

# ADVANCING HALAL VACCINE CERTIFICATION IN MALAYSIA: EXPLORING THE LEGAL STATUS CRITERIA OF ISLAMIC PRINCIPLES THROUGH *FIQH* RULES

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## ABSTRACT

In Malaysia, it is essential to establish a system for the halal certification of vaccine products. In 2019, the Department of Standards Malaysia (DSM) expanded the scope and criteria of the Malaysian Standard MS 2424, titled Halal Pharmaceuticals—General Requirements, in collaboration with various relevant government entities and the pharmaceutical industry. This standard serves as a comprehensive guideline for halal pharmaceutical and vaccine products, representing a favourable development. The lack of a well-defined legal framework based on Islamic principles derived from the *fiqh* rules and other relevant legal sources currently impedes the implementation of halal certification for vaccine products. Furthermore, prior to this, the status of vaccine products was determined using fatwas issued by the governing body rather than following a halal certification procedure. The potential issuance of halal certification for vaccine products raises concerns

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regarding the public's potential rejection of noncertified vaccines, especially during a pandemic. The primary objective of this study was to conduct an analysis of the Islamic principles employed in the certification procedure for halal vaccines. Qualitative research methodologies were utilized to achieve this objective. Data for this study was collected through document analysis and semi-structured interviews with significant stakeholders. The study's findings suggest that a number of Islamic principles derived from *Fiqh* rules can direct the implementation of halal vaccine certification. The aforementioned principles include the Principles of Halal Substances, *Ḍarūrah*, *Maṣlahah*, *Iḥtiyāt*, *Istiḥālah Tāmmah*, *Istiḥlāk*, and Fatwa.

**Keywords:** Halal; Vaccine; Certification; Principles; Malaysia.

## INTRODUCTION

The emerging halal vaccine sector in Malaysia has emerged as a promising catalyst for economic expansion. With its ability to cater to a sizable yet specialized market, this industry holds significant potential and promises lucrative prospects for growth. The government of Malaysia has begun an attempt to produce the halal vaccine, which is expected to serve as a catalyst for economic growth in the country. Vaccines that are advertised as halal must adhere to the guidelines set forth by Shariah law and fatwa. This entails utilizing substances that are permissible under these religious regulations, while also ensuring their safety and efficacy for human consumption in accordance with required dose, quality standards, and hygienic practices.

Moreover, it is imperative that these products do not encompass any substances that are deemed *najis* according to Shariah law and fatwa. Additionally, they must not have undergone any form of preparation, processing, or manufacturing involving non-halal materials or equipment. Furthermore, it is crucial that the animals used in the

production process adhere to the guidelines set forth by Shariah law and fatwa in terms of their slaughter during the stages of preparation, processing, handling, packing, storage, and distribution. The halal vaccine products are effectively separated from other vaccine products that do not meet the specified standards or any other items that have been deemed non-halal and *najs* according to Shariah law and fatwa.<sup>1</sup>

In order to meet the criteria for halal vaccines and comply with various standards and certification guidelines, it is crucial to adhere to the principles of Shariah law. Previously, Shariah law only addressed the necessity of vaccine use in the context of *darūrah* and for individuals and communities, without specifically addressing halal certification. Consequently, there exists a delay in establishing the parameters for halal vaccine certification in Malaysia, which is contingent upon the legal standing of Islamic principles. Given this information, it is crucial to implement the conclusions of this study.

## PROBLEM STATEMENT

Many pharmaceutical businesses have expressed interest in Malaysia as a potential hub for Southeast Asian and other Muslim markets around the world as a result of the stringent and stringently regulated halal certifications.<sup>2</sup> This appeared to be an opportunity for the vaccine manufacturers to increase their market share. In 2014, the Minister of International Trade and Industry Datuk Seri Mustapa Mohamed said that Malaysia would be a significant manufacturer of halal vaccine for meningitis, hepatitis, and meningococcus.<sup>3</sup> This ambition to create halal

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<sup>1</sup> Department of Standards Malaysia, *MS 2424:2019 Halal Pharmaceuticals General Requirements (First Revision)* (Selangor: Department of Standards Malaysia, 2019), 3-4.

<sup>2</sup> Radzi Razak, "Malaysia could become hub for halal vaccines, says Khairy" *malaymail*, accessed 21 December 2023, <https://www.malaymail.com/news/malaysia/2021/02/17/malaysia-could-becomehub-for-halal-vaccines-says-khairi/1950522>.

<sup>3</sup> Ahmad Badri Abdullah, "Vaksin halal covid-19 demi penuhi keperluan Muslim," *Beirta Harian Online*, accessed 27 December 2023, <https://www.bharian.com.my/rencana/komentar/2020/12/761438/vaksinhalal-covid-19-demi-penuhi-keperluan-muslim>.

vaccines in Malaysia is not a recent development. Soon after that, AJ Pharma Holding Sdn Bhd, a company that is a subsidiary of AJ Vaccines Group, which is based in Saudi Arabia, indicated interest in constructing vaccine production facilities in Malaysia during the first quarter of 2018.<sup>4</sup> Most recently, the vaccine maker MSD Wellcome Trust Hilleman Laboratories Private Ltd (Hilleman) in Delhi linked up with Pharmaniaga, a pharmaceutical firm in Malaysia, on a plan to collaborate on the development of their first vaccine in 2022. The plan calls for the two companies to work together on the project.<sup>5</sup>

As a direct response to these events, Malaysia's ninth Prime Minister, Datuk Seri Ismail Sabri Yaakob, announced the establishment of the Malaysian Genome and Vaccine Institute (MGVI) as well as the National Vaccine Development Roadmap (PPVN). These initiatives are part of an overarching plan to transform Malaysia into a global hub for the manufacture of vaccines and to instill greater faith in their efficacy. This is making it possible for Malaysia to pave the way in the creation of its own vaccine products that are of a high quality, are effective, and are safe, and all of which are in line with the requirements established by the National Pharmaceutical Regulatory Agency (NPRA) and Drug Control Authority (DCA).<sup>6</sup>

In parallel with this, Malaysia amended the Malaysian Standard MS 2424:2012 (first version) in 2019,<sup>7</sup> issuing a new version that has substantial modifications relating to vaccines and the standards that must be met in order to obtain them: Halal Pharmaceuticals-General

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<sup>4</sup> "AJ Pharma to turn Malaysia into halal vaccine hub," *malaymail*, accessed on 28 December 2023, <https://www.malaymail.com/news/malaysia/2018/01/04/aj-pharmato-turnmalaysia-into-halal-vaccine-hub/1546277>.

<sup>5</sup> Radzi Razak, "Malaysia could become hub for halal vaccines, says Khairy" *malaymail*, accessed 21 December 2023, <https://www.malaymail.com/news/malaysia/2021/02/17/malaysia-could-becomehub-for-halal-vaccines-says-khairy/1950522>.

<sup>6</sup> "PM lancar Pelan Hala Tuju Pembangunan Vaksin Negara" *Sinar Harian*, accessed 21 December 2023, <https://www.sinarharian.com.my/article/169913/KHAS/Covid19/PM-lancar-Pelan-Hala-Tuju-Pembangunan-Vaksin-Negara>.

<sup>7</sup> Department of Standards Malaysia, *MS 2424:2019 Halal Pharmaceuticals General Requirements (First Revision)*, 1-19.

Requirements (First Revision) is the name of the standard that was developed in Malaysia and assigned the number MS 2424:2019. However, during that time period and continuing into the present day, Malaysia has been unable to successfully certify any vaccine products as halal.

In the context of the implementation of halal certification for vaccine products, one of the most significant challenges is the absence of precise Islamic legal concepts that can be used to determine whether or not vaccine products adhere to the halal criteria. At this moment in time in Malaysia, the status of halal for vaccines is only determined in general by The National Fatwa Committee Council for Islamic Religious Affairs Malaysia or by fatwas at the state level for the aim of using them against the community. This is because the National Fatwa Committee is the only body authorized to issue decisions at the federal level in Malaysia.

As a consequence of this, the legitimacy of a vaccine is evaluated within the context of the *darūrah* principle; in addition, there is an emphasis placed on the utilization of components that are not derived from pigs or their products. Therefore, research on the legal status of Islamic principles in relation to the determination of halal vaccine certification is required in order to meet the requirements of the halal competent authority and the vaccine sector for the provision of guidance and information.

## **RESEARCH METHODOLOGY**

In order to determine the legal standing of halal vaccine certification, The researchers have chosen a qualitative method for this study. This study selected document analysis and semi-structured interviews for data collection. NVivo 12 qualitative data analysis software was used to analyze data in order to increase efficiency, uncover deeper insights, simplify analysis, and organize and manage data. The research results indicate that a legal framework for halal vaccine certification is already established in the *fiqh* rules and other relevant legal sources.

## ANALYSIS AND RESEARCH FINDING

Based on the study, seven juristic principles are applicable and can be proposed for determining the legal status of halal vaccine certification: the principle of halal substances, the principle of *darūrah* (necessity), the principle of *maṣlahah* (benefit), the principle of *iḥtiyāt* (caution), the principle of *istiḥālah tāmmah* (complete transformation), the principle of *istiḥlāk*, and the principle of fatwa (Malaysia). The NVivo 12 visual representation of this framework is depicted in Figure 1.

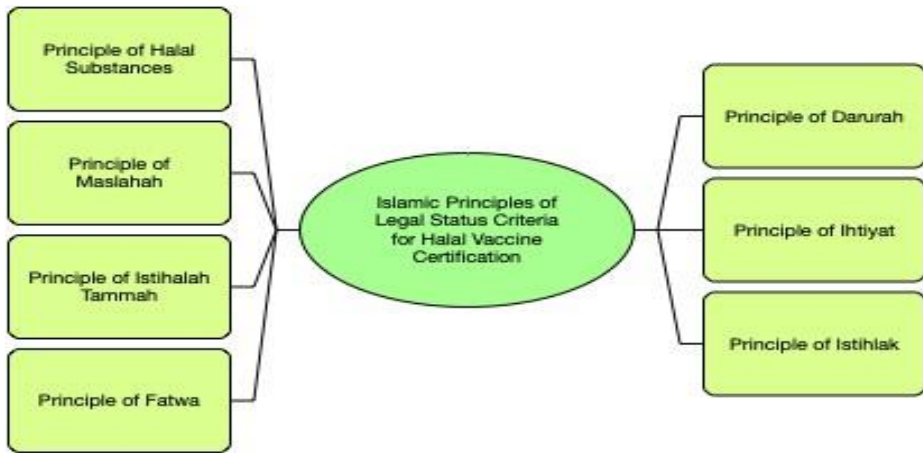


Figure 1. Islamic Principle of Legal Status Criteria for Halal Vaccine Certification

### The Principle of Halal Substances

Muslims uphold the supreme divine law; as a result, the *fiqh* rules and other authoritative sources should be used as the basis for the usage and production of any medication or vaccine. Basically, everything that Allah created on the globe as a gift to his followers, including plants, animals, minerals, bacteria, synthesis materials, natural chemicals, and genetically modified organisms (GMOs), serves to support human existence. They are deserving of praise as a result. However, these creatures—plants, animals, and others—come in many varieties and species, some of which are halal and others haram. Allah established

halal and haram. for the benefit of humans. Allah SWT commands in the Qur'an,

فَكُلُوا مِمَّا رَزَقَكُمُ اللَّهُ حَلَالًا طَيِّبًا وَاشْكُرُوا نِعْمَتَ اللَّهِ إِنْ كُنْتُمْ إِيَّاهُ  
تَعْبُدُونَ إِنَّمَا حَرَّمَ عَلَيْكُمُ الْمَيْتَةَ وَالْدَّمَ وَلَحْمَ الْخِنْزِيرِ وَمَا أُهْلَ لِغَيْرِ اللَّهِ  
بِهِ فَمَنْ أَضْطُرَّ غَيْرَ بَاغٍ وَلَا عَادٍ فَإِنَّ اللَّهَ غَفُورٌ رَحِيمٌ

Translation: *So eat of the lawful and good food which Allah has provided for you and thank the bounty of your Lord if it is Him you serve. He has forbidden for you only carrion and blood and swine flesh and that which has been immolated in the name of any other than Allah; but he who is driven thereto, neither craving nor transgressing, lo! Then Allah is Forgiving, Merciful.*<sup>8</sup>

It is forbidden to use impure materials, such as those made from swine and other flawed substances, to make food, medicines, vaccines, or for any other purpose. The Prophet Muhammad's (PBUH) hadith makes explicit mention of the substances used to manufacture medicines and vaccines. Take the following hadith, which Abu Darda is said to have narrated:

إِنَّ اللَّهَ أَنْزَلَ الدَّاءَ وَالِدَّوَاءَ وَجَعَلَ لِكُلِّ دَاءٍ دَوَاءً فَتَدَاوَوْا وَلَا تَدَاوَوْا  
بِحَرَامٍ

Translation: *Allah has sent down both the disease and the cure, and He has appointed a cure for every disease. So treat yourselves medically, but use nothing unlawful.*<sup>9</sup>

<sup>8</sup> Surah *An-Nahl* 16: 114-115; Department of Islamic Development Malaysia, *Tafsir Al-Rahman, Interpretation of the Meaning of the Quran* (Putrajaya: Department of Islamic Development Malaysia, 2007), 490.

<sup>9</sup> Abū Dāwūd, *Sunan Abī Dāwūd* (Beirut: Dar al-Kitab al-Ilmiyah, 2005), 610.

This shows that people may produce vaccines using a variety of resources, including plants, animals, minerals, microorganisms, synthesis materials, natural chemicals, genetically modified organisms (GMOs), etc. API, API starting material, intermediate, excipient, process aid, solvent, seed, cell bank, cell culture, growth medium, adjuvant, stabilizer, preservative, buffer, and packaging materials are among the materials used in the production of vaccines. All of these substances must adhere to halal principles and be devoid of *najs* or *haram* substances. The method of making vaccines involves four steps. These include propagation, isolation, purification, bulk formulation, and final product. Based on Shariah law, none of the stages can contain anything that isn't halal. The vaccine product will not be certified halal if any non-halal materials are utilized at any point during the manufacturing process.

### The Principle of *Darūrah*

The protection of human life is crucial and given top priority in Islam. Islam is flexible in difficult circumstances. If there is nothing else to eat, drink, consume and their lives are in danger, Islam allows Muslims to consume non-halal foods or materials. Allah SWT mentioned;

إِنَّمَا حَرَّمَ عَلَيْكُمُ الْمَيْتَةَ وَالْدَّمَ وَالْخِنْزِيرَ وَمَا أُهْلَ بِهِ لَعَيْرِ اللَّهِ  
فَمَنْ أَضْطُرَّ غَيْرَ بَاغٍ وَلَا عَادٍ فَلَا إِثْمَ عَلَيْهِ إِنَّ اللَّهَ غَفُورٌ رَحِيمٌ

Translation: *If one is forced by necessity, without willful disobedience, nor transgressing due limits, then he is guiltless. for Allah is Most Forgiving and Most Merciful.*<sup>10</sup>

Islamic scholars have developed a number of *fiqh* norms to govern behavior in emergency situations, including "*Necessities override prohibitions,*" in response to this verse.<sup>11</sup> As a result, many Muslim

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<sup>10</sup> Surah *al-Baqarah*, 2: 173; Department of Islamic Development Malaysia, *Tafsir Al-Rahman, Interpretation of the Meaning of the Quran*, 49.

<sup>11</sup> Abd al-Rahmān Ibn Abī Bakr al-Suyūṭī, *al-Ashbāh wa al-Nazā'ir fī Madhhab al-Shafī'ī* (Beirut: Dār al-Kutub al-'Ilmiyyah, 2001), 1: 168; See also, Aḥmad Ibn Muḥammad al-Zarqā', *Sharḥ al-Qawā'id al-Fiqhiyyah* (Dimashq: Dar al-Qalam, 1993), 185.



scholars permit patients to take medications obtained from non-halal sources. An unavoidable incident or emergency is what the word “*Ḍarūrah*”, which is derived from it, refers to. Many definitions of the notion of *Ḍarūrah* have been provided by Islamic scholars; Wahbah al-Zuhaylī is likely the most thorough and understandable:

*"Ḍarūrah is when a person is in danger or faces a challenge (mashaqqah) that makes them dread for their lives, limbs, dignity, intellect, money, and the things that come after it. And in this instance, he was permitted to carry out a previously forbidden act, to forego a requirement, or to disregard it in order to prevent harm that he believed would be too great for Islam,"*<sup>12</sup>

Islamic scholars agree that when someone is under a time constraint of at least one day and feels hungry but cannot find anything else to eat but illegal food, they are permitted to eat it because it satisfies their need and keeps them from dying. However, opinions among academics on using medical items in an emergency are divided. On the one hand, a hadith attributed to the Prophet Muhammad (PBUH) and related by Abu Hurayrah claims:

حَدَّثَنَا هَارُونُ بْنُ عَبْدِ اللَّهِ، حَدَّثَنَا مُحَمَّدُ بْنُ بَشْرٍ، حَدَّثَنَا يُونُسُ بْنُ  
أَبِي إِسْحَاقَ، عَنْ مُجَاهِدٍ، عَنْ أَبِي هُرَيْرَةَ، قَالَ نَهَى رَسُولُ اللَّهِ صَلَّى  
اللَّهُ عَلَيْهِ وَسَلَّمَ عَنِ الدَّوَاءِ الْخَبِيثِ .

Translation: *Allah's Messenger (PBUH) forbade using unclean medicine.*<sup>13</sup>

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<sup>12</sup> Wahbah al-Zuhaylī, *Naẓariyyah al-Ḍarurah al-Shariyyah*, cet. 5 (Beirut: Mu'assasah al-Risālah, 1997), 67-68.

<sup>13</sup> Abū Dāwud, *Sunan Abī Dāwud* (Beirut: al-Maktabah al-‘Asriyyah, t.t.), hadis no. 3870, 4: 6.

However, other academics contend that because food and medication are both essential for human survival, they can also be considered emergencies. This second group refutes the claim that the Prophet Muhammad (PBUH) ever permitted Abd al-Rahman bin Auf and al-Zubair bin al-Awwam RA to wear silk while they were itching, even though he had previously forewarned them about the prohibition on men donning silk. Anas wrote:

حَدَّثَنِي مُحَمَّدٌ، أَخْبَرَنَا وَكَيْعٌ، أَخْبَرَنَا شُعْبَةُ، عَنْ فَتَادَةَ، عَنْ أَنَسٍ، قَالَ  
رَخَّصَ النَّبِيُّ صَلَّى اللَّهُ عَلَيْهِ وَسَلَّمَ لِلزُّبَيْرِ وَعَبْدِ الرَّحْمَنِ فِي لُبْسِ الْحَرِيرِ  
لِحِكَّةٍ بِهِمَا.

Translation: *The Prophet (PBUH) allowed Al-Zubair and `Abd al-Rahman to wear silk because they were suffering from an itch.*<sup>14</sup>

This would seem to imply that, in certain emergency situations, if there is no halal material that can be utilized to treat illness, then *non-halāl* or *najs*-containing medicine should be employed. The following prerequisites must be met by these extraordinary circumstances:<sup>15</sup>

- i. There are no halal materials available to treat the pertinent condition.
- ii. The item must be used with a medical officer's guidance and approval.
- iii. Only take medicine made from illegal substances if it is really necessary.

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<sup>14</sup> Muḥammad bin Isma‘īl al-Bukhārī, *Ṣaḥīḥ al-Bukhārī*, ed. Muḥammad Zuhayr bin Nāṣir al-Nāṣir (t.tp.: Dār Tūq al-Najah, 1422), hadis no. 5839, 7: 151.

<sup>15</sup> MABIMS, “Joint Guidelines for the Control of Medicines in Islam,” *Department of Islamic Development Malaysia (JAKIM) Official Portal*, accessed on 28 December 2023, <https://www.islam.gov.my/ms/garis-panduan/462-garis-panduan-bersama-kawalan-ubat-ubat-dalam-islam>.

In essence, the application of *darūrah* (the necessity principle), based on specific parameters established by Syariah law for medical products, can be done to implement halal certification for vaccination products by modifying their use in the context of vaccines.

### **The Principle of *Maṣlahah***

Al-Ghazālī and Al- Shāṭibī are two of the most renowned jurists to have addressed the concept of *maṣlahah* indepth. The idea's initial formulation is credited to the former, and its development and improvement to the latter. *Al-Muwafaqat Fi Usul Al-Shariah* by al- Shāṭibī is recognized as the first in-depth study on the topic written by a jurist. Al-Ghazālī defined the *maṣlahah* as the preservation of money, offspring, children, life, and faith. According to him, everything that helps keep these five pillars in place is called *maṣlahah*, while anything that causes their disruption is called *mafsadah* and their eradication is called *maṣlahah*.<sup>16</sup> These definitions lead to the conclusion that people perceive things similarly to one another. *maṣlahah* must be consistent with the goals of the Shariah (*Maqasid* Shariah), it cannot be founded in lust, and it must include two crucial components: gaining advantage and avoiding harm.

*Maṣlahah* can also be broken down into three categories based on its strength or necessity. The first is *daruriyyah*, or essentials, which are the activities and things necessary for upholding the five pillars of communal and personal existence. Ignoring these causes complete disturbance and turmoil in life. The second is *hajīyyah*, which refers to all products and acts that are necessary to lessen or eliminate difficulties in life but are not absolutely necessary to uphold the five pillars. Last but not least, *taḥsinīyyah*, or "refinements," refers to activities and things that go beyond the realm of the practical and whose accomplishment enhances and brings about that which is desirable, such as jewelry, fun activities, and so on.<sup>17</sup>

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<sup>16</sup> Abū Ḥāmid bin Muḥammad bin Muḥammad al-Ghazālī, *al-Mustasfā min 'Ilm al-Usūl*, 1st Edition (Beirut: Mu'assasah al-Risālah, 1997), 1: 416.

<sup>17</sup> Ibrāhīm Mūsā al-Shāṭibī, *al-Muwāfaqāt fi Uṣūl al-Shari'ah*, (Beirut: Mu'assasah al-Risalah, 1997), 2: 26.

What role do the terms *ḍarūrīyyah*, *ḥajīyyah*, and *taḥsinīyyah* have in the certification of halal vaccines? *ḍarūrīyyah* is applicable in that the creation and administration of vaccines are essential, and that the consequences of failing to immunize could be severe injury or even death. Of course, halal materials and ingredients are recommended. However, using haram components occasionally may be acceptable in particular circumstances. For instance, the COVID-19 vaccine (i.e., in the event of a pandemic) or vaccinations for immunizations to shield children from damaging or potentially fatal diseases like polio, diphtheria, measles, mumps, and others.

While *ḥajīyyah*, the use or production of this vaccine is moderately vital, and failure to do so could cause harm or illness to a person or patients. Its use can also be used to medications that are not vaccines. Examples of over-the-counter (OTC) medications include cough and fever medications, which are sold without a prescription at pharmacies, drug stores, and supermarkets and do not cause harm or death when used as directed. When it comes to the utilization of raw materials in the manufacturing process, alternatives to non-halal sources are available.

Last but not least, *taḥsinīyyah* is a concept that can be understood as not taking or producing something will not result in harm or death. Its use is also implemented against pharmaceuticals that do not fall under the vaccine category, for example, traditional medicine, dietary supplements, or nutraceuticals, where its use is the only *taḥsinīyyah*, not taking it will not result in harm or death, and there are alternative or complementary treatments.

### **The Principle of *Iḥtiyāṭ***

The verb *fi 'il khumasi* (verb with five letters) *ihṭata*, which means to maintain, block, and take care of things, is the root of the word *iḥtiyāṭ*. *Iḥtiyāṭ* is the guideline that states that one should use caution, abstain from doing anything dubious, and complete duties that appear to be essential when there is uncertainty.<sup>18</sup> This method is founded on the

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<sup>18</sup> Muḥammad Ibn Ya'qūb al-Fayruḏabādī, *al-Qāmūs al-Muḥīṭ*. 2nd Edition (Beirut: Mu'assasah al-Risālah, 1987), 856.

notion that the legal agent is always under a religious responsibility, regardless of whether the divine-law ruling is clearly stated or not. This verse, revealed by Allah S.W.T., is one of many in the Qur'an that serve as the foundation for the application of *ihtiyāf*:

يَا أَيُّهَا الَّذِينَ ءَامَنُوا اجْتَنِبُوا كَثِيرًا مِّنَ الظَّنِّ إِنَّ بَعْضَ الظَّنِّ إِثْمٌ وَلَا  
تَجَسَّسُوا وَلَا يَغْتَب بَّعْضُكُم بَعْضًا ؕ أَيُحِبُّ أَحَدُكُمْ أَن يَأْكُلَ لَحْمَ أَخِيهِ  
مَيْتًا فَكَرِهْتُمُوهُ ؕ وَاتَّقُوا اللَّهَ ؕ إِنَّ اللَّهَ تَوَّابٌ رَّحِيمٌ

Translation: *O ye who believe! Avoid suspicion as much (as possible): for suspicion in some cases is a sin: And spy not on each other, nor speak ill of each other behind their backs. Would any of you like to eat the flesh of his dead brother? Nay, ye would abhor it...but fear Allah: for Allah is Oft-Returning, Most Merciful.*<sup>19</sup>

In this verse, Allah SWT warns believers against prejudice in order to prevent them from committing the evil that prejudice entails. Al-Numan bin Bashir cited the Prophet Muhammad (PBUH) as saying:

الْحَلَالُ بَيِّنٌ وَالْحَرَامُ بَيِّنٌ وَبَيْنَ ذَلِكَ أُمُورٌ مُّشْتَبِهَاتٌ لَا يَدْرِي كَثِيرٌ مِّنَ  
النَّاسِ أَمِنَ الْحَلَالِ هِيَ أَمْ مِنَ الْحَرَامِ فَمَنْ تَرَكَهَا اسْتَبْرَأَ لِدِينِهِ وَعَرْضِهِ  
فَقَدْ سَلِمَ وَمَنْ وَّاقَعَ شَيْئًا مِنْهَا يُوشِكُ أَنْ يُوَاقِعَ الْحَرَامَ كَمَا أَنَّ مَنْ  
يَرَعَى حَوْلَ الْحِمَى يُوشِكُ أَنْ يُوَاقِعَهُ أَلَا وَإِنَّ لِكُلِّ مَلِكٍ حِمًى أَلَا وَإِنَّ  
حِمَى اللَّهِ مَحَارِمُهُ

Translation: *The lawful is clear, the unlawful is clear, and between that are topics that are questionable (not clear); many people do not know whether it is lawful or unlawful. Therefore, whoever quits it to uphold his*

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<sup>19</sup> Surah *al-Hujurat* 49: 12; Department of Islamic Development Malaysia, *Tafsir Al-Rahman, Interpretation of the Meaning of the Quran*, 1016.

*religion and his honor will be protected, and whoever falls into something related to them will soon have engaged in illegal activity. Similar to how someone would eventually end up within a sanctuary if they allowed their animals to graze there. Every king does have a sanctuary (pasture), and Allah rendered that refuge forbidden.*<sup>20</sup>

So as a precaution (*iḥtiyāt*), the Prophet Muhammad (PBUH) instructed people to avoid stumbling upon unlawful items by exercising care (*iḥtiyāt*). This implies that when a law is uncertain as to whether it is permitted or *ḥarām*, the case for *ḥarām* or unlawfulness, is stronger, and we must avoid it (even if it has the potential to be halal).<sup>21</sup> A source of *iḥtiyāt* based on athar Sahabat is also available. Abdullah ibn Umar RA was questioned about wearing soiled or *najs*-contaminated garments in this source. He said he needed to wash all of his clothes because he didn't know where they were. This conveys a certain level of caution (*iḥtiyāt*) because it is unclear precisely which components are dirty.<sup>22</sup>

It is important to remember that vaccine are heavily regulated precisely because of the considerable risk they pose in terms of their safety and adverse effects of use when discussing halal certification for vaccine products. Antigens, membrane separation and purification units, host cells for virus production, growth media for host-cell consumption, proteolytic enzymes - trypsin, and stabilizers are all frequently used in the vaccine manufacturing process. Additionally, vaccine production is always associated with the use of questionable sources (in terms of halal or *ḥarām* status). To assess whether the use of a drug in a vaccination is permitted by Shariah law or not, it is necessary in this context to apply the precautionary principle, or *Iḥtiyāt*.

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<sup>20</sup> Muḥammad bin 'Isā bin Sawrah al-Tirmidhī, *Sunan al-Tirmidhī*, ed. Muḥammad Fu'ād 'Abd al-Bāqī (Mesir: Syarikah Maktabah wa Maṭba'ah Muṣṭafā al-Bābī al-Ḥalabī, 1975), hadis no. 1205, 3: 503.

<sup>21</sup> Muḥammad Ibn 'Ali Ibn Daqīq al-'Id, *Iḥkām al-Aḥkām Sharḥ 'Umdah al-Aḥkām*, (Cairo: Maṭba'ah al-Sunnah al-Muḥammadiyah, n.d.), 2: 278.

<sup>22</sup> Abdullah Ibn Muḥammad Ibn Abī Shaybah, *al-Muṣannaḥ fī al-Aḥādīth wa al-Athār*, (Riyāḍ: Maktabah al-Rusyd, 1409H), 1: 112.

## The Principle of *Istihālah* Tāmmah

The term "*istihālah*" originates etymologically from the Arabic verb (حال) or (حول) which means to change.<sup>23</sup> It's called an exchange, transformation, or mutation in English.<sup>24</sup> In terms of *fiqh*, it is defined by scholars with various definitions. Among them is the transformation of a substance from one characteristic to a different characteristic. Additionally, Ibn 'Abidin from the Hanafī school has defined it as the transition from one reality to another.<sup>25</sup> *Istihālah* encompasses three types of transformation: the first is the change of physical attributes; the second is the change of chemical components; and the third is the change of both chemical and physical changes.<sup>26</sup>

All Islamic scholars concur that *istihālah* is a method of cleansing impure or forbidden objects, albeit having various viewpoints and methods. The basics of the Qur'an, the Hadith, and other relevant legal texts serve as the basis for this theory. According to the Qur'an, Allah SWT says:

وَإِنَّ لَكُمْ فِي الْأَنْعَامِ لَعِبْرَةً ۗ نُسْقِيكُمْ مِمَّا فِي بُطُونِهِمْ مِنْ بَيْنِ فَرْثٍ وَدَمٍ  
لَبِنًا خَالِصًا سَائِعًا لِلشَّارِبِينَ

Translation: *And verily in cattle (too) will ye find an instructive sign. From what is within their bodies, between excretions and blood, We produce, for your drink, milk, pure and agreeable to those who drink it.*<sup>27</sup>

<sup>23</sup> Muḥammad bin Mukrim Ibn Manzūr, *Lisān al-‘Arab*, (t.tp.: Dār Sadir, 1990), 185.

<sup>24</sup> Ḥārith Sulaymān al-Farūqī, *Mu‘jam al-Qanūnī* (Lebanon: Lebanese Studies, 1991), 23.

<sup>25</sup> Abū Muḥammad, Izz al-Dīn ‘Abd al-‘Aziz ‘Abd al-Salām al-Sulamī, *al-Qawā‘id al-Kubrā, al-Mausu‘ah bi Qawā‘id al-Aḥkām fī Iṣlāḥ al-Anām* (Dimashq: Dār Qalam, 2000), 1: 520.

<sup>26</sup> Jamaludin, Mohammad Aizat. "Fiqh Istihalah: integration of science and islamic law." *Revelation and Science* 2, no. 02 (2012): 118.

<sup>27</sup> Surah *al-Nahl* 16: 66; Department of Islamic Development Malaysia, *Tafsir Al-Rahman, Interpretation of the Meaning of the Quran*, 478.

This verse makes it very clear that milk produced by animals is holy and may be consumed despite being wedged between the forbidden substances of blood and feces. This milk is produced using the animal's food's blood. Only a small portion of the remaining processed goods, which are impurities, contain meat, blood, or milk. In verse 69 of Surah al-Nahl, which describes honey made by bees, similar hints are found:

ثُمَّ كُلِي مِن كُلِّ الثَّمَرَاتِ فَاسْلُكِي سُبُلَ رَبِّكِ ذُلُلًا ۗ يَخْرُجُ مِنْ بُطُونِهَا  
شَرَابٌ مُّخْتَلِفٌ أَلْوَانُهُ فِيهِ شِفَاءٌ لِّلنَّاسِ ۗ إِنَّ فِي ذَٰلِكَ لَآيَةً لِّقَوْمٍ  
يَتَفَكَّرُونَ

Translation: *Then to eat of all the produce (of the earth), and find with skill the spacious paths of its Lord: there issues from within their bodies a drink of varying colours, wherein is healing for men: verily in this is a sign for those who give thought.*<sup>28</sup>

According to the scripture above, honey made by bees is permissible to consume even though it comes from the stomachs of insects. As you are aware, the hadith specifically forbids killing bees, hence bees are among the insects that people are not allowed to consume. Additionally, there are numerous instances of the application of conventional techniques that have been supported by hadith, such as vinegar made from *khamar* (liquor) and musk made from deer blood and clean animal skin. It is well known that *khamar* is intoxicating and that intoxication is a grave sin, which is why *khamar* is converted into vinegar. Aisyah RA claims that the Prophet Muhammad (PBUH) declared in a hadith that the vinegar brought from the wine was pure and halal and that this is why:

نِعْمَ الْأُدْمُ - أَوِ الْإِدَامُ - الْحَلُّ

Translation: *The best of condiments or condiment is vinegar.*<sup>29</sup>

<sup>28</sup> Surah *an-Nahl* 16: 69; *Ibid.*, 479.

<sup>29</sup> Muslim bin al-Ḥajjāj, *Ṣaḥīḥ Muslim*, ed. Muḥammad Fu'ad 'Abd al-Bāqī (Beirut: Dār Iḥyā' al-Turāth al-Arabī, t.t.), hadis no. 2051, 3: 1621.



Given that deer blood is used to make sacred musk aroma, it is obvious that drinking blood is prohibited because it belongs to the same category as feces. However, when processed using a specific way, a deer's blood (the portion of the gland center of the male deer) turns into a holy aroma. Based on a hadith attributed to the Prophet (PBUH):

أَطْيَبُ الطَّيِّبِ الْمِسْكُ

Translation: *Musk is the best perfume.*<sup>30</sup>

Similarly, the Prophet (PBUH) ordered his companions to take advantage of sacred animal skins that were consumed but died without being slaughtered; this is according to Saudah RA.

رَوَّجَ النَّبِيُّ صَلَّى اللَّهُ عَلَيْهِ وَسَلَّمَ قَالَتْ مَاتَتْ لَنَا شَاةٌ فَدَبَعْنَا مَسْكَهَا  
ثُمَّ مَا زِلْنَا نَنْبُدُ فِيهِ حَتَّى صَارَتْ شِنًّا

Translation: *(the wife of the Prophet) One of our sheep died and we tanned its skin and kept on infusing dates in it till it was a worn out water skin.*<sup>31</sup>

We discover that the *istihālah* concept should not be viewed as being either too open or too rigid by taking into account the opinions of Islamic scholars on its application. The ideal approach is *istihālah tāmmah*, or flawless transformation, to direct halal vaccine certification processes. Three different types of transformation are covered in *istihālah tāmmah*: changing physical qualities, changing chemical components, and changing both physical and chemical components. This issue can be utilized as a factor in determining eligibility for halal vaccine certification because the creation of vaccine products necessitates significant processing (transformation) and the DNA present in a vaccine may not be traceable or even exist as DNA.

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<sup>30</sup> Abū ‘Abd al-Raḥmān Aḥmad bin Shu‘ayb al-Nasā’ī, *Sunan al-Nasā’ī*, ed. ‘Abd al-Fattāh Abū Ghuddah (Ḥalab: Maktab al-Maṭbū‘āt al-Islāmiyyah, 1986), hadis no. 1905, 4: 39.

<sup>31</sup> Muḥammad bin Isma‘īl al-Bukhārī, *Ṣaḥīḥ al-Bukhārī*, ed. Muḥammad Zuhayr bin Nāṣir al-Nāṣir, hadis no. 6686, 8: 139.

## The Principle of *Istihlāk*

Some scholars assert that *istihlāk* is a component of *istihālah*. They cited the words of Ibn Taymiyyah in support of their position: "In general, this opinion is correct because Allah SWT has prohibited *al-khābith* substances, such as blood, carcasses, pork, etc. If the substance of *alkhābith* falls into water or another liquid, decomposes, and no longer contains blood, carcasses, or pork, just as wine does when it falls into liquid, the drinker is not considered to be imbibing wine.

*Istihlāk* is derived from the Arabic root, which means "perish". This *istihlāk* alludes to the process of decay. In this instance, a contaminant is being eliminated. Several procedures could eliminate or demolish impure components. The Islamic school of thought frequently uses the example of combining a dash of alcohol with a great deal of water. This theoretical concept of *istihlāk* entails combining a small amount of impure element with other advantageous, clean, all, and abundant elements to the point where the impure element loses its characteristics, such as its color, odor, and flavor. According to Shariah law, this type of blending would eradicate the impure characteristics of the final product.<sup>32</sup>

*Istihlāk* is also defined as something that loses the characteristics of the original material because it decomposes in water or a liquid with a greater volume, dissolving in it and then having an effect on the law. Among the examples is impure water that is added to or mixed with a large quantity of clean water, and then punished as clean when it is discovered that the water is colorless, odorless, and does not have a disagreeable flavor.<sup>33</sup>

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<sup>32</sup> Al-Zuhaylī, Wahbah, *Qadaya al-Mu'asirah* (Damascus: Dar al-Fikr, 2007), 72.

<sup>33</sup> Mamat, Zulfaqar. "Istihalah In Malaysian Fatwa: Istihalah Dalam Fatwa Di Malaysia." *Journal of Fiqhiyyat* 1, no. 1 (2021): 30-38. See also; *Majlis Penyelidikan dan Fatwa Eropah*. 2013. Keputusan Mesyuarat Kali ke-23. 25-28 Jun 2013. Sarajevo. Bosnia; Ab Rahman, Zulfaqar Mamat. "Pemakaian Kaedah Istihlāk dan Istihalah dalam Penentuan Produk Halal di Malaysia Berdasarkan Bidangkuasa Perundangan dan Keputusan Hukum Muzakarah Jawatankuasa Fatwa Majlis Kebangsaan Bagi Hal Ehwal Ugama Islam Malaysia." *Journal of Fatwa Management and Research* (2019), 24.

In general, the method of *istihlāk* and *istihālah* is derived from the source of Allah SWT's revelation, as recorded in the Qur'an:

وَإِنَّ لَكُمْ فِي الْأَنْعَامِ لَعِبْرَةً ۚ نُسْقِيكُمْ مِمَّا فِي بُطُونِهِ ۚ مِنْ بَيْنِ فَرْثٍ  
وَدَمٍ لَبَنًا خَالِصًا سَائِغًا لِلشَّارِبِينَ

Translation: *And verily in cattle (too) will ye find an instructive sign. From what is within their bodies, between excretions and blood, We produce, for your drink, milk, pure and agreeable to those who drink it.*<sup>34</sup>

In the meantime, the *istihlāk* approach is also founded on a well-known hadith in which the Prophet SAW is cited as saying,

سُئِلَ رَسُولُ اللَّهِ صَلَّى اللَّهُ عَلَيْهِ وَسَلَّمَ عَنِ الْمَاءِ وَمَا يَنْبُؤُهُ مِنَ الدَّوَابِّ  
وَالسَّبَاعِ فَقَالَ صَلَّى اللَّهُ عَلَيْهِ وَسَلَّمَ " إِذَا كَانَ الْمَاءُ قُلَّتَيْنِ لَمْ يَحْمِلِ  
الْحَبْثُ "

Translation: *The Prophet (PBUH) was asked about water (in desert country) and what animals and wild animals frequent. When there is sufficient water to fill two vessels, there is no impurity.*<sup>35</sup>

The application of this principle to the production of vaccines may be expanded to include the use of trypsin. It suggests that, despite the use of porcine trypsin in the initial cultivation of the seed strain, the extensive purification process eliminates any detectable traces of porcine DNA or trypsin in the final vaccine product. Consequently, it is permissible from a halal perspective, so long as the critical criteria of purity and absence of haram (prohibited) elements are met during vaccine production. In fact, 15–20 years ago, a biocatalyst called porcine pancreas trypsin enzyme was used in the cultivation of certain vaccine seed strains to

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<sup>34</sup> Surah *al-Nahl* 16: 66; Department of Islamic Development Malaysia, *Tafsir Al-Rahman, Interpretation of the Meaning of the Quran*, 478.

<sup>35</sup> Abū Dāwud, *Sunan Abī Dāwud*, hadis no. 63, 1: 17.

liberate the vaccine seed from cultivation. The vaccine seed was then rinsed and purified 65 million times (over 8–10 years) via ultrafiltration, rendering trace elements of trypsin undetectable.

## **The Principle of Fatwa**

In Islam, the formulation of religious judgments, known as *ifta*, is an essential practice, notably in the field of medicine, which includes the production of vaccines. It involves the interpretation and justification of divine statutes, and as new issues or challenges frequently demand legal clarification, its significance cannot be denied. New difficulties or challenges usually require legal clarification. Fatwa means legal opinion concerning Islamic law issued by competent Muslim scholar. In Malaysia, the process of issuing fatwas is governed by various legal measures that have been passed. In every state and federal territory, there is a *mufti* who has been ordained, and the ruler is also involved in the process of legislating and enforcing fatwas. In Malaysia context, fatwa means any religious decree which is verified by an authority related to the religion of Islam and is approved by the Yang di-Pertuan Agong to be in force in the Federal Territory or by the Ruler of any State to be in force in that state within Malaysia.<sup>36</sup>The foundation for halal certification administration in terms of fatwas is the National Fatwa Committee Council for Islamic Religious Affairs Malaysia. Fatwas issued at the state level are also utilized, but their applicability is restricted to the state that issued them. This is due to the fact that each state has its own unique perspective on the law. As a standard practice, the process of issuing a fatwa in Malaysia will also involve the issuance of a final *qawl* that is derived from the Shafi'i school of thought.

In the context of the application of halal vaccine certification, a legal view, also known as a fatwa, is extremely required, particularly when it involves the use of critical materials. The evaluation of the ingredients and processing will be carried out based on the decision of the fatwa for the halal competent authority as well as the producer of the

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<sup>36</sup> Department of Standards Malaysia, *MS 2424:2019 Halal Pharmaceuticals General Requirements (First Revision)*, 7.

vaccine product. This evaluation will serve as a reference and guidance for both of these parties.

The issuing of fatwas occupies the pinnacle of importance on the list of considerations relevant to the introduction of halal certification for vaccination products in Malaysia. In the context of halal vaccine certification, the principles of halal substances, *ḍarūrah* (necessity), *maṣlahah* (benefit), *iḥtiyāt* (caution), *istiḥālah tāmmah* (complete transformation), the principle of *istiḥlāk*, and the principle of fatwa (Malaysia) will be helpful in the process of formulating a fatwa conclusion. These principles can be thought of as the fatwa's guiding principles or procedures.

The process of obtaining halal certification for vaccines must involve laboratory analysis, which plays an essential part in ensuring that items satisfy the requirements and standards of halal. Laboratory analysis also includes a variety of scientific tests and exams that are performed on products to verify their conformity with halal criteria. The following is a rundown of the reasons why laboratory analysis is important for halal certification: ingredient verification, crosscontamination checks, processing methods, microbiological analysis, nutritional content verification, allergen testing, quality assurance and documentation, and transparency because laboratory analysis provides objective and scientific evidence to support halal certification approval. In the context of halal certification for vaccines, laboratory analysis can serve as a foundation or support for the principles of fatwa and others that have been discussed previously through the analysis of the vaccine product. This analysis helps ensure that the halal vaccines produced are truly pure and free from any non-halal elements or contaminants.

## CONCLUSION

The study findings indicate the presence of seven pertinent legal principles that are advocated for the successful implementation of halal vaccine certification. The following are the fundamental principles pertaining to halal vaccine: the principle of halal substances, the principle of *darūrah* (necessity), the principle of *maṣlahah* (benefit), the principle of *iḥtiyāt* (caution), the principle of *istiḥālah tāmmah* (complete transformation), the principle of *istiḥlāk*, and lastly, the principle of fatwa as applied in Malaysia. The aforementioned concepts were derived from the general principles that are present in the *fiqh* rules and other authoritative references. The determination of what qualifies as a halal vaccine is subject to varying perspectives among jurists. However, these divergences can be reconciled by considering the norms and principles that are relevant to Malaysia. The seven elements outlined above will facilitate the determination of the legal status of vaccine within the framework of halal certification.

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