

The Cold Chain and Vaccine storage

Cliona Kiersey
Chief Pharmacist
National Immunisation Office



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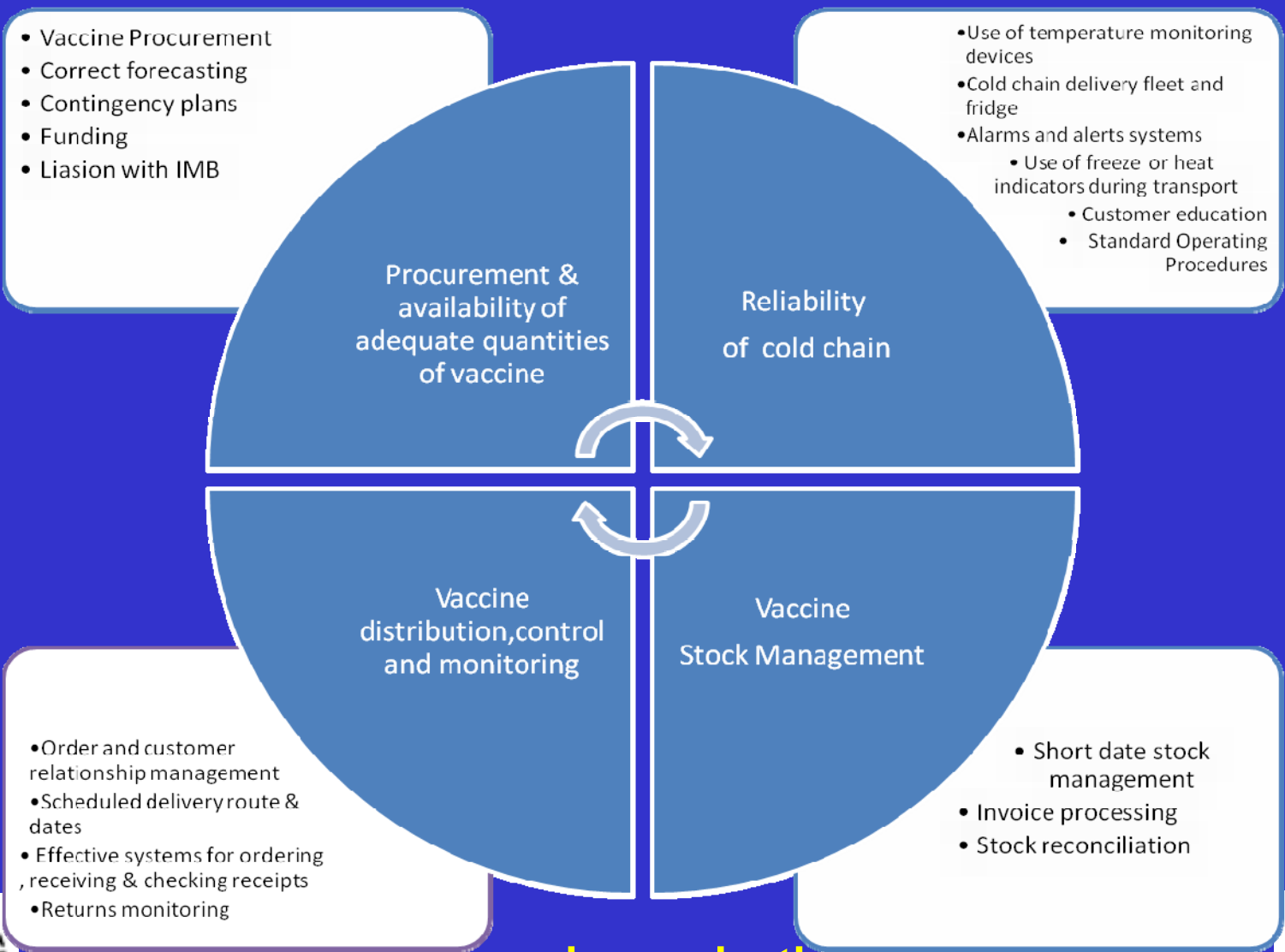
Objectives

- 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 explain recommendations for breaks in cold chain



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Factors affecting vaccine management performance



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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

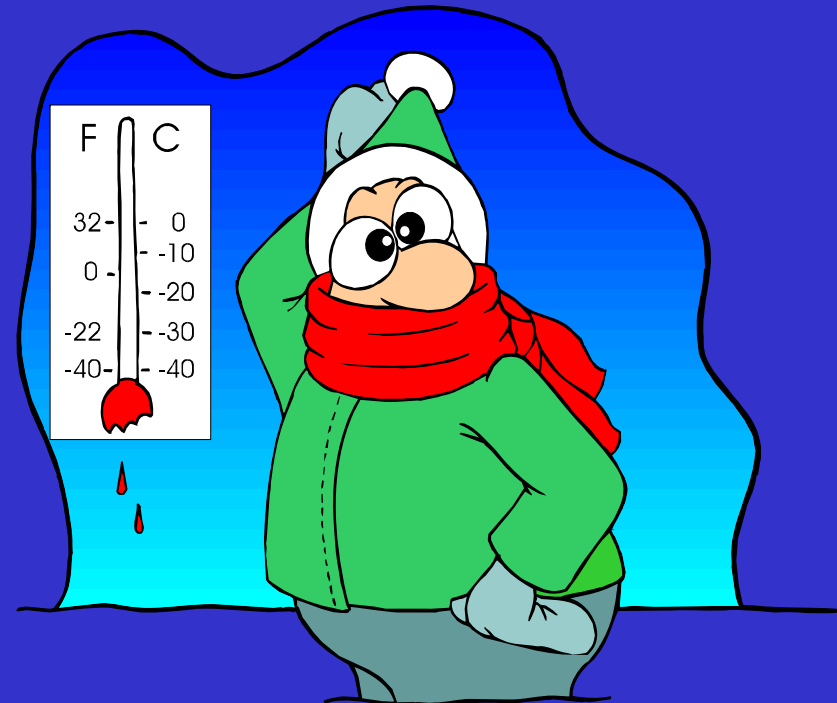
- Order and customer relationship management
- Scheduled delivery route & dates
- Effective systems for ordering, receiving & checking receipts
- Returns monitoring



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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)
- Every vaccine from time of manufacture up to point of delivery to surgery has a verified temperature record
- Assurance in product potency ensures maximum benefit from immunisation



Reliability of 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



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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 in 2013
- responsible for ~€39 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.



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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 5 scheduled deliveries within two and a half months (2 weekly cycle).
- There are an extra ~1000 sites who get only flu / PPV deliveries in flu season.
- Unscheduled
- Emergency



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YOUR NATIONAL COLD CHAIN DELIVERY SCHEDULE
AUGUST 2014– JULY 2015.



PLEASE PLACE YOUR ORDER BY

RED on your Calendar is your last date to place order

Fax – 01 4637788

Green on your Calendar is your delivery date.

Email – vaccines@udd.ie

PLEASE NOTE YOUR ADDITIONAL DELIVERIES FOR FLU

AUGUST						
S	M	T	W	T	F	S
					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						

SEPTEMBER						
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NOVEMBER						
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DECEMBER						
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MARCH						
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APRIL						
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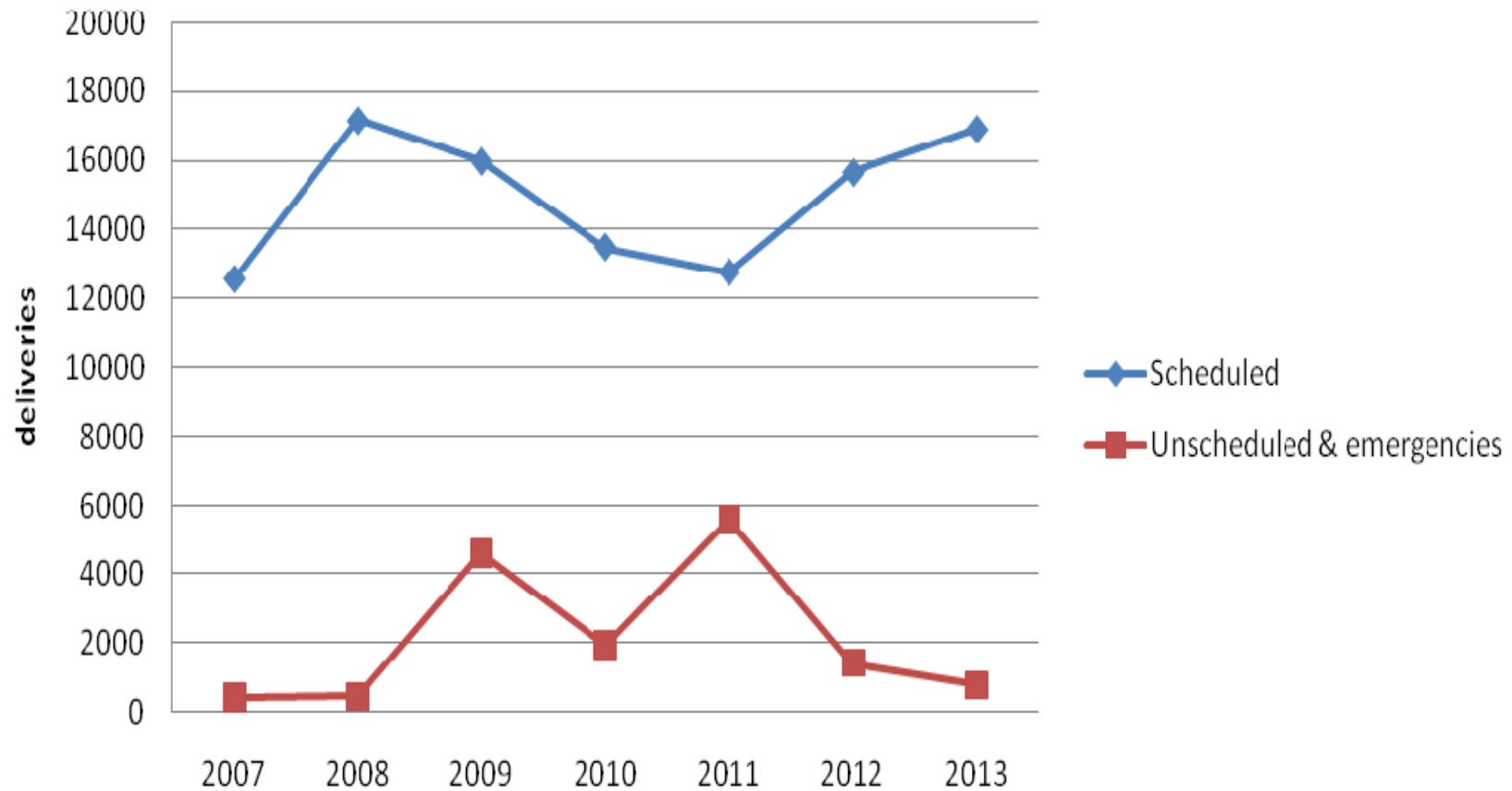
JUNE						
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JULY						
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Returns Service

Please avail of our returns service by filling out a returns form and giving your expired or unused suboptimal vaccines to the driver

Number of Deliveries 2007- 2013



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Unscheduled / Emergency Deliveries

- Contract is for 14 scheduled deliveries to each site.
- Each non scheduled / emergency delivery is an extra charge.
- Disruption to routine deliveries



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Vaccine distribution, Control & Monitoring

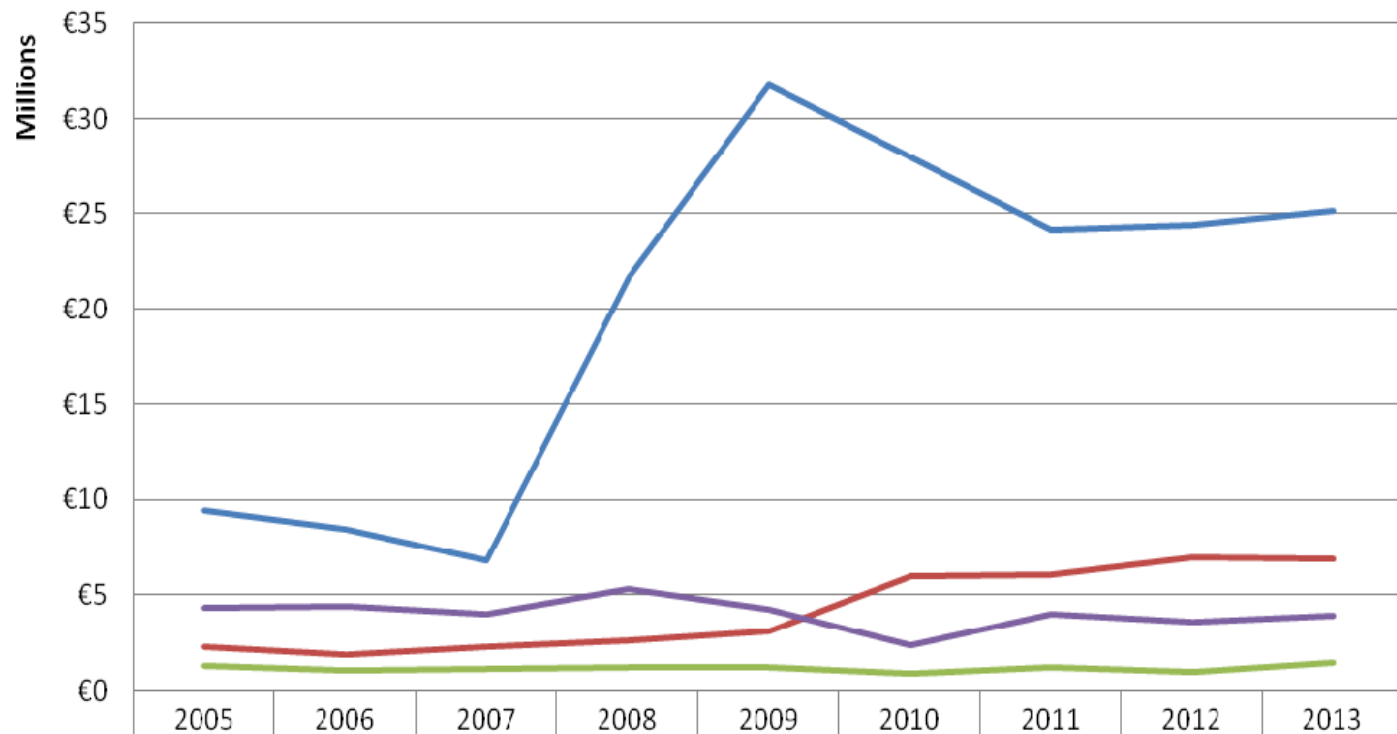
Vaccine distribution is monitored to ensure it is consistent with target cohort requirements as significant deviations may indicate over or under stocking.

Each site can order monthly to facilitate proper stock levels.



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Cost of Vaccines Purchased

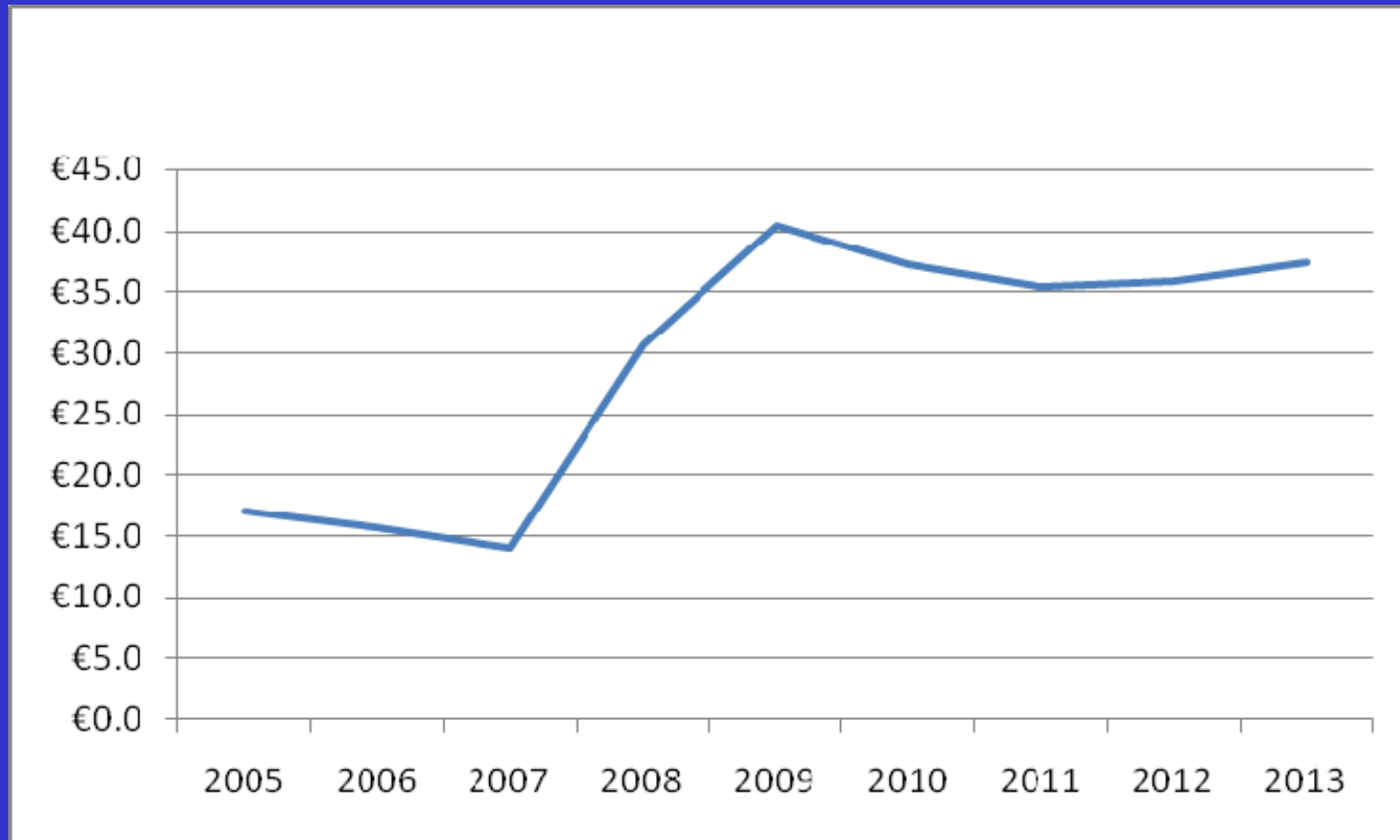


	2005	2006	2007	2008	2009	2010	2011	2012	2013
Primary Childhood	€9,431,984	€8,484,443	€6,818,046	€21,607,75	€31,741,70	€27,922,88	€24,179,89	€24,417,52	€25,135,58
Schools	€2,212,655	€1,813,192	€2,213,546	€2,520,387	€3,052,991	€6,001,067	€6,039,511	€6,961,166	€6,883,913
Others	€1,233,952	€1,055,661	€1,069,055	€1,180,174	€1,190,185	€855,082	€1,179,949	€937,007	€1,432,818
Flu and PPV	€4,315,082	€4,404,046	€4,003,625	€5,288,291	€4,272,191	€2,385,705	€4,034,385	€3,566,576	€3,950,265



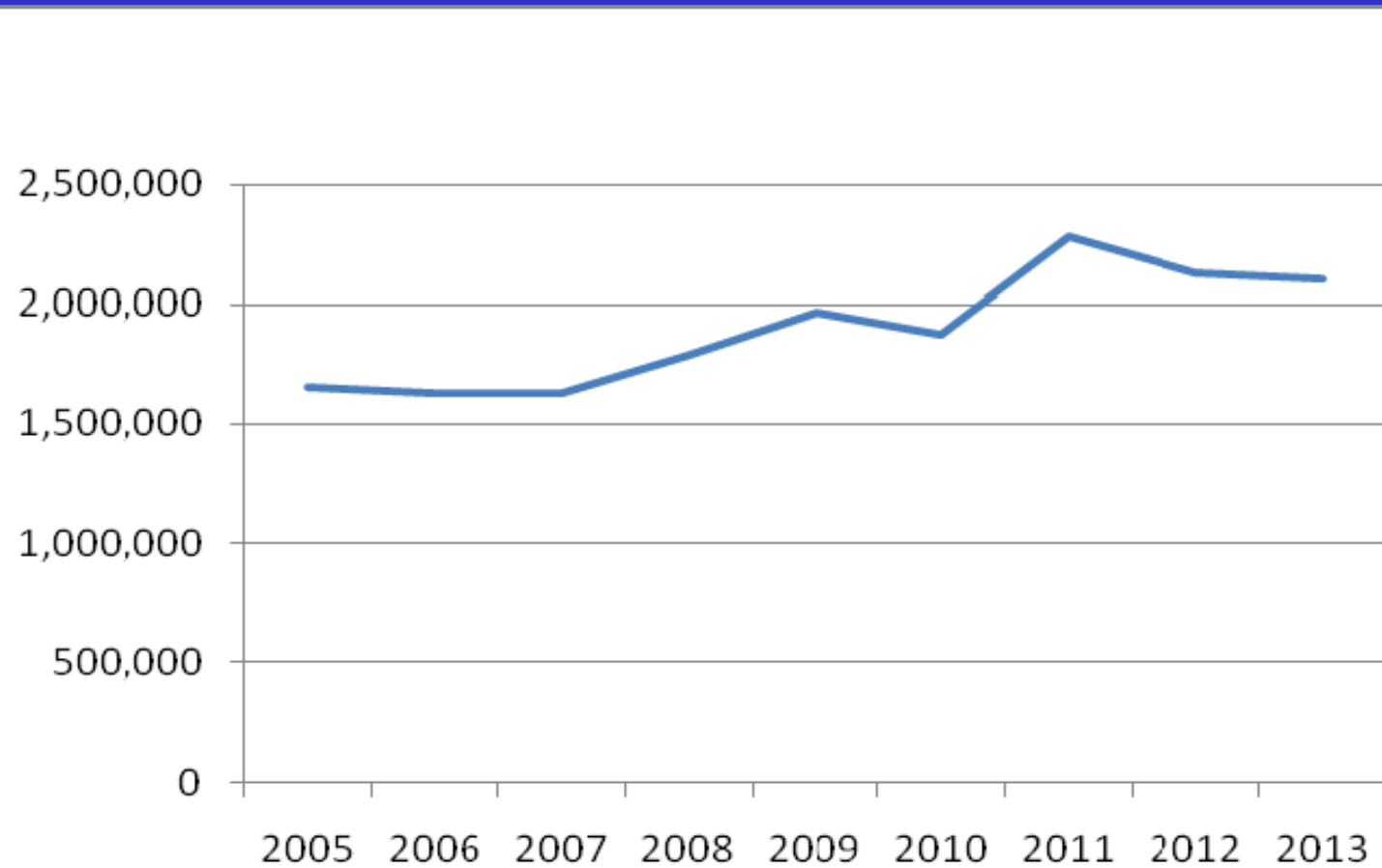
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Total Annual Spend (€m)



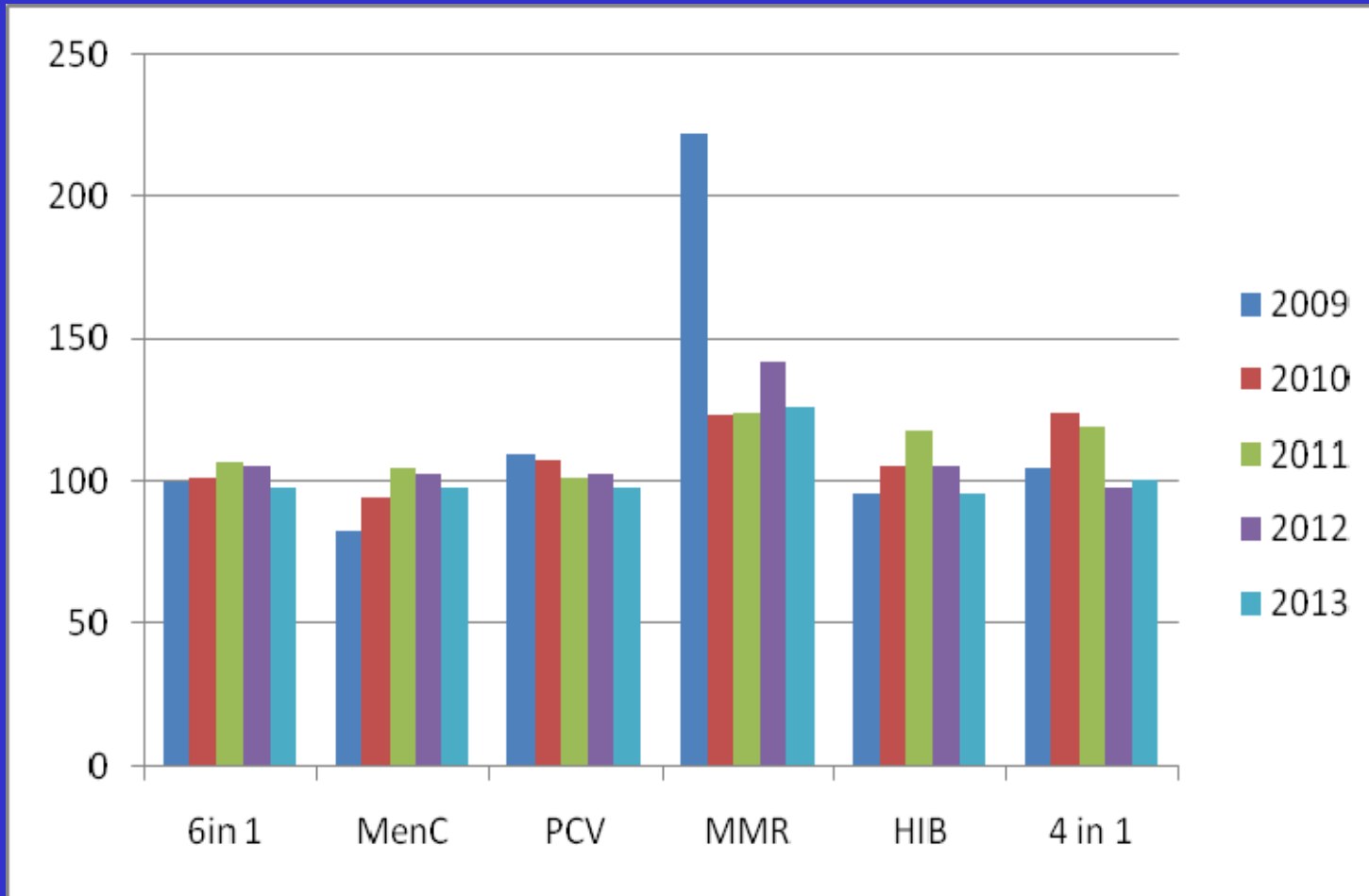
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Number of Doses Distributed



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Number of doses distributed as % of cohort requirements in 2009-2013



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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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How much vaccine should be ordered?

- The quantity of vaccine order can be determined by
 - Quantity used since last delivery
 - Storage volume within the refrigerator
 - Vaccines currently in the refrigerator
 - Seasonal variation e.g. influenza vaccine
 - Disease outbreaks



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Some typical vaccine orders with Values

Qty	Vaccine
10	INFANRIX HEXA
10	PREVENAR
10	MEN C
10	MMR
5	HIB
5	DITE BOOSTER
Total	<u>€2,488.17</u>

Qty	Vaccine
30	INFANRIX HEXA
30	PREVENAR
30	MEN C
10	MMR
10	HIB
10	DITE BOOSTER
Total	<u>€6,844.46</u>

Qty	Vaccine
70	INFANRIX HEXA
70	PREVENAR
70	MEN C
40	MMR
25	HIB
30	DITE BOOSTER
20	TETRAVAC
Total	<u>€16,818.34</u>



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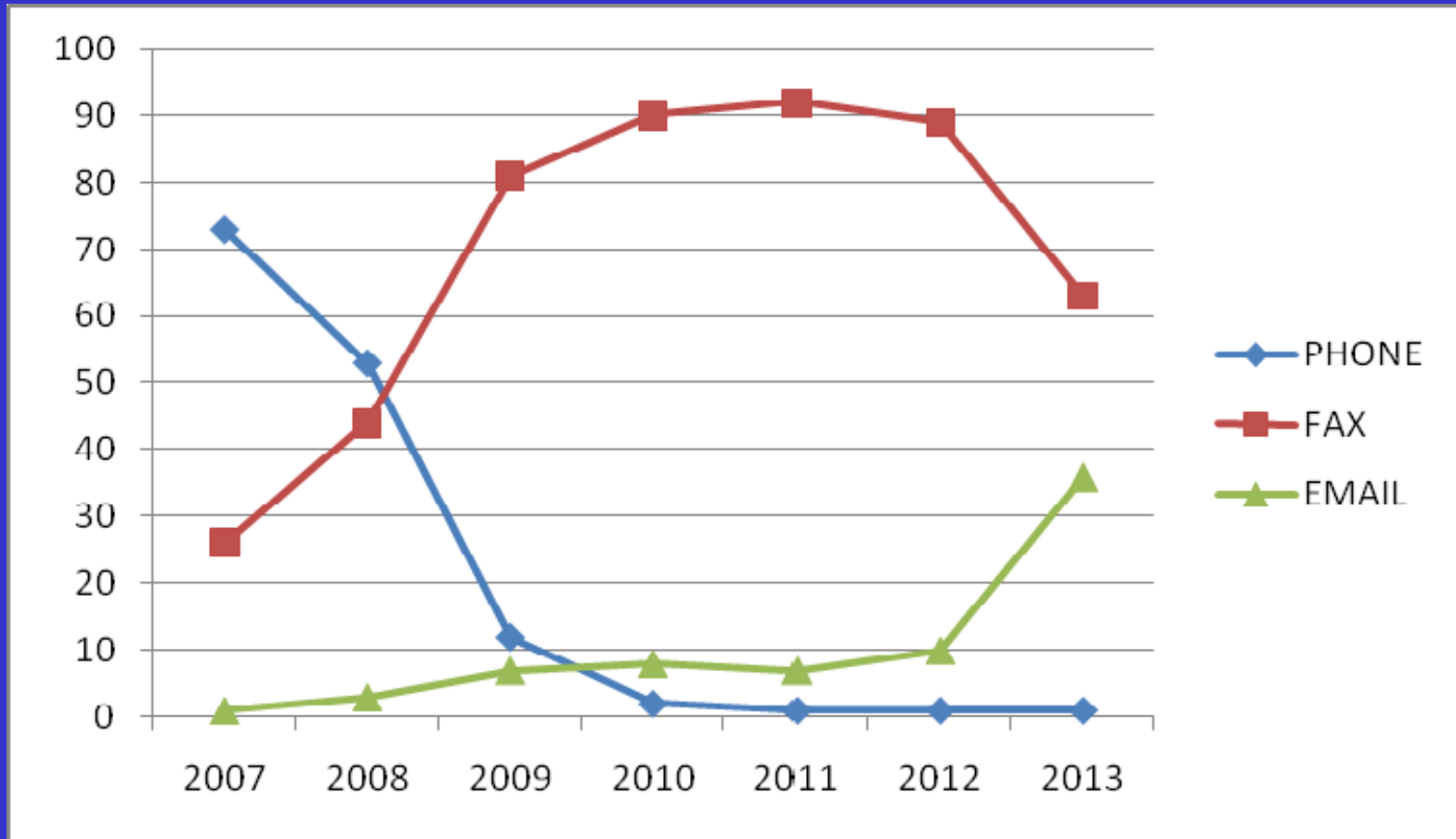
Recommended procedure for ordering and accepting vaccines

- Should have a named, trained and designated person and deputy
- E-mail or fax order to UD 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



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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
- Store on shelves, not touching the sides
- Record fridge temperature twice daily
- Wire fridge directly to power without use of a plug.
- **Never unplug the fridge**
- **Never use out of date vaccines**



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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)



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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.
- Vaccines which cannot be used must be returned to the National Cold Chain Delivery Service



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Details Required after Cold Chain Issue

- Name of practice
- Account number
- 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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“Borrowed Vaccines”

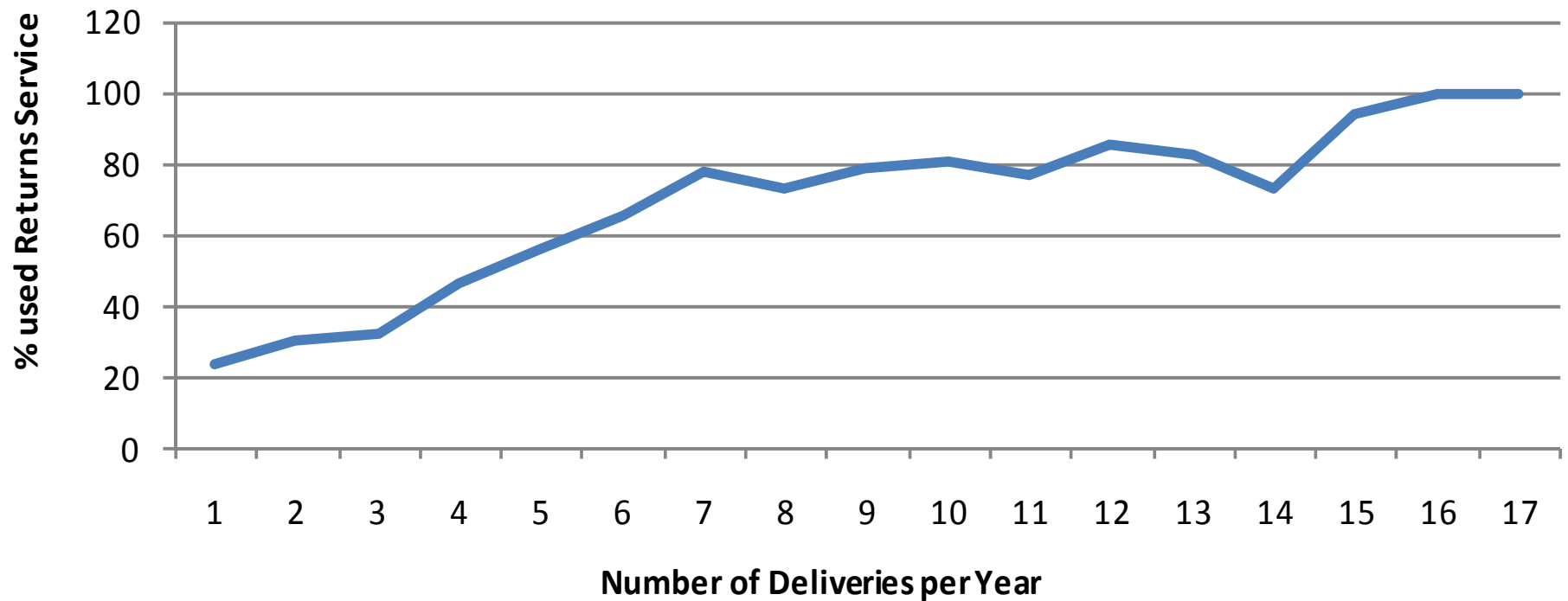
If vaccines are required due to stock out or a fridge issue you can get vaccines from another practice.

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 the returns service by number of deliveries per year

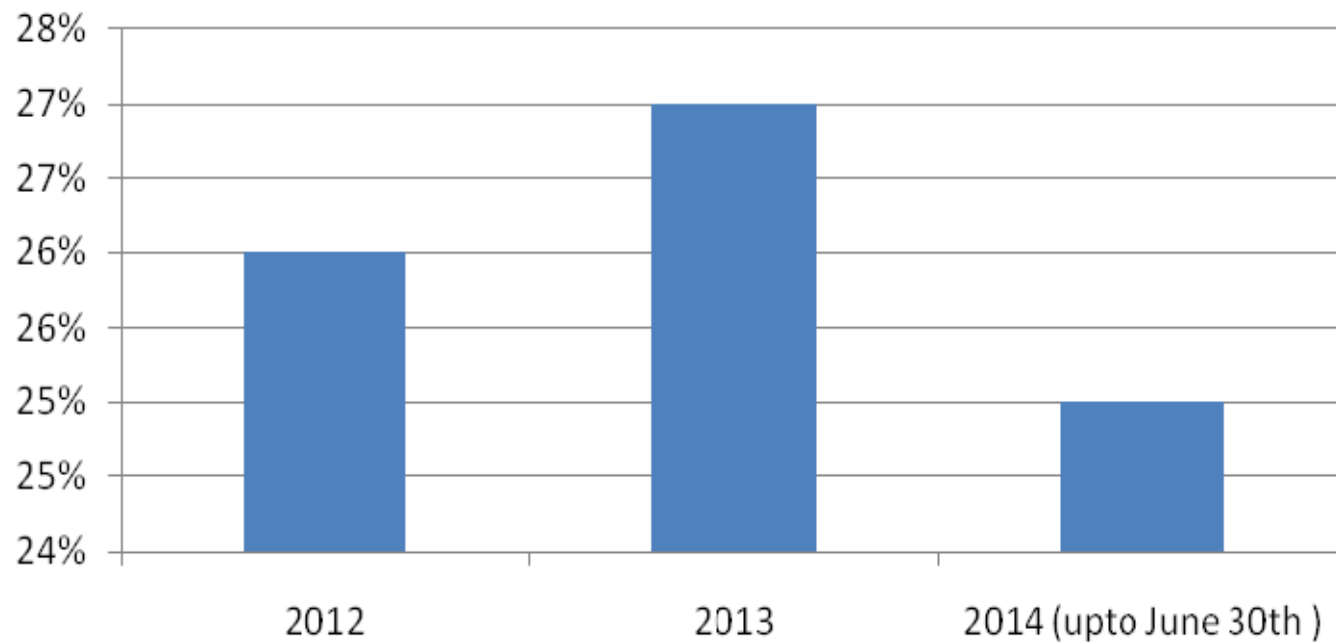


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Expired Stock Returned

**% of total sites which returned
vaccines >6 months expired**



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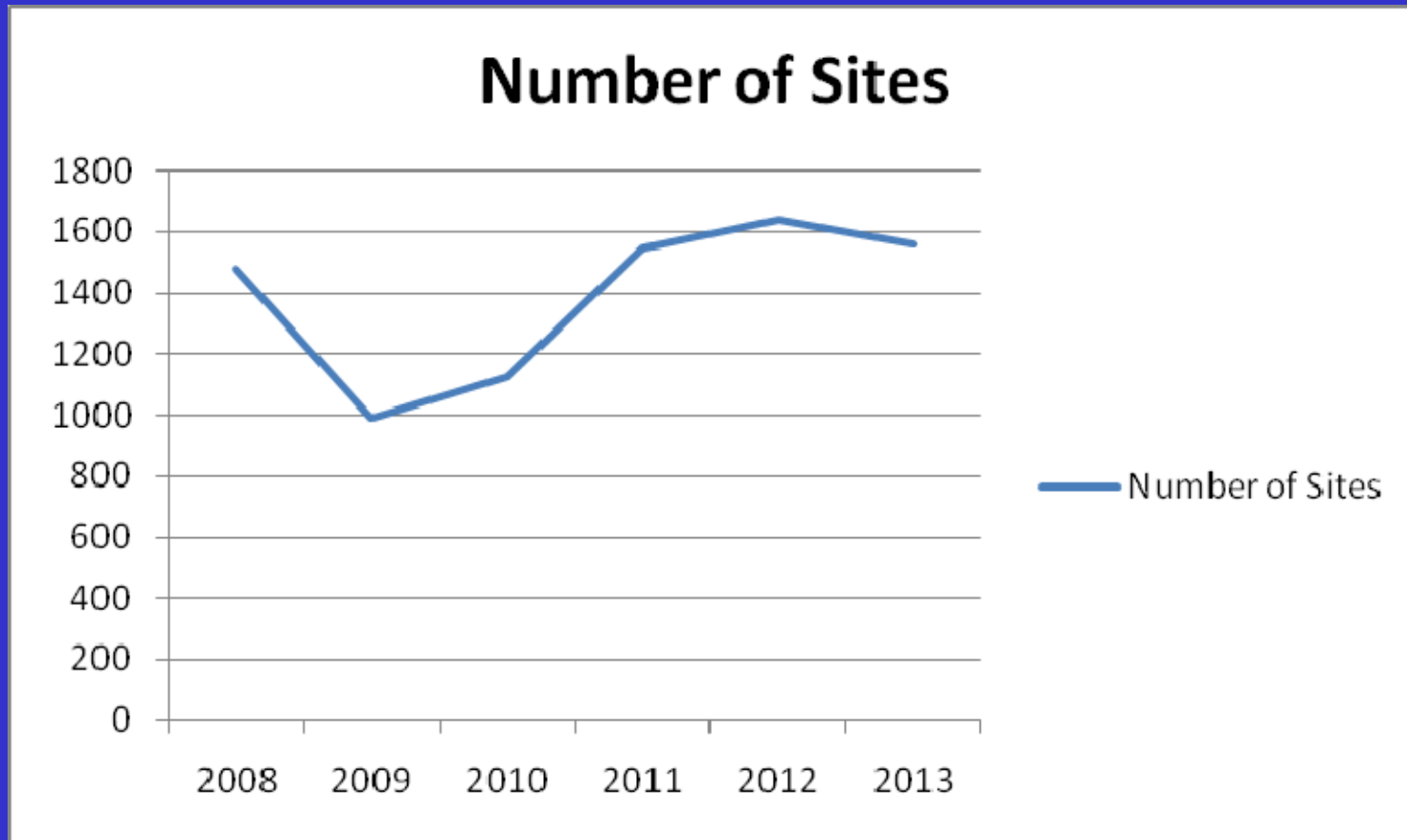
Returns service commenced in 2005

- In 2012, 2TU Mantoux test (expiry 05/2002) was 10 years and two months expired when returned.
- In 2013, Pneumovax (expiry 03/2007) was 6 years and three months expired when returned.
- In 2014, Pentavac (expiry 09 /2002) was 11 years and 6 months expired when returned. Removed from schedule in 2009.



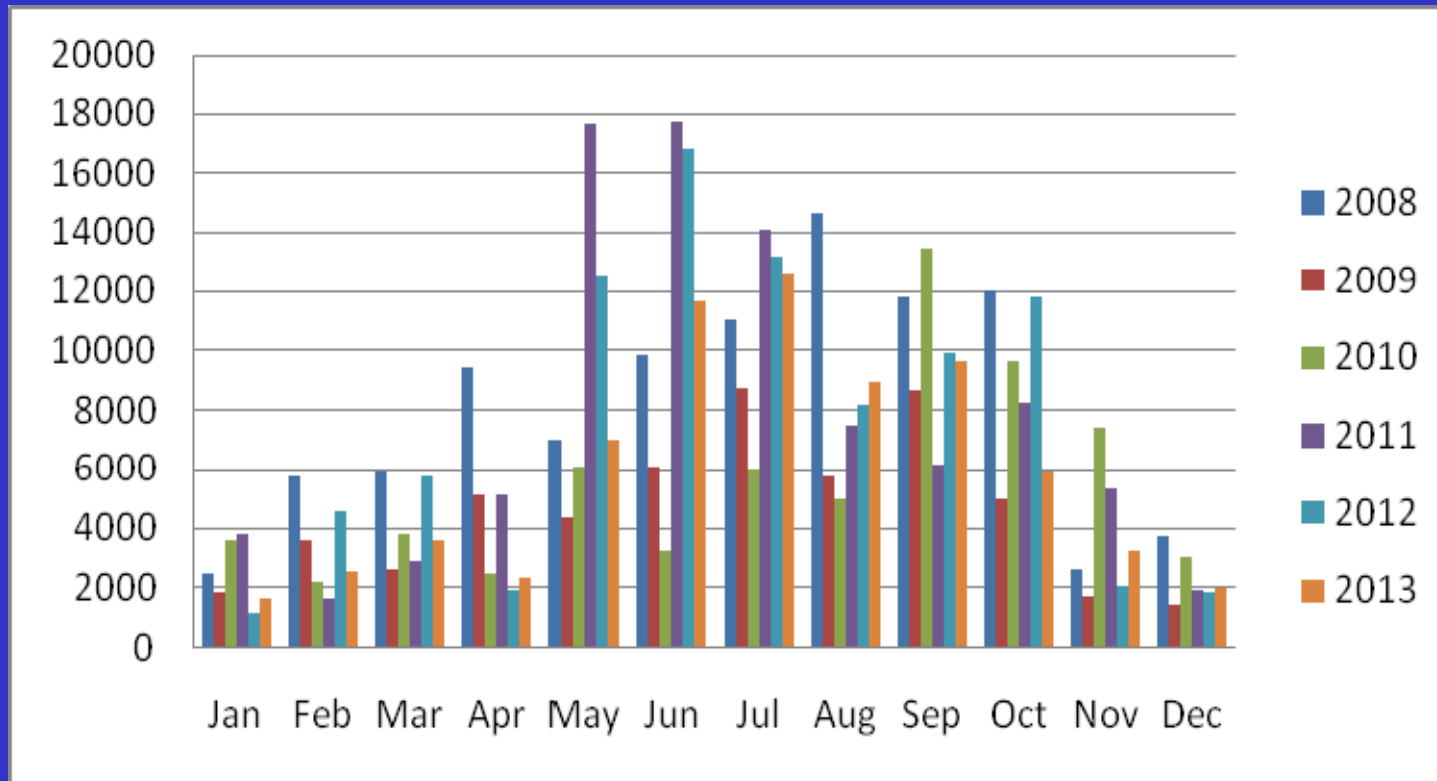
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Number of Sites using returns service 2008 - 2013



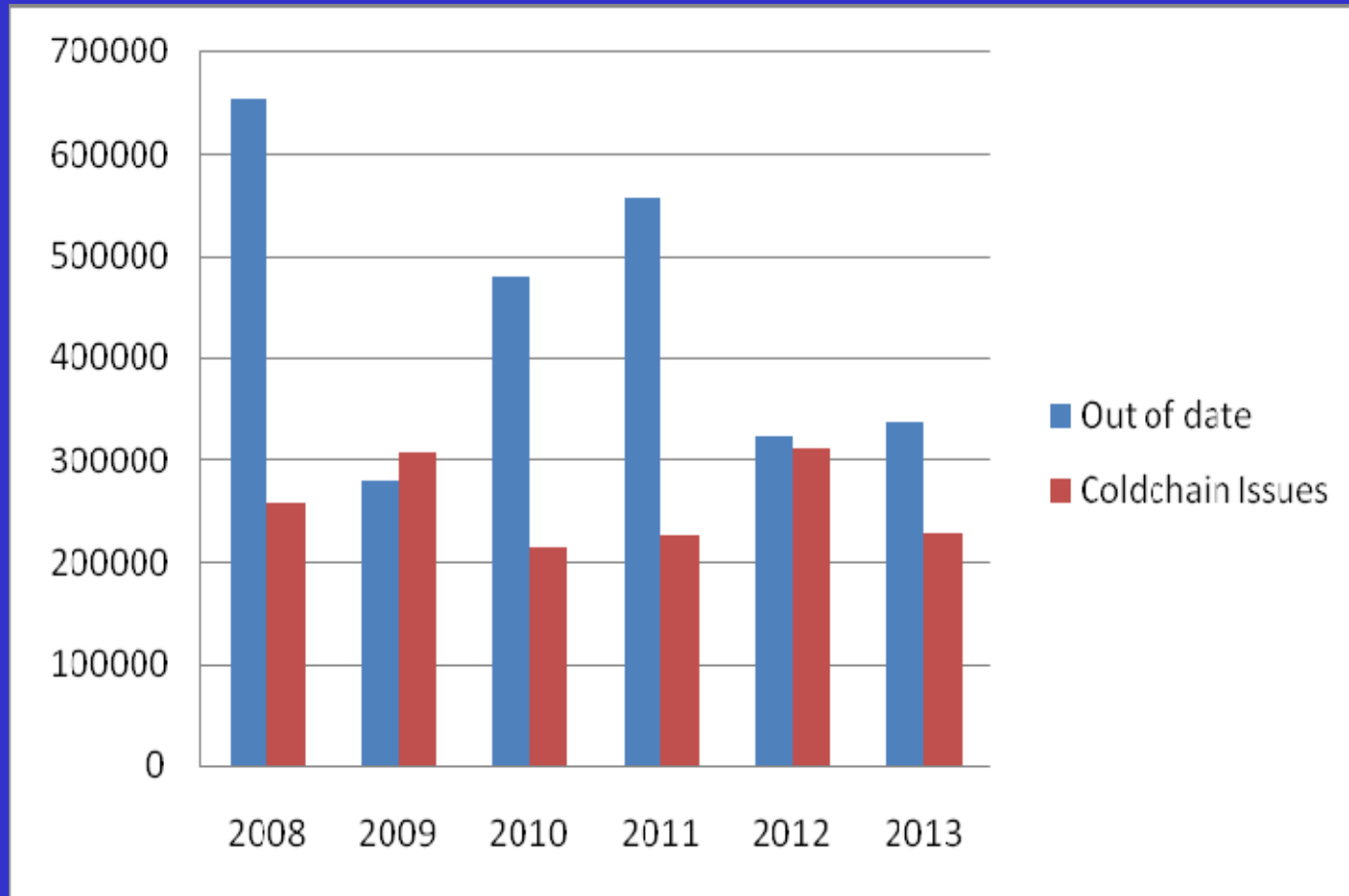
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Number of doses returned by month 2008 – 2013



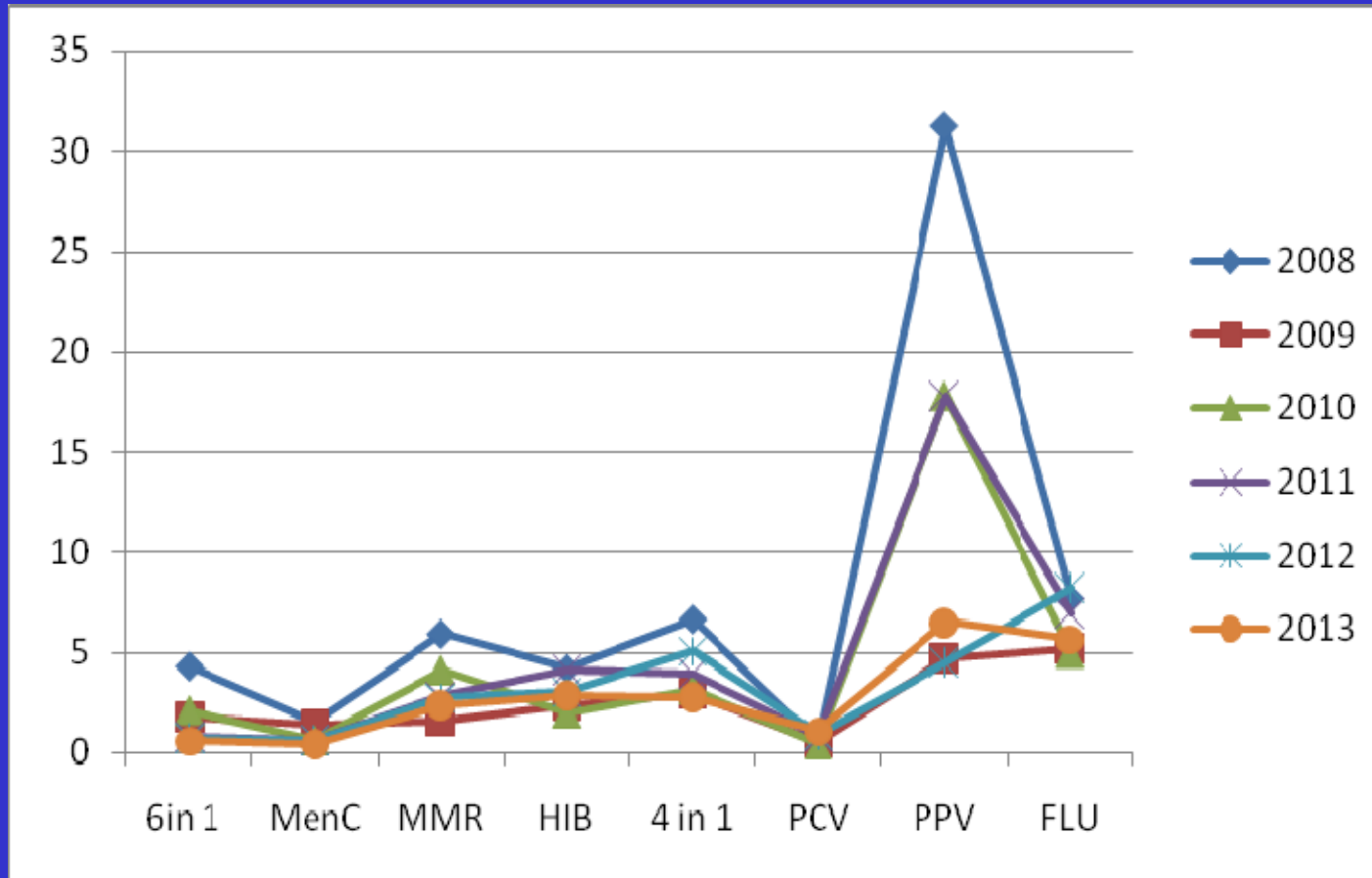
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Value of vaccines Expired compared to Coldchain issues



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% Vaccines Returned compared to Distributed



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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



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Data loggers



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Max/Min Thermometers

- Maximum / Minimum temperatures should be recorded daily.
- ENSURE the memory is erased daily, preferably before closing surgery.
- Recording only shows the highest temperature registered but not the duration.
- Usually the highest recorded temperature is while the door is open.



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 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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