



*Note: Some of this information was originally published as a
MIROW Microguide in 2015. This document replaces earlier guidance.*

Background

Some vaccine manufacturers use a different lot number on the unit of use (UoU; e.g., vial or syringe) than on the unit of sale (UoS; e.g., carton or box) for certain vaccines. This may be done to denote a meaning such as the location of the manufacturers' facility or the packaging level. The variation in lot numbers between packaging levels poses a challenge to electronic systems that rely on the vaccine lot number to relate a vaccination encounter to vaccine inventory.

There is no industry standard for vaccine lot numbers; traditionally, manufacturers used (and most still do) the same lot for the vaccine products on all levels of packaging. The Federal Drug Administration (FDA) regulations allow for different lot numbers for vaccine products on the different levels of packaging (UoU/UoS), but the regulations do not require it.

A survey of vaccine manufacturers in September 2014 indicated that some manufacturers, for selected vaccine products, were using "non-traditional" lot number conventions by using different lot numbers for the UoU and the UoS for the same vaccine products. This survey was repeated in December 2016. Both surveys were distributed to vaccine manufacturers participating in the Vaccines for Children (VFC) program but included information on both public and private vaccines. Vaccine manufacturers were asked to identify vaccines in use with different lot numbers on the UoS and the UoU for vaccines currently sold in the U.S. market, and the associated lot number patterns on those lot numbers. In both surveys, all participating VFC vaccine manufacturers responded, seven in the September 2014 and seven in the December 2016 survey. Participants in the 2016 survey included the following: GSK, MedImmune, Merck, Pfizer, Protein Science, Sanofi, and Seqirus. The information in this document is based on the results of the December 2016 survey.

Document Use

The purpose of this document is to share the results of the December 2016 survey; describe the scope of the challenge of having different lot numbers on the two vaccine products, and provide tools for system developers to ameliorate the situation. The intent is to facilitate identification and tracking of the appropriate lot numbers in various areas of immunization information system (IIS) operations, from inventory management to vaccine administration. In addition to IIS, many health information management (HIM) systems reference the UoS lot number for vaccine ordering and inventory management, but reference the UoU number during vaccine administration. This document shows the relationship, when differences exist, between lot numbers used primarily for inventory management (UoS) and those used for vaccine administration (UoU).

This document contains three tables.

- The first table lists those vaccines with different UoU/UoS lot numbers and shows the corresponding patterns for those lot numbers. Vaccines not on this list are assumed to have the same UoU/UoS lot numbers. For a list of all vaccines, see the NDC Crosswalk Table on the IIS Code Set web-page: https://www2a.cdc.gov/vaccines/iis/iisstandards/ndc_crosswalk.asp.
- The second table shows an estimate of the volume (percentage) of the vaccines with different UoS/UoU vaccines based upon VTrckS orders in 2015 and 2016.
- The third table shows those vaccines from the manufacturers not included in the request for information.

Vaccines with Different Lot Numbers: UoS and UoU

The following table shows those vaccines with different UoS/UoU lot number and the associated lot number patterns.

Table 1: Vaccines with Different Lot Numbers: UoU and UoS, With Associated Patterns Table

| Company | Brand Name | NDC | | Lot Number Patterns*, English Notation | | Note |
|----------------|---|--------------------------|----------------------------|--|------------------------------------|--|
| | | Unit of Sale (Outer box) | Unit of Use (Vial/Syringe) | Unit of Sale (Outer box) | Unit of Use (Vial/Syringe) | |
| Sanofi Pasteur | ActHIB (Lyophilized vaccine powder) | 49281-545-03 | 49281-547-58 | AA###AA <u>A</u> | AA###AA (Lyophilized) | UoS has extra alpha at end of lot number. First 7 digits same on UoU & UoS |
| | ActHIB (Liquid Diluent) | 49281-545-03 | 49281-546-58 | AA###AA <u>A</u> | See Note (Diluent) | No relationship between the UoS lot number and the Diluent UoU lot number |
| Sanofi Pasteur | IMOVAX RABIES (Lyophilized vaccine powder) | 49281-250-51 | 49281-248-58 | A##### <u>A</u> | A##### (Lyophilized) | UoS has an extra number and alpha at the end of the lot number. First 5 characters same on UoU & UoS |
| | IMOVAX RABIES, Sterile water (Liquid Diluent) | 49281-250-51 | 49281-249-01 | A##### <u>A</u> | See Note (Diluent) | No relationship between the UoS lot number and the Diluent UoU lot number |
| Sanofi Pasteur | IPOL vial | 49281-860-10 | 49281-860-78 | A##### <u>A</u> | A##### | UoS has an extra number and alpha at the end of the lot number. First 5 characters same on UoU & UoS |
| GSK | Menveo, MenA lyophilized conjugate component (Lyophilized vaccine powder) | 46028-208-01 | 46028-218-11 | <u>M</u>##### | <u>A</u>##### (Lyophilized) | UoS outer box lot number begins with the letter M (actual letter M) and is followed by 5 numbers. MenA UoU lot number begins with A (actual letter A) while the peel-off label begins with M (actual letter M). |
| | Menveo, MenCWY-135 liquid conjugate component (Liquid Diluent) | 46028-208-01 | 46028-219-11 | <u>M</u>##### | <u>X</u>##### (Diluent) | MenCYW begins with a X (actual letter X). The 5 digits remain the same for the three components in the same UoS. A one to one UoU to UoS mapping is possible, substitute "M" with "A" in 1 st character |

| Company | Brand Name | NDC | | Lot Number Patterns*, English Notation | | Note |
|--|-------------------|--------------------------|----------------------------|--|----------------------------|---|
| | | Unit of Sale (Outer box) | Unit of Use (Vial/Syringe) | Unit of Sale (Outer box) | Unit of Use (Vial/Syringe) | |
| Sanofi Pasteur | Typhim Vi syringe | 49281-790-51 | 49281-790-88 | <i>A#####</i> <u>#</u> | A##### | UoS has a hyphen and an extra number at the end of the UoU lot number. First 5 characters same on UoU & UoS |
| Sanofi Pasteur | Typhim Vi vial | 49281-790-20 | 49281-790-38 | <i>A#####</i> <u>#</u> | A##### | UoS has a hyphen and an extra number at the end of the UoU lot number. First 5 characters same on UoU & UoS |
| *Key: 'A' indicates a capital alphabetical (alpha) character A pound sign (#) indicates a number Italicized, underlined, and red alpha-numeric character indicates a change from UoS and UoU | | | | | | |

Notes: Matching, Reconstituted Vaccines, and Regular Expression

The lot numbers differ by one or two additional characters on the UoS item. Mapping from the UoS to the UoU is relatively simple; however, mapping from the UoU to UoS is problematic, except for Menveo (see the Menveo Note). That being said, many IIS have full knowledge of lot numbers in the provider's inventory (see explanation in AIRA MIROW Decrementing Inventory via Electronic Data Exchange) and can match the reported UoU lot number to the single UoS lot number for that provider in many or most situations. Discrepancies will need to be resolved during the reconciliation process.

For reconstituted vaccines, the lot numbers on the UoS and the UoU Lyophilized vaccine powder are the same, except for the reconstituted vaccines in Table 1 (above). Typically, the UoU Liquid diluent has a different lot number. For a list of reconstituted vaccines, see <http://www.immunize.org/catg.d/p3040.pdf>. The Lot Number Patterns, English Notation columns in Table 1 above have been converted to Regular Expression, POSIX Notation. See table in Appendix A at the end of this document. This table is primarily for use by software developers.

Different UoS/UoU Lot Numbers – Estimate of Volume

This table shows an estimate of the volume (percentage) of the vaccines with different UoS/UoU vaccines based upon the VTrckS orders in 2015 and 2016. These estimates show that the practice of using different lot numbers of the UoS vs. the UoU affects from 7.5 to 8.6 percent of all VFC vaccines. We were not able to estimate the volume of the rabies and typhoid vaccines.

Table 2: Vaccines with Different Lot Numbers – Estimated percent of Total

| Company | Brand Name | VTrckS 2015 % | VTrckS 2016 % |
|----------------|-------------------|---------------|---------------|
| Sanofi Pasteur | ActHIB | 4.22 | 4.86 |
| Sanofi Pasteur | IMOVAX RABIES | | |
| Sanofi Pasteur | IPOL vial | 2.11 | 2.5 |
| GSK | Menveo | 1.15 | 1.25 |
| Sanofi Pasteur | Typhim Vi syringe | | |
| Sanofi Pasteur | Typhim Vi vial | | |
| Total | | 7.48 | 8.61 |

Vaccine Manufacturers' Vaccines Not Included in Survey

Below is a list of vaccines from vaccine manufacturers not included in the survey. These vaccine manufacturers include Akorn Pharmaceuticals; Barr laboratories; Emergent BioDefense Operation; Massachusetts Biologic Laboratories; PaxVax; and Valneva.

Table 3: Vaccines from Manufacturers Not Included in Request for Information

| Brand Name | Company | Company Code |
|--------------------------|--|--------------|
| Td, adsorbed | Akorn Pharmaceuticals | AKR |
| Adenovirus types 4 and 7 | Barr Laboratories | BRR |
| BIOTHRAX | Emergent BioDefense Operations Lansing | MIP |
| TD (GENERIC) | Massachusetts Biologic Laboratories | MBL |
| VAXCHORA | PaxVax | PAX |
| Vivotif | PaxVax | PAX |
| Ixiaro | Valneva | VAL |

Vaccines with Same Lot Numbers - UoS and UoU

Vaccines not included in Table 1 are assumed to have the same UoS/UoU lot numbers. For a list of all vaccines see the NDC Crosswalk Tables on the IIS Code Set web-page:

https://www2a.cdc.gov/vaccines/iis/iisstandards/ndc_crosswalk.asp.

Updating Information

If you become aware of any vaccines where the lot number differs on the UoS and the UoU (or on the UoS and the UoU lyophilized vaccine powder for a reconstituted vaccine), please share that information with IISinfo@cdc.org. If possible, please include some images of the respective packages.

Appendix A

Lot Number (#) Patterns, English Notation and POSIX Notation

| Lot # Patterns - English Notation | Lot # Patterns - Regular Expression, POSIX Notation | Note |
|-----------------------------------|---|-------------------|
| A##### | ^[A-Z][0-9]{4,4}\$ | |
| A#####-# | ^[A-Z][0-9]{4,4}'-[0-9]\$ | Actual char. '-' |
| A##### | ^[A-Z][0-9]{5,5}\$ | |
| A#####A | ^[A-Z][0-9]{5,5}[A-Z]\$ | |
| AA#####AA | ^[A-Z]{2,2}[0-9]{3,3}[A-Z]{2,2}\$ | |
| AA#####AAA | ^[A-Z]{2,2}[0-9]{3,3}[A-Z]{3,3}\$ | |
| M##### | ^\QM\E[0-9]{5,5}\$ | Actual letter 'M' |
| X##### | ^\QX\E[0-9]{5,5}\$ | Actual letter 'X' |
| A##### | ^\QA\E[0-9]{5,5}\$ | Actual letter 'A' |