

Health Sciences Authority of Singapore (HSA)

Pharmacovigilance Journey- Making Health Products Safer



HSA is the national regulator of health products in Singapore. The Vigilance and Compliance Branch (VCB) of HSA ensures that health products used in Singapore continue to be safe through the administration of pharmacovigilance activities and post-market surveillance measures. Our pharmacovigilance (PV) journey started from humble beginnings in 1993, and has brought us to where we are today, an internationally recognised regulatory authority that uses strong scientific basis for decisions and innovativeness in its regulatory approaches.

Our growth milestones- from one to many

Our PV team started as a 1-man unit and grew to become a 40-man strong team today. The team is constantly monitoring for safety signals from adverse events (AEs) reported locally by healthcare professionals and companies and internationally, through the collaboration with international regulatory counterparts and organisations such as the World Health Organisation (WHO). One of the achievements which we are proud of is our adverse event reporting being ranked No. 1 in the world by the WHO in 2011 because of the extent to which we can pick up signals in our population. We have continued to maintain our Top 3 position to date.

A key milestone occurred in 2001, when a new statutory board, HSA, was established under Singapore's Ministry of Health. The scope for vigilance was expanded to include cosmetics and complementary health products and the unit was renamed 'Pharmacovigilance Branch'. The scope was further expanded to include vaccines and advanced therapeutic products which are now under the watchful eye of the VCB of HSA.

Success is a journey, not a destination

It has been a 25-year-long journey, marked with successes and challenges. These experiences became opportunities for learning and growth.

One of these was the 'Slim 10' experience in 2002 where an illegal Chinese Proprietary Medicine (CPM) was found adulterated with undeclared potent active ingredients. This led to the strengthening of the regulatory framework for CPMs.

In 2008, we achieved a PV success. HSA detected 'Power 1 Walnut', an illegal sexual enhancement product, adulterated with glibenclamide and sildenafil. With the reporting of these AEs by healthcare professionals and the collaboration with the police, HSA successfully seized more than 1,000,000 tablets, pills and capsules of 'Power 1 Walnut' and other illegal sexual enhancement products and prosecuted more than 50 illegal sellers of these products.

The H1N1 flu pandemic in 2009 showcased HSA's vaccine vigilance. An active surveillance sentinel site was started in one of the local hospitals and since then, has continued to monitor vaccine-related AEs from the national immunisation programme.

In addition, HSA's pharmacogenomics team had collaborated with public sector hospitals to investigate possible genetic associations behind serious skin reactions. This project led to a significant achievement. In 2013, the recommendation for genotyping of the HLA-B*1502 allele before initiation of carbamazepine therapy in new patients of Asian ancestry was approved as a standard of care in Singapore.

Moving forward

These milestone events in our 25-year-long journey have contributed significantly to our success. Moving forward, the VCB of HSA will continue to build on the strong collaborative networks with local and international partners and pursue new methods for signal detection such as harnessing big data analytics and pharmacogenetics research. We endeavour to be at the forefront of pharmacovigilance excellence and be vigilantes to advance and protect public health and safety.