



Review | COLD CHAIN LOGISTICS

Keeping medicine cool

COLD CHAIN LOGISTICS ARE CRITICAL TO KEEPING COMMUNITY PHARMACIES ACROSS AUSTRALIA SUPPLIED WITH TEMPERATURE-SENSITIVE MEDICINES IN A TIMELY AND SECURE MANNER.

Every day, more than 40,000 units of refrigerated medicine are delivered to pharmacies throughout Australia.

They range from simple and inexpensive items—such as eye and ear drops—through to critical and expensive oncology medicines such as Kepivance, which is used to reduce mouth ulcers in patients undergoing high dose chemotherapy and radiation therapy for blood cancers.

But their arrival into the hands of patients only marks the end of a carefully managed and rigorously controlled process to ensure the products make their destination exactly as the manufacturer had intended.

‘Cold chain logistics is a critical part of keeping pharmacies across Australia supplied with PBS medicines in a timely and secure manner,’ says Labrini Nassis, regulatory compliance manager at Sigma.

‘These are medicines which, in many cases, have very exact tolerances in terms of their safety and efficacy.

‘If they’re inappropriately handled or the process breaks down somewhere, there could potentially

be issues with the safety and efficacy of the medicines—which is a concern, particularly if the product is deemed as medically critical. Therefore, it is imperative we ensure our cold chain logistics are right.’

For wholesalers who are signatories to the Community Service Obligation (CSO), their operations are set by—and strictly audited against—the Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 and 8, ensuring independent, third party scrutiny of their systems and procedures.

It’s all about checking and re-checking. And it all starts in the warehouses.

‘We have very large walk-in refrigeration units in all our warehouse facilities across Australia, and these are capable of carrying tens of thousands of individual medicines,’ says Simon Bunde, general manager of group operations at Symbion.

In fact, Symbion alone holds an average of almost 240,000 refrigerated units at its facilities with a stock value in excess of \$30 million. The refrigeration units are supported by an elaborate system to ensure

there are no single points of failure, so if something does happen to go wrong, there is a back-up.

‘That means having plenty of redundancy in the system, so we have generators in case we lose power, we have extra compressors for the refrigeration units, alarms and SMS alerts,’ Bunde says.

‘The process continues with the delivery of the medicines, where we pack the medicines in insulated containers for transport. We have validated the process and the containers so we can be confident that the medicines remain within the manufacturer’s defined tolerances while they’re in transit to pharmacies.’

Like Symbion and Sigma, National Pharmacies continues to invest heavily in its infrastructure, recently commissioning a new cold store facility in South Australia.

Although some of the refrigerated items being distributed might only attract a tiny margin for the wholesaler, there’s no change in the rigorous approach taken to each and every order.

‘Even a short drop to zero degrees or a spike to above eight degrees Celsius can significantly reduce the efficacy of many cold chain medicines or even render them useless,’ says Neale Burton, general manager of dispensary and logistics at National Pharmacies.

‘Despite the low cost and often low sales of many of these cold

chain products, some of which are high impact medicines, they all attract specialised packaging and verified temperature control throughout the delivery process.’

As with all CSO distributors, National Pharmacies’ cold chain logistics process is under constant scrutiny.

‘As a CSO distributor, we are audited annually, not just against the stringent standards imposed by the Department of Health through the Deed of Agreement but also against the Code of Good Wholesaling Practice,’ Burton says.

‘Given our commitment, and the confidence gained from this audit process, we believe that our customers can have 100% confidence in refrigerated products supplied by any of the CSO distributors.’

Data collected by the wholesalers is recoded and supplied on a monthly basis to the CSO for monitoring and penalties apply if there’s a break in the chain.

‘The Code ensures we look at each and every medicine we handle. It provides us with a strict operational framework and a communication path to understand more about the medicines we hold,’ says Sigma’s Labrini Nassis.

The Code runs across 24 pages and includes strict guidelines around logistics, recalls, security and more.

However, it is not a document which was written arbitrarily and forced upon the industry. Indeed, it started life as a voluntary code produced by the National Pharmaceutical Services Association (NPSA). It was then adopted over time by state governments and upgraded with the NPSA’s assistance as well as law enforcement agencies.

Now, the Code is fully adopted by governments and the Therapeutic Goods Association and all the CSO wholesalers are audited against it.

It’s the kind of rigour which the industry has embraced—and from which every patient benefits. ■