

**(Draft)**

## **PhAMA's POSITION ON HALAL PHARMACEUTICAL**

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The Pharmaceutical Industry is highly regulated and structured with existing laws and regulations in place by the Ministry of Health.

All products which fall under the category of pharmaceutical within the MOH's Guidance on Classification for drug registrations are required to undergo a stringent evaluation and review processes before they are granted regulatory approval or marketing authorization from the Drug Control Authority (DCA) of Malaysia

The receipt of the regulatory approval from the DCA mandates that the products can now be used for purpose of administration or consumption by the public as it has fulfilled the criterion of quality, safe and efficacy. The aim for the product should be to prevent or control diseases or epidemic in an individual or public at large, with the objective to provide better health outcomes, alleviate sufferings, reduce the contraction of illness and provide for better sustainable public health in the long run.

Halal pharmaceutical on the other hand is a term used for any pharmaceutical products that adheres to the Standard's Guidelines of MS2424: 2010(P) Halal Pharmaceuticals – General Guidelines, which stipulates the terms and specification concerning the criteria of the ingredients on manufacturing requirement as well as the handling of the ingredients during the production processes. This is above and beyond the main objective of making medicines available and accessible for the health of Malaysians.

The application of the voluntary certification is made through JAKIM and is enforceable through the jurisdiction of the Ministry of Domestic Trade, Co- operatives and consumerism.

PhAMA would like to highlight that the pharmaceutical industry itself has set its own universal standards as also ascribed by the Ministry of Health.

As such, PhAMA is of the opinion that the procurement process by MOH should apply similar rigorous evaluation criteria used by the Drug Control Authority (DCA) to access and approve as they have underwent and fulfilled the very stringent regulatory requirement of achieving the quality, safety & efficacy required by DCA itself, the governing and trusted body under MOH.

PhAMA respects the rigorous evaluation criteria of DCA which are mandated on pharmaceuticals before it can be approved for registration. PhAMA understands the extreme need for accurate and stringent evaluation processes due to the nature and complexity of the pharmaceutical itself. For the very same reason, PhAMA is of the opinion that it is necessary to provide distinctive contexts for pharmaceutical products in comparison to food and beverage, cosmetics as well as consumer goods where certification of halal is concern, more so of its very intent and purpose of production as one of the crucial elements in maintaining and improving public health outcomes.

At the moment, the industry is already complying with the labeling guideline issued in March 2009 by the National Pharmaceutical Control Bureau (NPCB), mandating manufacturers of pharmaceutical/supplements products to have mandatory declaration of all active ingredients and excipients that uses animal origin based ingredients /gelatin for capsule case and 'softgel' on the product label.

Furthermore, MOH's terms and conditions concerning the issue on certification of halal for pharmaceutical, is already provided for under its section 13.6 of the Drug Registration Guidance Document (DRGD) which stipulates as follows:

***13.6.1 The use of HALAL logo on the labels of pharmaceutical products will not be allowed.***

PhAMA would like to reiterate that halal certification should not be made as any criteria during the procurement processes. The same rigorous criteria used by DCA when assessing and approving pharmaceuticals for registration should also be the same criteria made by MOH in ensuring access of the product by the public. Ensuring that only safe, efficacious and quality pharmaceuticals are registered in the country is as

significant as ensuring that the pharmaceuticals are made available and accessible to the general public.

Pharmaceuticals contribute greatly to decrease in mortality rate and reduction of contraction of illness by the public at large, which translates into better maintenance of sustainable public health in the long run. As pharmaceuticals has its own scientific based dosage, protocol and regime, PhAMA is of the opinion that qualified healthcare professionals would be the most appropriate person to make the decision to ensure the best healthcare outcomes for the patients as well as the public at large.

Lastly, PhAMA recommends that halal certification should remain “voluntary”. PhAMA would like to recommend that this term should be made explicit in all relevant documents/guidelines for reference of the industry.

PhAMA would also like to reiterate that access and availability of safe, efficacious and quality of life-saving pharmaceuticals should be made based on clinical consideration.

**Pharmaceutical Association of Malaysia (PhAMA)**