

Challenges facing halal vaccine industry

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The recent state visit of King Salman Abdulaziz Al-Saud of Saudi Arabia to Malaysia significantly drew high-impact investments to the country.

This includes a big investment that bolsters Malaysia's plan to become the world's main producer of halal vaccines by next year. A memorandum of understanding was signed between AJ Pharma, a Saudi-based pharmaceutical company under al-Jomaiah Group, and the Halal Development Corporation for an investment of US\$300 million (RM1.32 billion) for facilities and infrastructure in Malaysia.

Despite being promising in terms of the technological and financial prospects, the newly established halal vaccines industry (HVI) is facing complex socio-legal challenges. The industry will need to tackle three challenges: the religious-ethical; safety and manufacturing; and social issues.

Firstly, the halal vaccines and the Islamic legal issues arise from the absence of a standard definition of halal, which has led to differences in the degree of acceptance in different countries.

In some countries, halal requirements are confined to the prohibition of porcine and alcohol-based products that are clearly stipulated in the Quran.

In other countries, the halal standard's requirements include manufacturing tools, raw materials and processes.

Even when it comes to clear-cut halal standards — such as the proscription of alcohol and religiously unclean substances, opinion on the exact specifications vary. For example, the usage of alcohol in vaccines is outlawed in some countries, but permitted within certain limits in other countries. Some Muslim jurists allow the use of alcohol merely as a catalyst, not as the end product.

Differences in opinion and specifications also relate to filthy ingredients, including pus from the sores of diseased animals, horse and calf serum, urine and macerated cancer cells.

The manufacturing of a new vaccine is a complicated process that poses major challenges to the industry. From small-scale production in labs to large-scale productions, it often takes nine to 11 years to develop a new vaccine. Production is subjected to stringent regulatory requirements such as the setting up of syariah-compliant facilities that may, in some cases, cost up to US\$750 million (RM3.3 billion).

Additional costs are also incurred in logistics, as halal vaccines need to be transported separately from non-halal products. There is also a shortage of trained experts capable of auditing the halal manufacturing process.

The lengthy certification process for halal pharmaceutical products might also affect the marketing and sales of new products, which may, in turn, slow down the growth of the halal vaccine market. These factors could discourage leading vaccine manufacturers from entering the global halal vaccine industry.

In terms of social challenges, Malaysian society is witnessing a growing trend of parents refusing vaccinations for their children. The emergence of global anti-vaccine movements and accessibility to unfiltered information are influencing parents' view on the halal status of vaccines.

This growing anti-vaccine trend, if left unchecked, can hinder the market growth of halal vaccine as the movement is not merely apprehensive of the halal status of vaccines but totally rejects vaccination as a valid healthcare procedure.

An HDC report titled "Global Market Potential for Halal Vaccines 2014" indicates that Malaysia is taking various initiatives to develop a standard definition for halal vaccines to keep up with the global market.

Halal vaccines should be free of parts or products of animals that are non-halal, and parts or products of animals that are not slaughtered according to syariah. The entire production line and manufacturing facility, including devices, machines and processing aides must be exclusive, i.e. reserved for the production of halal products. The process of packaging, keeping and transporting the vaccines must be kept separate from those of non-halal products.

Although it involves complicated procedures and higher cost, the good manufacturing process of halal vaccines should never be compromised. There is also a need for suitable premises, storage and transport, adequate laboratory facilities, written and enforced procedures, batch and distribution records and systems to investigate complaints.

The halal certification institution in Malaysia, the Department of Islamic Development Malaysia (Jakim), may also need to establish a special halal certification procedure for biologics like vaccines. This is due to the products' peculiar nature and long and complex manufacturing processes. Lengthy procedures that are unnecessary need to be avoided or eliminated.

These steps are necessary to build better prospects and promote market growth of halal vaccines products in Malaysia.

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