



*British Association of  
Pharmaceutical Wholesalers*

**THE BAPW GOLD STANDARD**



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### Good Distribution Practice by Pharmaceutical Wholesalers

The British Association of Pharmaceutical Wholesalers (BAPW) represents full-line pharmaceutical wholesalers in the UK. Our member companies distribute the comprehensive range of licensed medicines to pharmacies, hospitals, doctors, and even directly to patients in certain cases, across the country. Full-line wholesalers act as a one-stop shop for almost all pharmaceutical products and services, playing a key role in the cost effective and safe distribution of a diverse range of healthcare products, all to exact orders on a same day basis.

Patient safety is of paramount importance and our members adhere to the highest principles of distribution practice. Our Gold Standard outlines this Good Distribution Practice (GDP) and the quality checks and standards to which all our members adhere.

*“Control of the storage and distribution network is essential for the maintenance of the quality of medicines in the supply chain from manufacturer to patient. Of primary importance in this regard is the implementation by wholesaler distributors of appropriate standards of good pharmaceutical distribution practice. The MHRA applauds the introduction of the BAPW’s Gold Standard, which will provide an important contribution to the protection of public health.”*

John Taylor  
Quality and Standards Manager  
Medicines and Healthcare products Regulatory Agency (MHRA)

The BAPW Gold Standard of Good Distribution Practice by Pharmaceutical Wholesalers is endorsed by the Medicines and Healthcare products Regulatory Agency (MHRA)



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<b>STANDARD OPERATING PROCEDURES (SOPS)</b>	<ul style="list-style-type: none"><li>• Full-line wholesalers maintain quality systems to ensure that medicinal products are distributed in accordance with all current legislation, both from the UK's MHRA and the EU.</li><li>• SOP documents cover every area of our wholesaling practice and are inspected by the MHRA, according to its Orange Guide.</li><li>• SOPs are visible to all staff to which they should apply and are integral to company staff training.</li><li>• Any alterations to the SOP must be approved and signed off by the company director and company responsible person (R.P.). Any changes must be notified to all staff.</li><li>• Staff understanding of SOPs is tested by the MHRA.</li></ul>
<b>PERSONNEL</b>	<ul style="list-style-type: none"><li>• A 'Responsible Person' (R.P.) is appointed by each wholesaler. This R.P. must be approved by the MHRA to ensure Good Distribution Practice is followed.</li><li>• A management representative is appointed at each distribution site, with defined authority and responsibility for ensuring that the quality system is implemented and maintained on site.</li><li>• There is a standardised skills matrix across branches, managed centrally by the R.P. to ensure that all current wholesale activities meet all the relevant requirements as per the Orange Guide.</li></ul>

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	<ul style="list-style-type: none"><li>• GDP is introduced to new employees as an integral part of their induction.</li><li>• As a specific example, procedures are in place to train employees on recognising counterfeit product and in the follow-up procedures.</li><li>• A readily available record is kept of staff SOP training and entitlement to practice in each wholesaler depot.</li></ul>
<b>PRODUCT RECALLS</b>	<ul style="list-style-type: none"><li>• We are a trusted partner of the MHRA and marketing authorisation holders in product recalls.</li><li>• There is a fast, secure, confidential system linking the MHRA to full-line wholesalers and in turn to all wholesalers' customers, for immediate contact by telephone if required.</li><li>• If products are removed from the supply chain, full-line wholesalers:<ul style="list-style-type: none"><li>- Accept returns from any company's customer;</li><li>- Quarantine the product;</li><li>- Cross-check batch numbers; and</li><li>- Liaise with the manufacturer on final disposal.</li></ul></li><li>• The recall message, as approved by the marketing authorisation holder and when appropriate by the competent authorities, should indicate whether the recall should also be carried out at retail level.</li><li>• The message should request that the recalled products be removed immediately from the saleable stock and stored separately in a secure area until they are returned according to the instructions of the marketing</li></ul>

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	<p>authorisation holder.</p> <ul style="list-style-type: none"><li>• Emergency plans are in place for urgent recalls.</li></ul>
<b>COUNTERFEIT MEDICINAL PRODUCTS</b>	<ul style="list-style-type: none"><li>• Counterfeit medicinal products found in the distribution network are quarantined, clearly labelled as not for sale and the marketing authorisation holder and competent authorities are informed immediately.</li><li>• Full-line wholesalers work closely with industry and the MHRA in devising staff training in how to recognise counterfeit products.</li></ul>
<b>COLD CHAIN AND CONTROLLED DRUGS - DISTRIBUTION AND STORAGE</b>	<ul style="list-style-type: none"><li>• We operate in an MHRA-approved temperature controlled environment, including during deliveries and inter-depot transfers, for all products for which this is needed.</li><li>• This requires continuous monitoring and in-built warning systems.</li><li>• We also maintain a similarly appropriate environment in all our vehicles.</li><li>• All Cold Chain (CC) products are checked immediately at point of receipt and stored as a priority within one hour.</li><li>• Any delivery that does not provide evidence of CC maintenance is rejected and the supplier notified.</li><li>• All our systems are validated.</li><li>• All our maintenance contracts are in place.</li><li>• Contingency plans are in place in the event of equipment failures.</li><li>• Security records are kept of all persons entering and</li></ul>

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	<p>leaving the secure area.</p> <ul style="list-style-type: none"><li>• All personnel working within Controlled Drug Distribution (CDs) and transporting them are subject to criminal record checks.</li><li>• Panic alarms are fitted in CD vaults.</li><li>• There are Home Office-approved secure stores in all 52 full-line depots.</li><li>• There is strict record-keeping of receipt and supply.</li><li>• Annual returns are sent to the Home Office and the World Health Organisation.</li><li>• There is a stock check after every shift.</li><li>• Signatures are taken at the point of delivery.</li><li>• The handling costs for CDs are six times those for regular products.</li><li>• Each depot must obtain an individual license for each product handled.</li><li>• Home Office inspectors undertake random visits.</li></ul>
<b>WAREHOUSE TEMPERATURE MAPPING</b>	<ul style="list-style-type: none"><li>• All warehouses are continuously self-monitored.</li><li>• Temperature mapping is undertaken after stock location/building changes and every three years.</li><li>• Any excursions from the set range, as monitored by temperature recorders in the storage area, are annotated with the corrective action recorded.</li></ul>

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<b>RETURNS OF NON-DEFECTIVE MEDICINES</b>	<ul style="list-style-type: none"><li>• All products returned must have an invoice number and returns note.</li><li>• Defaced or damaged products must be quarantined.</li><li>• Safety checks are conducted before stock is returned to the shelf.</li></ul>
<b>SELF-INSPECTION</b>	<ul style="list-style-type: none"><li>• Self-inspection of wholesale depots is carried out twice yearly as a minimum and results are reviewed.</li></ul>
<b>SECURITY</b>	<ul style="list-style-type: none"><li>• Appropriate access control to the warehouse is ensured.</li><li>• Alarm systems, monitoring and emergency out-of-hours services are in place.</li><li>• There are random vehicle searches.</li></ul>
<b>AUTHORISED SUPPLY TO CUSTOMERS</b>	<ul style="list-style-type: none"><li>• Full-line wholesalers can retrieve all orders electronically and offer 24-hour, seven days a week availability of all products.</li><li>• Checks are undertaken on the credentials of customers and product is only supplied if the correct category of license is held. Our orders are only addressed to persons authorised to supply medicinal product as wholesalers in accordance with Article 3 of Directive 92/25/EEC or holders of a manufacturing or importing authorisation granted in accordance with Article 16 of Directive 75/319/EEC.</li><li>• For all supplies to a person authorised or entitled to supply medicinal products to the public, an</li></ul>

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	<p>invoice/delivery note is enclosed, making it easy to ascertain the date, name and pharmaceutical form of the product, the quantity supplied and its supplier source.</p> <ul style="list-style-type: none"><li>• Wholesalers planning to distribute or currently distributing medicinal products in EU Member State(s) (MS) other than the MS in which the wholesale dealer license was granted should make available on request to the competent authorities of the other MS any information in relation to the authorisation granted in the MS of origin. This would comprise the nature of the wholesaling activity, the address of storage sites and distribution points and the area covered. Where appropriate, the competent authorities of the other MS inform the wholesaler of any public service obligation imposed on wholesalers operating within their territory.</li></ul>
<b>TRANSPORT</b>	<ul style="list-style-type: none"><li>• We operate secure delivery vans.</li><li>• Our drivers are trained in basic GDP, product safety and security.</li><li>• Products are transported to ensure that:<ol style="list-style-type: none"><li>a) Their identification is not lost.</li><li>b) They do not contaminate, and are not contaminated by, other products or materials.</li><li>c) Adequate precautions are taken against spillage, breakage or theft.</li><li>d) They are secure and not subjected to unacceptable degrees of heat, cold, light, moisture, attack by micro-</li></ol></li></ul>

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	organisms or pests, or other adverse influences.
<b>STOCK ROTATION</b>	<ul style="list-style-type: none"><li>• Stock is rotated – first in, first expiry out, as relevant - and audited externally and internally.</li><li>• All returns are date-checked.</li><li>• Products beyond their expiry date are separated from saleable stock and are not distributed.</li><li>• Products with broken seals, damaged packaging or suspected of possible contamination are withdrawn from saleable stock and, if not immediately destroyed, are stored separately.</li></ul>
<b>RECORD-KEEPING, SALE &amp; SUPPLY (ARTICLE 82)</b>	<ul style="list-style-type: none"><li>• We operate a rigorous audit trail of supplies to customers.</li><li>• All documentation is available on the request of the relevant authorities.</li><li>• Records are kept of each purchase and sale. All documents are dated with supplier/delivery address, product name and quantity.</li><li>• Records are retained for a minimum of five years.</li></ul>
<b>PREMISES AND EQUIPMENT</b>	<ul style="list-style-type: none"><li>• Through continual investment, wholesalers maintain clean, modern premises and equipment that are suitable for ensuring proper conservation and distribution of medicinal products. Monitoring devices are calibrated.</li></ul>

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	<ul style="list-style-type: none"><li>• Our receiving bays protect deliveries from bad weather during unloading. Reception areas are separate from the storage area. Deliveries are examined on receipt to check that containers are intact and that the consignment corresponds to the order.</li><li>• Products subject to specific storage measures, e.g. controlled drugs such as narcotics and cold chain products requiring a specific storage temperature, are immediately identified and stored in accordance with written instructions and legislative requirements.</li><li>• All products are stored under the conditions specified by the manufacturer in order to avoid any deterioration by light, moisture or temperature.</li></ul>
<b>CONTINUITY OF SUPPLY</b>	<ul style="list-style-type: none"><li>• Wholesalers will take initial stocks of new branded products on a 90-day sale or return basis, to offer continuity of supply to patients.</li><li>• Any new products are covered under the BAPW new line listing form (available on <a href="http://www.bapw.net">www.bapw.net</a>).</li></ul>

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