# Information Services

**Notes to assist in understanding data supplied for Over the Counter products**

**Summary**

The legal category of the medicinal product pack, as specified by The Human Medicines Regulations, has been used to identify which medicines can be classified as ‘Over the Counter’ medicines.

The legal category for any pack is defined as one of the following four options:

* **GSL:** For a licenced medicine, the pack size of the product is included in the General Sales List.
* **P:** The pack size of the product is categorised as a Pharmacy medicine if it is a licenced medicine and is not included in the General Sales List or the Prescription Only Medicine order.
* **POM:** For a licenced medicine, the pack size of the product is included in the Prescription Only Medicine order.
* **Not Applicable:** The value of ‘not applicable’ is used for all non-medicine packs e.g. appliances, unlicensed medicines and Investigational Medicinal Products (IMPs) where the legal category cannot be determined.

Packs with a legal category of 'GSL' or 'P' can therefore be identified as ‘Over the Counter’ medicines.

**Prescribing method & total breakdown**

The legal category can only be directly attributed to actual products and therefore additional steps are needed to try and identify the legal category for any products that have been prescribed generically. This has been done by checking all the actual products associated with a generic item and where they all have the same legal category the assumption has been made that this category can be assigned to the generic item.

For a small number of generic products (circa 1.1%), the various associated actual products cover a variety of legal categories and therefore a single classification can’t be assigned as it is not certain which product was used. In these circumstances a legal category of ‘Unknown’ has been assigned to signify that the legal category can’t be confidently applied. Please see the ‘Prescribing Type’ below for further details.

The following tables show the overall volumes for both the number of items and the net ingredient cost:



**Report Sections**

* **GSL (Brand)** Includes a list of all products with a legal category of 'GSL', where the item has been prescribed as a brand and therefore the legal category can be identified.
* **GSL (Generic)** Includes a list of all products with a legal category of 'GSL' where the item has been prescribed generically and therefore the legal category has been assumed based on the associated products.
* **P (Brand)** Includes a list of all products with a legal category of 'P', where the item has been prescribed as a brand and therefore the legal category can be identified.
* **P (Generic)** Includes a list of all products with a legal category of 'P' where the item has been prescribed generically and therefore the legal category has been assumed based on the associated products.
* **Unknown (Generic)** Includes a list of all products that have been prescribed generically where the legal category can not be assumed, due to more than one legal category being represented within the associated products.
* **Prescribing Type** Includes some background around how legal categories have been identified for generic items (see [Appendix A](#Appendix_A)).
* **Mixed Legal Category** Includes an example of an item that is commonly prescribed generically, where the legal category can not be assumed due to multiple possible items (see [Appendix B](#Appendix_B))

**Data Source(s)**

* Data is sourced from the NHSBSA Information Services DALL environment which is a sand-pit development environment used for data analytics. Data within the DALL is sourced via ETL extracts from production databases at moments in time and is not maintained with any changes to original source material.
* Prescription data is based on data from the NHSBSA’s internal system (CIP) which contains NHS prescription data.
* Legal category data is based on data from the NHSBSA CDR (Common Drug Reference) database. Data is only included for prescription items where the patient’s NHS number could be identified from the prescription image. Patient number information can only be captured from approx. 91% of prescriptions, although the capture rate may vary depending on criteria used within an analysis.

**Time Period**

Prescribing data is included for the period of January 2016 to December 2016. The legal classification of medicines is based on the legal category for the product on the last day of the month for which the prescription was submitted.

**Prescribing Data**

Prescribing data is based on dispensed prescription items that were reimbursed by the NHSBSA, not including items not dispensed, disallowed and return backs. It includes all available items prescribed and dispensed in England, including prescribing of any items which have been flagged within the CDR database as discontinued. It excludes items prescribed but not presented for dispensing or not submitted to NHS Prescription Services by the dispenser.

**Appendix A**

Within NHSBSA data systems medicines prescribed are recorded by using either an AMPP (Actual Medicinal Product Pack) or VMPP (Virtual Medicinal Product Pack) code. When an actual product (branded items) has been prescribed the system will hold the AMPP code of the item and when an item has been prescribed as a generic the system will hold the VMPP code.

The legal category for any item is defined at the AMPP level. Therefore it is not possible to directly identify the legal category of any drugs at the VMPP level as there is no direct one-to-one match between the AMPP and VMPP codes.

As a larger proportion of items are prescribed generically using VMPP codes, where possible the legal category has been derived for each VMPP code. The method used to assign legal categories to VMPPs is to identify all the AMPPs that relate to an individual VMPP and then find the legal category for each of these AMPPs. When all of the AMPPs have the same legal category, it has been assumed that this legal category can be attributed to the VMPP.

In situations where the AMPPs for a single VMPP have different legal categories a status of 'Unknown' has been assigned as there is no way to confidently define which AMPP has been used when drugs have been prescribed at the VMPP level. This situation accounts for only 1.1% of all VMPPs. Please see the additional worksheet ‘Mixed Legal Category’ for an example.

Please note, as this analysis includes items for products which have been marked as discontinued this could also have impacted on the legal classifications. Therefore, if a discontinued product at AMPP level has a different legal category to the other products within the VMPP group, this will cause the legal category of the VMPP item to be set to 'Unknown', regardless of whether there was any prescribing assigned to the discontinued product or not.



**Appendix B**

The table below looks at a collection of AMPP (brand) products associated to a single VMPP (generic) product, where the legal status is different for a number of the AMPPs.

The drug being examined is the most commonly prescribed such item, ‘Aspirin 75mg dispersible tablets’ which was prescribed 1.5m times during January 2016 alone.

Looking at the AMPP legal categories, three of the four possible options are covered with items existing for categories of 'POM', 'GSL' and 'P'.

Manual checks have been performed on the CDR database to confirm that the legal categories are accurate based on CDR entries.