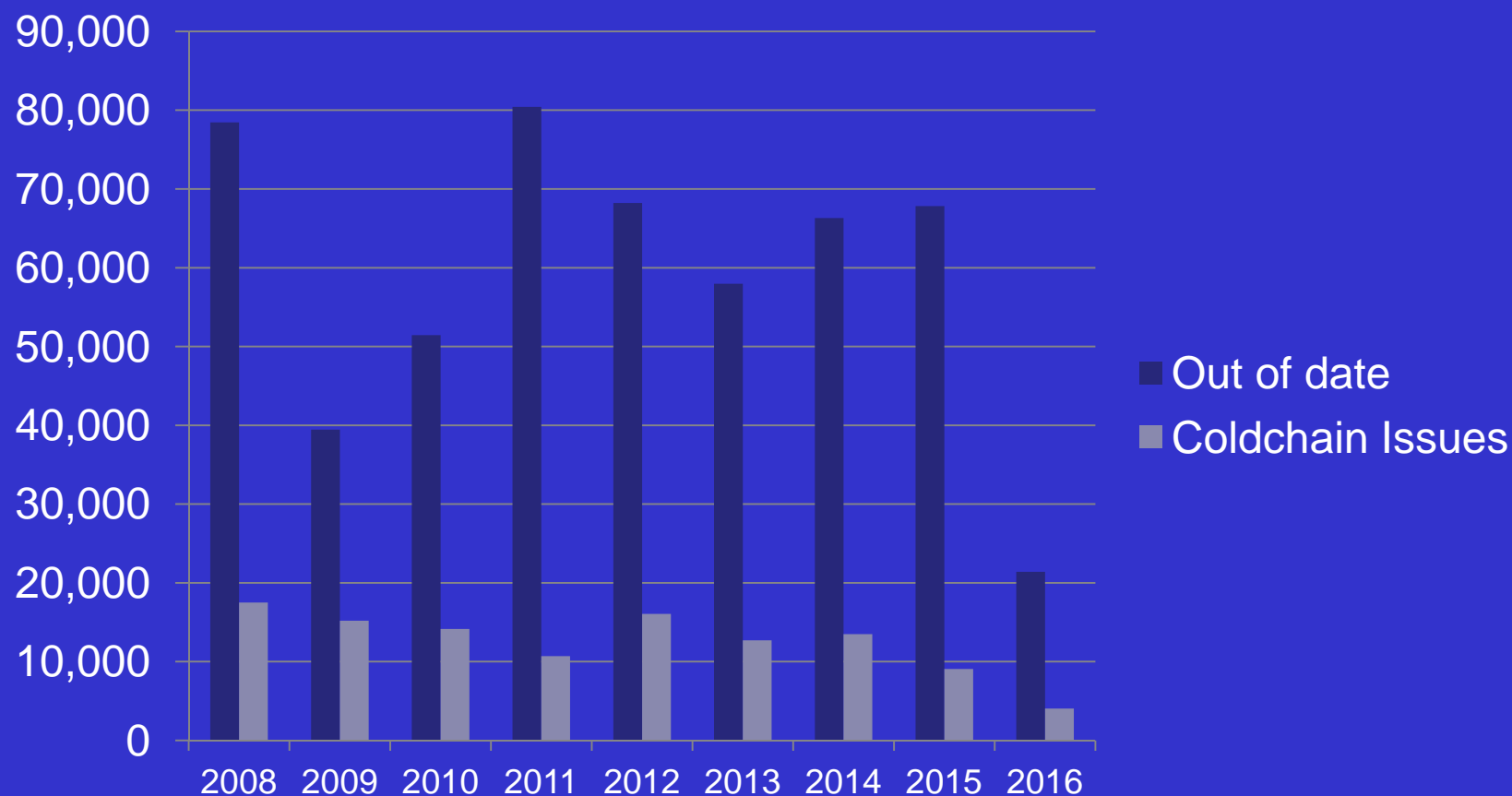


DOSES OF RETURNED VACCINES



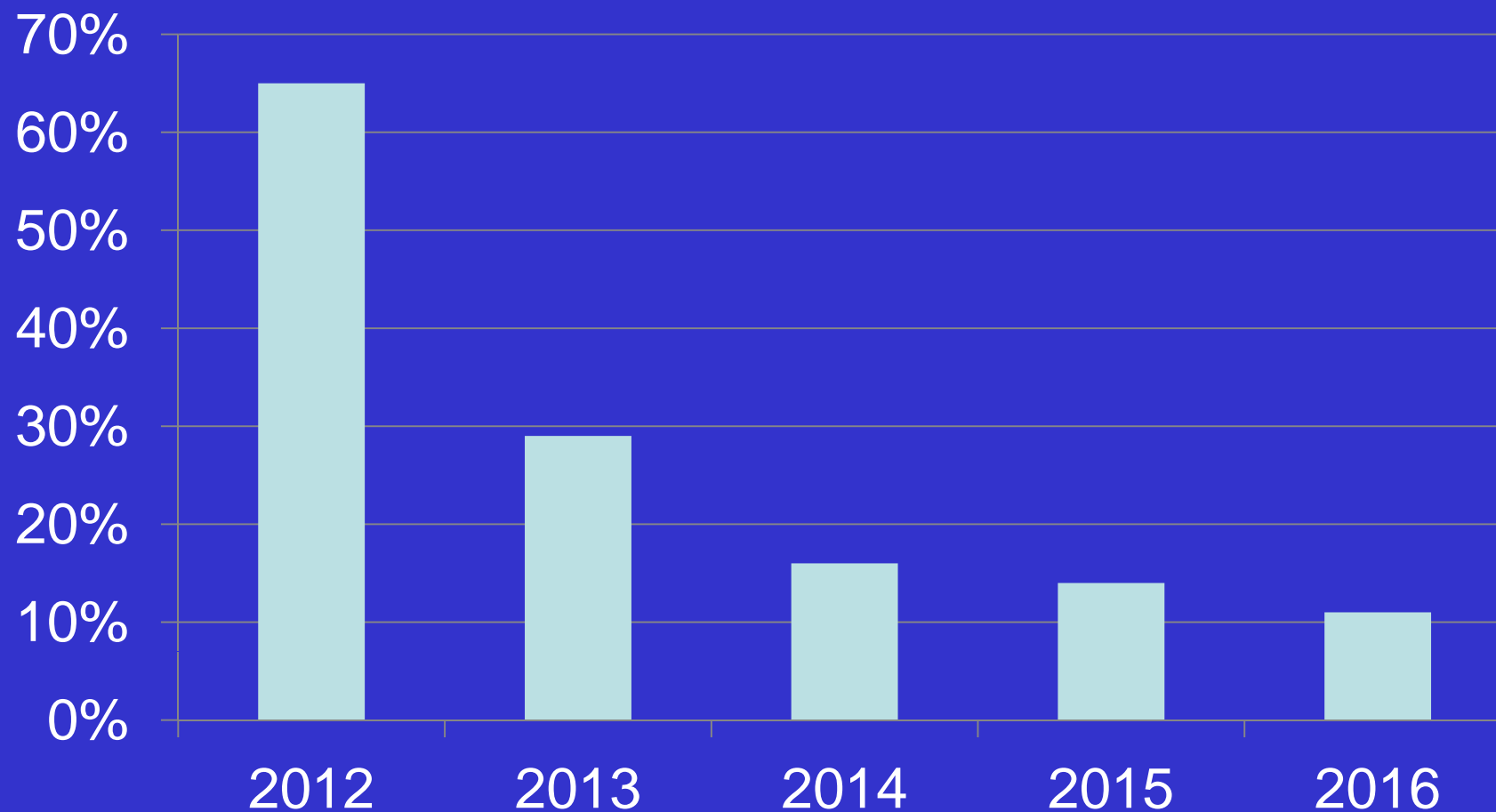
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Number of Doses of returned vaccines Expired compared to Coldchain issues



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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.
- 2016- 3,920 doses -Flu 5years and 2 months



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Storage of Vaccines & Monitoring of Vaccine Fridge temperature

- Vaccines must be stored in a Pharmaceutical fridge
- To comply with product licence, they must be
 - Stored within the temperature range of 2-8°C
 - Stored 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



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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.



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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

Do not remove them from a working fridge unless instructed to do so by the Chief Pharmacist or Medical officer in NIO



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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)



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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



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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 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 (Appendix 3).



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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**



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

*Recommendations for a
planned power outage*



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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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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.



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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, Strive for 5
<http://www.health.gov.au/internet/immunise/publishing.nsf/Content/provider-store>
- Department of Health UK. November. 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. <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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