

FREQUENTLY ASKED QUESTIONS

AUSTRALIAN CATALOGUE OF MEDICINES

What is ACOM?

The Australian Catalogue of Medicines (ACOM).

The ACOM is part of the National Product Catalogue, which uses the EANnet solution to host the system. Within the National Product Catalogue each medicine is uniquely identified and contains various information such as active ingredient and pack size.

Refer to the ACOM Fact Sheet.

Who is responsible for ACOM data?

The Therapeutic Goods Administration (TGA) sponsor of registered and listed medicines is responsible for adding data in ACOM.

The TGA Sponsor must also keep the data in ACOM up-to-date whenever there are changes to the medicinal product e.g. change in ingredients or pack size. Also, when a product is discontinued from the Australian market, this must be reflected in ACOM.

Only the TGA Sponsor has control over its ACOM data. While there is a quality assurance (QA) process to monitor the ACOM, the QA Unit does not have authorisation to change any data.

Which medicines are included in ACOM?

All registered and listed medicines with the TGA, that are current in the Australian market, will be added to ACOM.

How will ACOM be populated?

ACOM will initially be populated with data obtained from the TGA. Although there will be some additional data items that will need to be provided directly by Medicines Suppliers.

In the first instance, a list of medicines will be provided to each Supplier to review. The aim of this preliminary review is to:

- identify all current products;
- assign a product Global Trade Item Number (GTIN);
- provide information about pack size; and
- indicate if the product is free of any substance e.g. gluten.

This preliminary work is required for the Australian Medicines & Devices Terminology project.

Following this, Anatomical Therapeutic Chemical (ATC) codes will be assigned to each medicine.

The revised TGA data will then be loaded into the National Product Catalogue. And at the same time virtual medicine groups will be assigned to the medicines. At this point, the data will not be available until it has proceeded through the quality assurance process.

Why was TGA data used?

Data from the TGA SIME database was selected to be used in ACOM because it contains all medicines used in Australian healthcare including prescription, non-prescription and complementary medicines e.g. herbal preparations. The choice to use TGA data was also made from feedback obtained during industry consultation in 2004.

What is the QA process in ACOM?

The quality assurance process was built into the National Product Catalogue to ensure that data about medicines is accurate and reliable. The process involves the Medicines Supplier reviewing each ACOM data field for each medicine. Sometimes discrepancies may exist between data received from the TGA and how ACOM stores the same data. So the QA process will enable Suppliers to ensure the data is recorded correctly.

Once the data has been checked by the Medicines Supplier, NEHTA's QA Unit will review the data to see that it meets the business rules for ACOM. The QA Unit may request that the Medicines Supplier modify data, as the QA Unit cannot make any changes to the data directly. Once the data is agreed as complete the Medicines Supplier makes it available to the medicines data recipients.

The whole process is conducted within the National Product Catalogue, via the Web, using email for notifications.

What are ACOM business rules?

The ACOM business rules are guidelines that have been developed to complete each data

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item in ACOM. They have been developed to ensure that data in each field is collected consistently and uniformly. A copy of the business rules will be provided to each Medicines Supplier when they receive ACOM training.

What is “ACOM Ready”?

ACOM ready is a status given by GS1 Australia to Medicines Suppliers once they have completed the ACOM QA process for all of its registered and listed medicines. It indicates to State and Territory Health Departments that the medicines data is ready to be used.

Who is GS1?

GS1 Australia is a not-for-profit industry association and member of the global GS1 organisation. It has members from different industry sectors that work together to create standards. The ACOM utilises GS1's standards, namely the Global Trade Item Number (GTIN) for unique product identification.

What are EANnet and the National Product Catalogue?

EANnet is a standards-based and multi-industry data synchronisation solution. It has been developed by GS1 in conjunction with industry and is used by many industry sectors for supply chain purposes e.g. retail sector.

The health sector has adopted EANnet for its 'National Product Catalogue'. It will be used by State and Territory Health sectors in the management of product purchases for medicines, devices and other healthcare consumables.

What training is being offered?

NEHTA will provide training for Medicines Suppliers in EANnet to enable them to add new medicines data and to undertake the quality assurance process. Typically, this training will be conducted in one-on-one sessions or in small groups. Training will be interactive and hands-on with direct access to the system. Where appropriate, training will be conducted on-site on Medicines Supplier's premises.

At training you will be provided with:

- An ACOM User Guide; and
- ACOM Business Rules

NEHTA will not be providing training to enter supply chain data for the National Product Catalogue. For training in this area, please contact GS1.

How can I prepare for ACOM?

1. Ensure your company is a member of GS1 and has registered for EANnet/National Product Catalogue.
2. From the allocation of GTINs provided by GS1, assign a GTIN to each of your TGA registered and listed products.
3. Check that your systems collect all ACOM data items. Refer to the National Product Catalogue Supplier Guideline, available on the GS1 website: www.gs1au.org and click on the EANnet/NPC link.

Who will have access to ACOM data?

Anyone registered as a Medicines Data Recipient will have access to ACOM data. As there is no commercially sensitive information contained in ACOM, the Medicines Data Recipients will have access to all ACOM data.

Medicines Data Recipients must register with GS1 and EANnet.

Some examples of potential Medicines Data Recipients include:

- State and Territory Health Departments – to supplement supply chain information;
- Software vendors – to populate prescription and dispensing applications;
- Medicines database owners e.g. MIMS – to populate medicines databases; and
- NEHTA – to populate the Australian Medicines and Devices Terminology.

Is ACOM in a secure environment?

ACOM uses EANnet to store its information. EANnet is managed by GS1 Australia, who is responsible for system security. System security includes data encryption, firewalls, usernames and passwords to ensure that only authorised users can access EANnet. GS1 also initiates independent third party security reviews on a regular basis.

EANnet contains a full audit trail of all updates to medicines data, including the user identification. It also maintains a log of data recipients who access and download medicines data.

What involvement have Medicines Suppliers had in the development of ACOM?

In 2001, the Medicines Coding Council of Australia initiated a pilot of ACOM. A technical sub-group was established that had representation from six suppliers and three wholesalers. It was this subgroup that

determined the data requirements for ACOM and tested the capability of EANnet to capture these items.

Feedback from the companies involved in the initial pilot was taken into consideration when enhancements were made to EANnet to cater for the ACOM requirements.

Further consultation was made with Industry through the Walter Turnbull consultancy as well as directly with industry associations (Australian Self-Medication Industry, Medicines Australia, Generic Medicines Industry of Australia).

What are the deadlines for ACOM?

The preliminary medicines data review must be completed by February 2007.

Medicines data must have undergone the quality assurance process and be released to the EANnet public by 30 June 2007.

How often does ACOM need to be updated?

The ACOM must be updated by Medicines Suppliers whenever:

- A change is made to an existing medicine e.g. pack size change;
- A new product enters the market; and
- An existing product is discontinued in the market.

For further information go to www.nehta.gov.au

ACOM Contact

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