



Consumer Healthcare
Products Australia

2019 Good Supplier Practice

AN INDUSTRY GUIDELINE
For the management of quality
starting and packaging materials

Version 1.1



Contents

AN INDUSTRY GUIDELINE	1
1. Introduction.....	4
2. Scope	5
3. References.....	5
4. Interpretation	6
5. General Principles	8
6 Building/Facilities.....	8
7 Personnel	10
8 Transportation, Stock Handling (Storage) and Control	10
8.1 Transportation	11
8.2 Stock Handling and Control	12
9 Changes	13
9.1 Change or Deviation to Normal Steps of Material Manufacture	13
9.2 Reprocessed or Reworked Material	13
10 Documentation	13
10.1 The Material Specification	13
10.2 Compliance with Standards	14
10.3 Traceability and Management of Records.....	14
10.4 Quality Management and Standard Operating Procedures (SOPs)	14
10.5 Material Safety Data Sheets (MSDS).....	14
10.6 Material Specifications	14
10.7 Material Certificates of Analysis	14
10.8 Supplier/Agent Agreements	15
10.9 Vendor Qualification.....	15
11. Complaints, Deviations/Non-Conformance Reports, Returns and Recalls.....	16
11.1. Investigations.....	16
11.2. Returns	16
11.3. Recalls	16
11.4. Reviews.....	16
12. Amendments History	16

1 Introduction

Consumer Healthcare Products Australia (CHP Australia) is the peak body representing and advocating on behalf of sponsors and manufacturers of non-prescription consumer healthcare products.

Members of CHP Australia have identified an area of risk in the Australian environment which is not currently addressed by TGA Guidelines, and that would benefit from the proactive implementation of an Industry Guideline: the sourcing of starting materials for the manufacture of medicinal products through local agents and suppliers.

The medicine manufacturing industry in Australia places a strong reliance on agents or suppliers to source starting materials, with minimum order constraints often limiting the ability of the industry to source directly from the overseas manufacturer of the material.

While the Therapeutic Goods Administration licences manufacturers of APIs and finished medicinal goods to Good Manufacturing Practice (GMP) and has long term plans to implement licencing to a Code of Good Distribution Practice (GDP); and the States and Territories Health Departments licence wholesalers of scheduled substances and medicines to a Code of Good Wholesaling Practice (GWP), the supply of starting materials is a responsibility of the medicine manufacturer and/or sponsor to characterise and manage under GMP.

It is impractical for a sponsor or finished product manufacturer to audit all sites of manufacture of starting materials. The relationship between the medicinal product sponsor/manufacturer, the material manufacturer and/or the supplier or agent is therefore critical to the quality, safety and efficacy of the finished product. In delegating the responsibility to the agent/supplier, the sponsor/manufacturer needs to generate assurance that the agent/supplier has systems to ensure the consistent manufacture, packaging, testing, release, handling, transportation and storage of the starting material.

Prior to the development of this industry guideline, members of CHP Australia had been individually applying internal company standards to maintain their compliance with GMP, auditing suppliers and providing these suppliers with documentation to be completed by the material manufacturers. Members identified that a single agreed industry standard for Supplier Practice would generate benefits to all parties in the starting material supply chain. They therefore supported the development of a voluntary industry standard to be applied to their agents/suppliers.

The benefits of compliance with this code are therefore:

- A single published standard which will be applied to all agents/suppliers by medicine manufacturers and sponsors.
- A greater shared understanding of roles and responsibilities in the supply chain.
- An opportunity for the agent/supplier to be recognised as an accredited supplier of quality starting materials for medicinal products.
- A single agreed set of templates for 'desktop' vendor qualification, allowing the agent/supplier to source information on a material manufacturer that will meet the needs of subsequent customers to establish a "provisionally approved" source of supply.
- Audits of starting material manufacturers can be achieved in a cost-effective manner by grouping several audits of different material manufacturers in one country at one time, thereby incorporating back to back audits by the auditor. This would allow the supplier/agent to amortise the costs across contractual agreements with the medicine manufacturers wanting to procure the starting materials.
- Suppliers/agents will be able to build respected, material focussed relationships with material manufacturers rather than playing an intermediary for a series of 3rd parties.

- Material manufacturers will provide the necessary details on a material only once and communicate changes to the details as they occur or at an agreed interval and are audited by the supplier/agent only.
- Medicine manufacturers need only qualify the supplier/agent to the Guideline, rather than auditing every material manufacturer, where they are satisfied that the supplier/agent has qualified the material manufacturer.

Therefore, the expectation is that application of and compliance with the requirements of this document will allow the medicine manufacturer or sponsor to reduce its costs of internally establishing a quality assured supply of starting materials. The supplier/agent will take responsibility for the goods being imported to Australia in a consistent and cost-effective manner, while providing a quality assurance service to their client base of medicine manufacturers and/or sponsors. Suppliers/agents capable of providing this service will be recognised by CHP Australia and will build a reputation within the industry.

2 Scope

The Good Supplier Practice Guidelines are designed for application to the following starting materials when not sourced directly from the material manufacturer:

- active ingredients,
- excipients,
- primary packaging components (direct product contact) and
- pre-printed packaging materials.

The supporting Vendor Qualification Surveys (Section 10.9) may however also be of use for vendor qualification activities for starting materials sourced directly from the material manufacturer.

3 References

- Therapeutic Goods Act 1989¹
- Therapeutic Goods Regulations 1990²
- Manufacturing Principles for Medicinal Products³
- Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 and 8⁴
- Australian Regulatory Guidelines for Complementary Medicines (ARGCM)⁵
- Annex 6, WHO Technical Report Series 996, 2016 Good trade and distribution practices for pharmaceutical starting materials⁶

¹ [Therapeutic Goods Act 1989](#)

² [Therapeutic Goods Regulations 1990](#)

³ [Manufacturing principles for medicinal products](#)

⁴ [Code of GWP schedule2-3-4-8 2011.pdf](#)

⁵ [ARGCM](#)

⁶ [Annex 6, WHO Technical Report Series 996, 2016](#)

4 Interpretation

Active ingredient	Active ingredient, for a medicine, means a therapeutically active component in the medicine's final formulation that is responsible for its physiological or pharmacological action. ⁷
Batch number	Batch Number (or Lot Number) A unique combination of numbers, letters, and/or symbols that identifies a batch (or lot) and from which the production and distribution history can be determined. ⁸
C of A	Means certificate of analysis.
Clean Area	Means an area with defined environmental control of particulate and microbial contamination, constructed and used in such a way as to reduce the introduction, generation and retention of contaminants within the area.
Excipient	Means any component of a finished dosage form other than an active ingredient (in some cases the distinction between an active ingredient and an excipient may not be clear cut, e.g. use of sodium chloride to adjust tonicity of an injection is an excipient). ⁹
Expiry date	Means the date (expressed as the month and year) after which the goods should not be used. ¹⁰
FEFO	First expired first out.
FIFO	First in first out
Materials	<p>Means any substance or component used in the production of a medicinal product including active ingredients and excipients, packaging materials and labels.</p> <p>A general term used to denote raw materials (starting materials, reagents, solvents), process aids, intermediates, APIs and packaging and labelling materials.¹¹</p>
Material manufacturer	Means producer of the materials used in the manufacture of medicinal products.
Material supplier	Means the supplier/agent which sources and on sells starting materials or packaging materials to the finished medicine manufacturer or to the sponsor.
Medicine manufacturer	Means producer of the finished medicinal products.
Packaging materials	Means any material used in the packaging of a medicinal product, excluding outer packaging used for transportation and shipment. Packaging materials are referred to as primary or secondary according to whether they are intended to be in direct contact with the product.

⁷ Section 2, Part 1 of the [Therapeutic Goods Regulations 1990](#)

⁸ Section 20, Part II of the [PIC/S Guide to GMP PE009-13](#)

⁹ Section 21 part 4 of the [ARGCM](#)

¹⁰ Section 2 Part 1 of the [Therapeutic Goods Regulations 1990](#)

¹¹ Section 20 part II of the [PIC/S Guide to GMP PE009-13](#)

Qualification	See validation interpretation.
Quarantine	Means the status of materials isolated physically or by other effective means pending a decision on their subsequent approval or rejection. ¹²
Repacking/repackaging	Where an original container is opened, and materials removed from this original configuration to provide smaller or larger containers of that same batch of material; and where there is no blending of materials from different batches.
Reprocessing	Introducing material that does not conform to standards or specifications, back into the process and repeating a step or other appropriate chemical or physical manipulation steps (e.g., distillation, filtration, chromatography, milling) that are part of the established manufacturing process.
Reworking	Subjecting a material that does not conform to standards or specifications to one or more processing steps that are different from the established manufacturing process to obtain a material of acceptable quality (e.g., recrystallizing with a different solvent).
Sponsor	sponsor, in relation to therapeutic goods, means: (a) a person who exports, or arranges the exportation of, the goods from Australia; or (b) a person who imports, or arranges the importation of, the goods into Australia; or (c) a person who, in Australia, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere) ¹³
Standard	in relation to therapeutic goods, means a monograph of a default standard according to the Therapeutic Goods Act 1989: (a) the British Pharmacopoeia (b) the European Pharmacopoeia (c) the United States Pharmacopoeia-National Formulary or another appropriate Pharmacopoeial monograph where justified.
Supply	Means supply, by way of sale, free of charge or otherwise, by way of sample for the purpose of quality assessment or product development.
Tampered	means the materials are tampered with if: (a) they are interfered with in a way that affects, or could affect, the quality, safety or efficacy of the finished product; and (b) the interference has the potential to cause, or is done for the purpose of causing, injury or harm to any person.
Validation	A documented program that provides a high degree of assurance that a specific process, method, or system will consistently produce a result which meets pre-determined acceptance criteria, in accordance with the principles of Good Manufacturing Practice. ¹⁴

¹² Section 20 part II of the [PIC/S Guide to GMP PE009-13](#)

¹³ Section 3, subsection 1 of the [Therapeutic Goods Act 1989](#)

¹⁴ Section 20 part II of the [PIC/S Guide to GMP PE009-13](#)

5 General Principles

All parties involved in the supply of material for use in medicinal products have a responsibility to ensure the identity, efficacy, quality, safety, purity and traceability of the materials used to produce finished medicinal products; and thus to protect the health and safety of the patients and consumers who will use those medicines.

The Good Supplier Practice Guidelines should be applied by members of CHP Australia to their material suppliers/agents. Where members identify the need for changes to the guideline these should be proposed to the association as amendments to be considered by the members.

6 Building/Facilities

Warehousing areas for starting materials destined for Pharmaceutical or Complementary Medicine products shall comply with the relevant sections of the Code of GMP for Medicinal Products for warehousing.¹⁵

Considerations should include environmental conditions and controls, status control of all starting materials, general housekeeping and security. Warehouse construction materials should be designed to minimise the risk of contamination or dirt in the area, and for effective pest management.

6.1 Designed/adapted for purpose

Premises should be situated in an environment which is conducive to the storage of starting materials to be used in the manufacture of medicinal products. The premises should facilitate appropriate environmental conditions for the materials being stored; and should be of sufficient capacity to allow orderly storage of the various categories of materials being stored as well as to facilitate their status in the warehousing operations. For example, there should be separate areas for rejected materials, for quarantine of received goods, and for goods approved for despatch.

The design of the building/facility shall provide for good storage conditions by ensuring that it is clean and dry, maintained within acceptable temperature limits (and humidity where appropriate), and provided with adequate ventilation and lighting so as to not adversely affect, directly or indirectly, the goods being stored.

Where temperature and humidity controls are implemented for the building/facility they shall be checked and monitored routinely to ensure compliance to required conditions. Equipment used for monitoring conditions such as temperature and humidity should be calibrated at regular intervals.

The design of the facility shall ensure that goods are stored off the floor and suitably spaced to permit cleaning and inspection.

Pallets should be kept in a good state of cleanliness and repair at all times.

¹⁵ Ch.3 Part 1 of the [PIC/S Guide to GMP PE009-13](#).

Where sampling is to be conducted on any materials there shall be a separate area designated for this activity where the goods can be opened in a controlled environmental area, comparable to a controlled air sampling booth, which will not permit cross-contamination or the ingress of dust or dirt

6.2 Designed/adapted for purpose

The building/facility shall be maintained at all times to permit effective cleaning and maintenance in order to avoid cross-contamination, build-up of dust or dirt and in general, any adverse effect on the quality of products being stored.

Routine cleaning procedures for warehouse areas and ancillary areas shall be implemented and documented accordingly.

6.3 Pest Management

Premises shall be designed and equipped so as to afford maximum protection against the entry of insects or other animals. A pest management program shall be implemented and maintained.

6.4 Hygiene Control

Rest and refreshment areas should be separate from other areas and facilities for changing clothes, washing and toilet purposes should be easily accessible and appropriate for the number of users.

Toilets should not directly communicate with storage areas. Any maintenance areas should be separate from storage areas for goods destined for the manufacture of medicines.

6.5 Security

The design of the building/facility should ensure that there are adequate controls, to retain security of the warehouse, against visitors and unauthorised personnel at all times. Appropriate security measures shall be implemented to ensure that ingress to the site is not facilitated when the premises are unmanned by personnel.

The storage of goods and transportation of goods from the agent/supplier warehouse to the destination needs to be appropriately secure.

For goods that require additional security measures and/or special regulatory licensing (eg. controlled substances or goods with high illicit value (GHIV)), appropriate facilities and procedural arrangements shall be maintained eg alarms and safes.

6.6 GMP Requirements For Repacking

According to Good Wholesaling Practice, repackaging (including relabelling) of medicines must be carried out only by wholesalers who hold an appropriate licence or authority under State and Territory and/or Commonwealth legislation, unless the activity is exempt from these

requirements; and then only with the express approval of the sponsor¹⁶.

To repack any starting material it is a requirement that the facility or premises hold a GMP Licence appropriate to the proposed step/s in manufacture.

Sampling or repacking of a raw material shall be conducted in accordance with the current Australian Code of GMP to avoid mix-ups and loss of identity or purity of the ingredient.

Repackaging should be conducted under appropriate environmental conditions to avoid contamination and cross-contamination¹⁷.

Repackaging shall also be documented according to the current Australian Code of GMP. Each new batch of product created shall contain appropriate labelling and will have its own unique batch number which is traceable to the original pack size through batch documentation control records.

The certificate of analysis or conformance provided with the repackaged product shall also provide this traceability back to the original goods.

7 Personnel

The effectiveness of quality management systems within an organisation is dependent on its people.

The structure of the organisation should be clear and communicated to staff.

Individuals should understand the responsibilities of their role. They should receive initial and ongoing training in the duties of their role. They should understand the requirements of Good Manufacturing and how it relates to their responsibilities. They should be trained to follow standard operating procedures (SOPs) relevant to their work. They should understand how tasks are to be recorded in either soft or hard copy.

All personnel should have the appropriate education, training, experience and skill to perform their designated tasks to an acceptable level.

Suitably trained and qualified personnel should be identified as delegates to perform key tasks and functions during the absence of key personnel.

Persons in responsible positions should have the appropriate authority to discharge their responsibilities.

Casual or contract personnel should also receive an appropriate level of induction training in GMP and the SOPs necessary to perform their role.

8 Transportation, Stock Handling (Storage) and Control

Suppliers of starting materials (ingredients or packaging) used in the manufacture of medicinal products shall have a system for ensuring that transportation, handling and control of materials are

¹⁶ Section 4.8 of the [Code of GWP schedule2-3-4-8 2011.pdf](#)

¹⁷ Chapter 17.4, Part II of the [PIC/S Guide to GMP PE009-13](#)

performed within known guidelines across the entire supply chain from the site of the material manufacturer to the site of the medicine manufacturer or sponsor.

The system shall provide for documentation and evidence that materials are not at risk of mix-ups, adulteration, contamination, cross-contamination and counterfeit; and that the material has not been subject to conditions outside those specified by the manufacturer of that material.

The system should indicate if and where the normal supply chain has been interrupted e.g. where a shipment has been offloaded during transportation; and whether any additional unauthorised steps of manufacture have occurred, such as repacking and relabelling.

The Supplier shall have written procedures describing the transportation, receipt, identification, quarantine, storage and handling, approval or rejection of materials. Materials must be purchased from an approved material manufacturer against an agreed specification.

This section sets out the appropriate steps to assist in fulfilling the responsibilities involved in the different aspects of the supply process within the supply chain and also to avoid the introduction of counterfeits into the marketplace via the distribution chain.

8.1 Transportation

Procedures should be in place to ensure that the integrity of the material is not compromised during transportation.

Vehicles and equipment used to distribute, store or handle materials should be suitable for their use and appropriately equipped to prevent exposure of the products to conditions that could affect their stability and packaging integrity, and to prevent contamination of any kind. They should be well maintained in an operational and clean condition and should not pose a risk of contamination to the materials.

Materials for shipment should be secured in packaging designed to prevent or provide evidence of unauthorized access.

Materials should be stored and distributed in shipping containers which do not have an adverse effect on the quality of the products, and which offer adequate protection from external influences, including contamination.

Shipping containers should enable identification of the containers' contents and source. Shipping containers should bear labels including sufficient information on handling and storage conditions and precautions to ensure that the materials are properly handled and secure at all times. The need for any special transport and/or storage conditions should be clearly stated on the shipment container labels.

Where the material requires special storage conditions, (e.g. temperature and/or relative humidity) appropriate transportation should be specified, provided, checked, monitored and recorded. All monitoring records should be kept for a minimum of the shelf-life of the product distributed plus one year. Equipment used for monitoring conditions within vehicles and containers, e.g. temperature and humidity, should be calibrated at regular intervals.

Transport validation should be available for APIs and temperature sensitive materials.

Consideration should also be given to pallets used for the storage, handling and transportation of materials including the construction of the pallet or treatments applied to it

and potential for contamination of the material. For more detail refer to ISPM 15 Annex 2¹⁸. This universally recognized, non-language specific mark facilitates verification during inspection.

See also the relevant sections of the PIC/s Code¹⁹, and of Annex 6, WHO Technical Report Series 996.²⁰

8.1.1 From Material Manufacturer to Supplier or Agent, and from Supplier or Agent to Medicine Manufacturer or Sponsor

Transport qualification shall be provided upon request from the customer, for the goods being transported from the manufacturing site to the supplier/agent's storage facility and from this facility to the customer. The data should be provided in the form of a validation report which has verified the worst case transport times and conditions for the goods at the appropriate times of the year.

The supplier/agent in Australia should know, and have clearly documented, all parties in the supply chain particularly where there are agents involved in other countries which supply from the material manufacturer for export to Australia. This information should be made fully and readily available to the customer upon request.

8.2 Stock Handling and Control ²¹

8.2.1 Identity & Integrity of Material on Receipt

The integrity of containers received into the supplier/agent's facility from the material manufacturer needs to be ensured, for example by demonstrating that tamper-evident seals are intact upon receipt. Where the integrity of a seal has been breached before receipt by the supplier/agent, the material should be rejected.

There should be procedures in place to compare the material documentation to the original documents provided by the material manufacturer, and to confirm the identity of the material while taking into account the potential for contaminated, tampered or counterfeit materials.

This procedure should include provisions for notification, as appropriate, of the material manufacturer, medicine manufacturer/sponsor, the appropriate national and/or international regulatory bodies, as well as other relevant competent authorities, when a potentially tampered or counterfeit material is identified.

Integrity seals should not be broken unless this is performed in a clean room environment equipped with controlled air handling and with appropriate sampling conditions available to the supplier/agent. Should the supplier/agent require to open a container in this clean room and the integrity seal be broken, then a replacement seal must be applied to the container and appropriately documented prior to despatch to the customer.

¹⁸ See Annex 2 of [ISPM 15 Regulation of wood packaging material in international trade](#)

¹⁹ Sections 9.43 and 9.46 of Part II of the [PIC/S Guide to GMP PE009-13](#)

²⁰ Good trade and distribution practices for pharmaceutical starting materials [Annex 6, WHO Technical Report Series 996, 2016](#)

²¹ See Section 10 of Part II of the [PIC/S Guide to GMP PE009-13](#)

8.2.2 **Stock Rotation Control and Minimum Shelf Life Remaining for Supply**

Raw materials, whether actives or excipients, shall only be supplied to customers with a mutually agreed, material-specific minimum shelf life remaining on the goods. It is critical for the Supplier/Agent to manage their stock to ensure that a FEFO/FIFO system is implemented for goods to ensure the longest possible shelf life is provided to customers.

Systems should be in place to identify, review and control expired, damaged, returned or rejected material.

There should be appropriate segregation and/or restriction of quarantined and rejected product from saleable material.

8.2.3 **Material-Specific Environmental Conditions**

The supplier/agent should have appropriate environmental controls to demonstrate that the storage of the material is compliant with the conditions recommended by the material manufacturer. If the material has not been stored appropriately the goods can be refused at delivery to the customer²².

9 Changes

9.1 Change or Deviation to Normal Steps of Material Manufacture

Changes or deviations to the normal material manufacturing steps should be communicated in writing in a timely manner and with justification, to the supplier/agent and then to the medicine manufacturer and/or sponsor, to allow for the change or deviation to be assessed and approved.

9.2 Reprocessed or Reworked Material

Any reprocessing or reworking step by the material manufacturer or by the supplier/agent is prohibited unless previously agreed to by the medicine manufacturer and/or sponsor.

Reprocessing and reworking procedures, with justification and supporting data, must be provided to the customer for approval prior to supply.

Every batch of approved reprocessed or reworked material shall be produced in an appropriately licensed facility. It must be clearly identified in the supply documentation and must be traceable back to the original batch prior to reworking or reprocessing.

10 Documentation

10.1 The Material Specification

The material specification should be mutually agreed between the material manufacturer, the supplier/agent and the medicine manufacturer/sponsor.

²² See Section 10.10 of Part II of the [PIC/S Guide to GMP PE009-13](#)

10.2 Compliance with Standards

The material should comply with the mutually agreed specification. In general, materials should comply with the requirements of the current editions of the approved Australian default standards (the British Pharmacopoeia, the European Pharmacopoeia or the United States Pharmacopeia), and with TGA Guidelines, Standards and final Compositional Guidelines; unless otherwise specified and agreed by the customer.

Where applicable, materials should also comply with the requirements of the general monographs of the current editions of the approved Australian default standards relating to residual solvents and pesticide residues.

10.3 Traceability and Management of Records

Records should be held to enable identification, disposition and traceability of all materials being supplied.

10.4 Quality Management and Standard Operating Procedures (SOPs)

An effective system of managing quality should be established, documented, and implemented. As part of this process, standard operating procedures (SOPs) should be developed for all critical operations that may have an impact on the quality of the materials being supplied.

10.5 Safety Data Sheets (SDS)

SDS should be available for all materials being supplied.

SDS should be periodically reviewed and reissued every 5 years.

SDS must be prepared in accordance with the model Code of Practice for the Preparation of Safety Data Sheets for Hazardous Chemicals²³.

10.6 Material Specifications

Specifications should be provided on the original material manufacturer's letterhead and should not be transcribed or altered in any way.

Specifications should list each test in accordance with compendial or customer specifications, including the acceptance limits. Specifications may also list other criteria pertaining to the quality of the product.

10.7 Material Certificates of Analysis

Certificates of analysis should be provided on the original material manufacturer's letterhead and should not be transcribed or altered in any way.

²³ [Model Code of Practice for the Preparation of Safety Data Sheets for Hazardous Chemicals](#)

Certificates of analysis should list each test performed in accordance with compendial or customer specifications, including the acceptance limits and the results obtained.

Certificates of analysis should be dated and approved by the authorised personnel of the quality unit(s) and should show the name, address and telephone number of the original material manufacturer.

10.8 Supplier/Agent Agreements

There should be written and approved contracts or formal agreements between the supplier/agent and the medicine manufacturer/sponsor that define in detail the commercial and GMP responsibilities of each party. The mutually agreed material specification may form the minimum basis for this supplier/agent agreement.

10.9 Vendor Qualification

In the process of qualifying the supplier/agent, the customer should provide the supplier with copies of the relevant vendor qualification questionnaires. The supplier/agent should forward these to the medicine manufacturer and any other vendor in the supply chain.

On receipt of the completed questionnaires, the supplier/agent should provide a detailed vendor qualification report, the material manufacturer's original C of A, and a sample of the material for evaluation by the customer. For active ingredients stability data to support the material's shelf life and the Product Quality Review (PQR) should be available.

When all documents and samples have been assessed by the agent/supplier and the customer and found to be acceptable, a Supplier/Agent Agreement may be signed off along with relevant commercial contracts, and supply may commence.

Use the following questionnaire forms are relevant to the following vendor types:

Vendor Type	Name of Questionnaire
Raw Material Manufacturer	<ul style="list-style-type: none">• Raw Material Manufacturer Vendor Qualification Questionnaire• Transmissible Spongiform Encephalopathies (TSE) Questionnaire• Allergens and Substances of Concern Information Questionnaire
Packaging Material Manufacturer	<ul style="list-style-type: none">• Packaging Material Manufacturer Vendor Qualification Questionnaire
Supplier/Agent / Distributor/ Vendor	<ul style="list-style-type: none">• Supplier Vendor Qualification Questionnaire

11 Complaints, Deviations/Non-Conformance Reports, Returns and Recalls

11.1 Investigations

All complaints and deviations/non-conformance reports (NCRs) should be investigated and documented through a formal procedure, and records maintained.

11.2 Returns

Returns should be documented and managed through a formal procedure, and records maintained.

11.3 Recalls

A formal procedure should be in place that defines the circumstances under which a recall of a material should occur.

11.4 Reviews

Complaints and deviations/non-conformance reports (NCRs), returns and recalls should be reviewed to determine whether any further action is required in relation to other customers that have received the material.

12 Amendments History

Document Edition/Date	Description of Change	Section/ Page No.
Version 1.0 16/01/12	First Issue	
Version 1.1 Nov 2019	<ul style="list-style-type: none">• Update to reflect the association's name change from Australian Self Medication Industry (ASMI) to Consumer Healthcare Products Australia (CHP Australia).• Document formatting updated to CHP Australia's Style Guide.• Update to links and latest versions of references.• No change to content.	General