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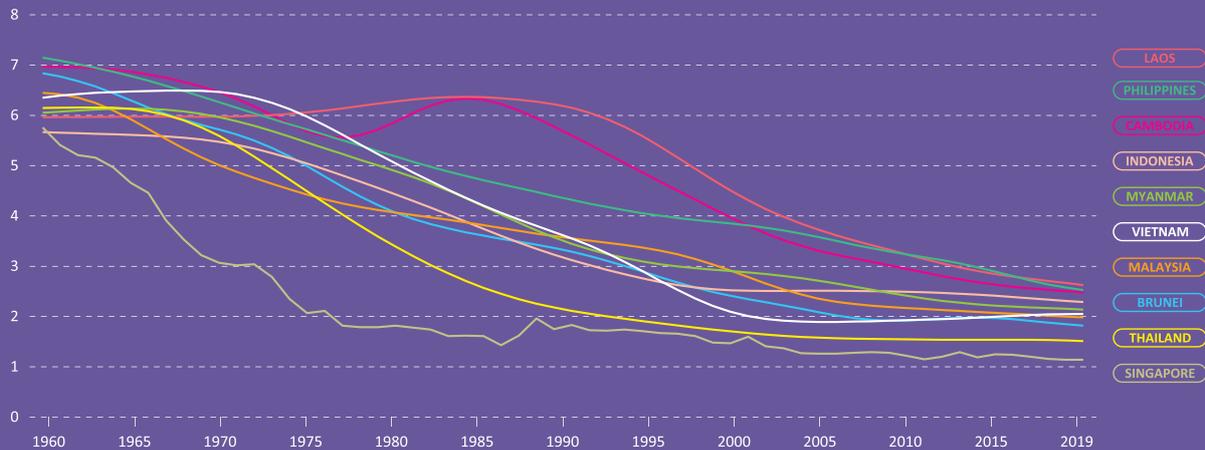
● JULY 2021

In-Vitro Fertilisation Laws and Regulations

IN-VITRO FERTILISATION LAWS AND REGULATIONS

In recent years, ASEAN countries have been reaching new heights in economic growth. However, fertility rates have been declining rapidly. Based on World Bank Data, the fertility rate of all ASEAN countries have dipped below the replacement level at 2.1 children per woman, which is the rate required to enable a population to replace itself from one generation to the next in order to sustain the population levels.

Data on the declining fertility rates in ASEAN



Fertility issues, challenges in accessing infertility treatments, late marriages, delay in giving birth, economic and career reasons, surge in living and education costs, and the mindset of having less children to provide better quality of life are some of the contributing factors to the declining fertility rate. It is expected that with further economic growth, the fertility rate will further decline. Such decline will have dire consequences, socially and economically, to a country as the population size will shrink, society will age, workforce will decrease, and taxpayers will reduce. These will cause a decline in economy and lower quality of life.

This is a looming crisis not only in ASEAN, but across the world.

Nonetheless, this has provided huge opportunities for the in-vitro fertilisation (“IVF”) industry, which is a type of assisted reproductive technology (“ART”) used to treat fertility or genetic problems to assist with the conception of children. As of now, this industry is still relatively undersupplied in ASEAN countries. This may be due to the low demand due to high costs of ART treatments, cultural barriers and religious reasons in some of the ASEAN countries, and the lack of proper IVF laws and regulations being in place.

However, we believe that this industry will thrive as people begin to overcome the cultural barrier and countries start to take measures to provide financial support and incentives to prevent the declining fertility rates. Such measures have already been introduced in Singapore and Malaysia.

This publication provides a snapshot of the various aspects and considerations of IVF laws regulations (including the feasibility of establishing an ART facility to conduct IVF, egg freezing and surrogacy) across ASEAN to date. As the industry is still in its infancy, IVF laws and regulations are still quite scarce for some of the ASEAN countries. We are certain that further laws and regulations will be enacted in the near future following the growth of the IVF industry.



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IVF & SURROGACY REGULATIONS IN ASEAN

IVF REGULATIONS		SURROGACY REGULATIONS
No specific laws or regulations	 BRUNEI	No specific laws or regulations, however Brunei is Syariah-compliant thus it could be deemed as an infraction of religious sensibilities.
No specific laws or regulations	 CAMBODIA	Prohibited
Minister of Health Regulation No. 43 of 2015 regarding Provisions of Assisted Reproductive Services or Pregnancy Outside of the Natural Way	 INDONESIA	Prohibited
No specific laws or regulations	 LAOS	No specific laws or regulations
No specific laws or regulations. Guidelines are issued by the Ministry of Health and Malaysian Medical Council.	 MALAYSIA	Prohibited for Muslims. While there is no prohibition for non-Muslims, it is still not advisable.
No specific laws or regulations	 MYANMAR	No specific laws or regulations
No specific laws, however the Philippine Family Code recognises artificial insemination.	 PHILIPPINES	No specific laws or regulations
<ul style="list-style-type: none"> • Private Hospitals and Medical Clinics Act • Private Hospitals and Medical Clinics Regulations • Licensing Terms and Conditions on Assisted Reproduction Services 2020 	 SINGAPORE	Not allowed to be carried out by IVF centres
<ul style="list-style-type: none"> • Sanatorium Act • Protection of a Child Born by Medically Assisted Reproductive Technology Act 	 THAILAND	Allowed
<ul style="list-style-type: none"> • Vietnam's WTO Schedule of Specific Commitments in Services • Law on Medical Examination and Treatment No. 40/2009/ND-CP dated 23 November 2009 • Decree No. 10/2015/ND-CP dated 28 January 2015 • Decree No. 98/2016/ND-CP dated 1 July 2016 • Decree No. 155/2018/ND-CP dated 12 November 2018 • Circular No. 57/2015/TT-BYT 	 VIETNAM	Allowed



Laws and Regulations on IVF	<p>There are no specific laws or regulations on IVF in Malaysia. However, guidelines have been issued by government departments and association (the Ministry of Health (“MOH”) and the Malaysian Medical Council (“MMC”)) such as the Standards for Assisted Reproductive Technology-Embryology Laboratory and Operation Theatre (“ART Guideline”) and the ‘Assisted Reproduction’ - Malaysian Medical Council MMC Guideline 003/2006 (“MMC Guidelines”) which set minimum standards and requirements for any ART facilities operating and any ART procedures in Malaysia.</p> <p>Further, ART facilities which falls under the definition of a “private ambulatory care centre” are also regulated and licensed by the Private Healthcare Facilities and Services Act 1998.</p>
Regulatory authority	MOH
Regulatory Framework	
Egg Freezing	<p>The ART Guidelines sets out in detail the guidelines on the ART procedures (including preparation prior to such procedure, the collection and handling of gametes, quality assurance of the examination procedures, and reporting of results).</p> <p>The MMC Guidelines also provides that all persons undergoing ART should be adequately tested for transmittable diseases before any procedures are conducted. Further, no ART treatment can be given without their written consent to the particular treatment.</p>
Surrogacy	<p>The National Council of Islamic Religious Affairs has issued a fatwa prohibiting surrogacy for Muslims.</p> <p>While there seems to be no prohibition for non-Muslims, the MMC Guidelines provides that a surrogate arrangement is not acceptable to most of the major religion in the country and can also potentially lead to many legal dilemmas.</p>

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Laws and Regulations on IVF	<p>Private Hospitals and Medical Clinics Act The operation of an IVF facility constitutes an operation of a medical clinic which falls under the Private Hospitals and Medical Clinics Act. The Act provides that no premises can be used as a medical clinic without a licence.</p> <p>Private Hospitals and Medical Clinics Regulations Further, as IVF business is considered as a special care service, the medical centre must obtain prior approval from the Director of Medical Services. The Regulations also provide that a medical practitioner (namely, a person registered under the Medical Registration Act) must manage the medical clinic.</p> <p>Licensing Terms and Conditions on Assisted Reproduction Services 2020 Imposes conditions on the licence and approval of medical clinics and centres. Conditions are imposed on facilities, clinical and laboratory practices, record keeping, quality and risk management, and others. The medical centre conducting assisted reproduction services (including IVF) (“AR Centre”) must only permit medical practitioners and embryologists, all of whom must be authorised by the Director of Medical Services to perform clinical and laboratory work in assisted reproduction. At minimum there must at least be one authorised medical practitioner and two authorised embryologist working at the AR Centre.</p>
Regulatory authority	Ministry of Health
Regulatory Framework	
Egg Freezing	AR Centres must ensure that its laboratories have appropriate labelling systems for identifying and tracing gametes/embryos from collection to freeze.
Surrogacy	Surrogacy activities, namely where a woman is artificially impregnated whether for monetary consideration or not, with the intention that the child is to be given and adopted by some other person or couple, are not allowed to be carried out by AR Centres.

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<p>Laws and Regulations on IVF</p>	<p>There are no specific laws and regulations on IVF in Cambodia.</p> <p>Depending on the activities of the IVF clinics, its operation may be governed under the Law on the Management of Donation and Transplantation of Human Cells, Tissue, and Organ dated 9 August 2016 (“LDTCTO”) and Prakas No. 679 on the Management of Human Blood, Reproductive Cells, Bone Marrow and Cells issued by the Ministry of Health dated 24 October 2016 (“Prakas No. 679”).</p> <p>Further, any institution providing services related to ART will need to seek prior approval from the Ministry of Health.</p>
<p>Regulatory authority</p>	<p>Ministry of Health</p>
<p style="text-align: center;">Regulatory Framework</p>	
<p>Egg Freezing</p>	<p>Under LDTCTO, egg freezing falls under the definition of transplantation of human cells, tissues, and organs. The medical professionals in charge of the egg freezing are required to take measures to preserve the egg.</p> <p>While egg freezing is provided for under the law, there are currently no publicly available guidelines or principles issued by the MOH to govern the technical standards of egg freezing.</p>
<p>Surrogacy</p>	<p>Although the provision of service of ART is permitted under Prakas No. 679, surrogacy is strictly prohibited. The Prakas also expressly bans any creation of embryo for commercial or any other purposes other than to assist legally married couples to have a child.</p> <p>It is worth noting that the Cambodian government is currently in the process of drafting a law on surrogacy. However, there is no official indication from the government on the timeline regarding the passing of such law.</p>

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Laws and Regulations on IVF	<p>Minister of Health Regulation No. 43 of 2015 regarding Provisions of Assisted Reproductive Services or Pregnancy Outside of the Natural Way (MoH Regulation 43/2015) provides that IVF (or “Assisted Reproductive Services”) can only be conducted in general hospitals or specialised mother and child hospitals.</p> <p>An IVF Licence can be issued to a health service facility intending to conduct Assisted Reproductive Services. The IVF Licence is issued by the Director General of Community Services on behalf of the Minister of Health based on the recommendation provided by the assessment team, which consists of representatives from the Ministry of Health and Perhimpunan Fertilisasi In Vitro Indonesia (PERFITRI). The assessment team will assess the compliance requirements in the provision of Assisted Reproductive Services by verifying documents and conducting site visit.</p> <p>In order to provide Assisted Reproductive Services, the hospital must comply with certain manpower, administrative and management, building facilities and infrastructure requirements.</p> <p>The suitable line of business for IVF clinic can be found in Head of Indonesia Central Statistic Board Regulation No. 2 of 2020 regarding Indonesian Standard Industrial Classification Code. Minister of Health Regulation No. 3 of 2020 regarding Classification and Licensing of Hospitals sets out the requirements to set up a clinic business in Indonesia.</p>
Regulatory authority	Ministry of Health
Regulatory Framework	
Egg Freezing	<p>While there are no laws or regulations governing egg freezing, Government Regulation No. 61 of 2014 regarding Reproductive Health allows for the storage of embryos as result of fertilisation outside of the human body that is not implanted in the uterus. The embryo shall be kept until the birth of a baby from Assisted Reproductive Services.</p> <p>Egg and sperm freezing activities can only be conducted by health service facility that has obtained IVF License and only for the Assisted Reproductive Services purpose. The stored embryos are prohibited from being implanted in:</p> <ul style="list-style-type: none"> (a) the mother’s uterus if the embryonic father dies or the marriage couple is divorced; or (b) the uterus of another woman.
Surrogacy	Surrogacy is prohibited in Indonesia.





<p>Laws and Regulations on IVF</p>	<p>Sanatorium Act and Protection of a Child Born by Medically Assisted Reproductive Technology Act IVF business is mainly governed by the Sanatorium Act and Protection of a Child Born by Medically Assisted Reproductive Technology Act and their related regulations.</p> <p>Under the Sanatorium Act, the operation of IVF business in Thailand must be conducted by sanatorium business operators, which are required to obtain the Sanatorium Business Licence.</p> <p>In addition, IVF businesses are also considered as providing medically assisted reproductive technology services (“ART Medical Services”) falling under the purview of the Protection of a Child Born by Medically Assisted Reproductive Technology Act.</p> <p>The Protection of a Child Born by Medically Assisted Reproductive Technology Act provides for general rules and requirements for ART Medical Services, such as:</p> <ul style="list-style-type: none"> • medical practitioners providing ART Medical Services has to be qualified and comply with the standards of service prescribed by Notifications of the Medical Council of Thailand with the approval of the committee of the Protection of a Child Born by Medically Assisted Reproductive Technology (“ART Committee”); • prior to providing any ART Medical Services, ART Medical Service providers shall provide an examination and assessment of physical and mental readiness of service applicants, surrogate mothers and sperm egg donors; and • any forming, storing, use or removal of embryo must comply with all the rules, procedures and conditions prescribed by the Medical Council of Thailand with the approval of the ART Committee. An embryo however, shall not be stored or used over 14 days of age as from the date of fertilisation, provided that duration of embryo cryopreservation shall not be counted in the age of an embryo.
<p>Regulatory authority</p>	<p>Ministry of Health</p>
<p>Regulatory Framework</p>	
<p>Egg Freezing</p>	<p>Egg freezing for IVF business purpose must comply with the provisions under the Protection of a Child Born by Medically Assisted Reproductive Technology Act.</p> <p>Further, Clause 4 of the Notification of Medical Council No. 95(9)/2558 Re: Rules, Procedures, Conditions of the Deposit, Donation and Usage from Sperm or an Egg or an Embryo Deposited or Donated because of the Operation of the ART or Termination of an Embryo Deposited or Donated specifically provides that egg freezing can only be conducted for the purposes of fertilising with the sperm of the lawful husband, or, due to receiving any chemical treatment that may be harmful to the ovaries.</p>
<p>Surrogacy</p>	<p>The surrogacy business falls under the supervision of the ART Committee. Every surrogacy case requires their approval. The Protection of a Child Born by Medically Assisted Reproductive Technology Act forbids surrogacy for medical purposes.</p> <p>The criteria for surrogacy is set out in the Protection of a Child Born by Medically Assisted Reproductive Technology Act and the Notification of the Protection Committee of a Child Born by Medically ART.</p> <p>Surrogacy can be performed through two methods:</p> <ul style="list-style-type: none"> • creation of an embryo using eggs and sperm of the intended parents implanted in the gestational carrier’s womb; and • creation of an embryo using either donated eggs fertilised with husband sperm or wife eggs fertilised with donated sperm implanted in the gestational carrier’s womb. <p>The use of the gestational carrier’s eggs is prohibited.</p>



Laws and Regulations on IVF	<p>IVF business is mainly regulated by the following:</p> <ul style="list-style-type: none"> Vietnam’s WTO Schedule of Specific Commitments in Services which came into force on 11 January 2007; Law on Medical Examination and Treatment No. 40/2009/ND-CP dated 23 November 2009 issued by the National Assembly of Vietnam; Decree No. 10/2015/ND-CP dated 28 January 2015 issued by the Government regulating giving birth by IVF and conditions for altruistic gestational surrogacy (“Decree 10”); Decree No. 98/2016/ND-CP dated 1 July 2016 amending and supplementing several articles of Decree 10; Decree No. 155/2018/ND-CP dated 12 November 2018 on amendments to some articles related to business conditions under State Management of the Ministry of Health (“MOH”); and Circular No. 57/2015/TT-BYT regulating in detail several articles of Decree 10. <p>Decree 10 specifically provides that only the following medical examination and treatment establishments are allowed to perform IVF:</p> <ul style="list-style-type: none"> State obstetrics or obstetrics-paediatrics establishments of provincial or higher level; private general hospitals with obstetrics or obstetrics-paediatrics departments; private hospitals specialising in obstetrics or obstetrics-paediatrics; and hospitals specialising in andrology and infertility.
Regulatory authority	Ministry of Health
Regulatory Framework	
Egg Freezing	<p>In general, the laws of Vietnam provide the following for egg, sperm and embryo storage:</p> <ul style="list-style-type: none"> Storage of egg, sperm and embryo can be carried out in medical examination and treatment establishments that are allowed to perform IVF to store and preserve egg, sperm and embryo for implementation of IVF techniques. The sender of egg, sperm or embryo must pay for storage and preservation fees through civil contracts with the facility storing sperm, oocyte, or embryo. If the storage and preservation fee is not paid within six months, the medical establishment has the right to destroy the egg, sperm or embryo.
Surrogacy	<p>In order to perform altruistic gestational surrogacy (surrogate cannot be paid for carrying the baby) the medical examination and treatment establishment must have at least two years experience performing IVF (from the date being allowed by MOH) and the total number of IVF cycles is at least 1,000 cases per year.</p> <p>The medical examination and treatment establishment is required to obtain a decision on recognition of being allowed to perform altruistic gestational surrogacy.</p>

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<p>Laws and Regulations on IVF</p>	<p>There are no specific laws and regulations on IVF in the Philippines.</p> <p>With regards to the subject of reproduction and fertility awareness, the Philippine Family Code only recognises artificial insemination. The laws have not been revised to regulate, or at the very least recognise, the latest scientific advancements on ART, such as IVF.</p> <p>Under the existing general laws it can be said that facility or centre providing IVF services, as well as oocyte or egg cryopreservation, egg donation, egg and sperm bank facilities, may be classified as a health facility under the regulations of the Department of Health (“DOH”).</p> <p>Under DOH Administrative Order (“AO”) No. 0012-12, or the Rules and Regulations Governing New Classification of Hospitals and Other Health Facilities in the Philippines, a facility performing IVF services is classified explicitly as a specialised out-patient facility. A specialised out-patient facility is a facility with highly competent and trained staff that performs highly specialised procedures on an out-patient basis, such as stem cell facilities, dialysis clinics, and ambulatory surgical clinics. Unlike IVF, these particular facilities have specific regulations governing their establishments and licensing procedures.</p> <p>In practice, medical procedures involved in IVF are considered ambulatory surgical procedures. Based on existing DOH guidelines, an ambulatory surgical clinic (“ASC”) is one established for the purpose of providing elective surgical treatment of out-patients whose recovery, under normal and routine circumstances, will not require inpatient care. Services of an ASC range from minor to major operations, whether requiring anaesthesia, where patients are safely sent home within the same day for continuing post-operative care.</p> <p>Ambulatory surgical clinic offering reproductive health services such as IVF would need to secure relevant licenses and permits from the DOH.</p>
<p>Regulatory authority</p>	<p>Department of Health</p>
<p style="text-align: center;">Regulatory Framework</p>	
<p>Egg Freezing</p>	<p>There are no express laws or rules regulating oocyte cryopreservation or egg freezing.</p>
<p>Surrogacy</p>	<p>There is no legal framework that governs surrogate motherhood in the Philippines.</p> <p>Since the Family Code of the Philippines was enacted prior to the advancement of ART techniques, the recognition with respect to legitimacy and filiation of a child is limited to a child conceived and delivered through natural birth and artificial insemination. There are no legal pronouncements yet with respect to children as products of a surrogacy arrangement.</p>

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Laws and Regulations on IVF	<p>There are no specific laws and regulations on IVF in Myanmar.</p> <p>In general, the Law Relating to Private Health Care Services 2007 is the primary law regulating private health care services in Myanmar, including private specialist clinic service. Any person who intends to establish a private specialist clinic shall apply to the relevant Township Supervisory Committee for a licence for a private health care services. Whilst there are no clear framework governing IVF in Myanmar, the application to conduct such services may be included as explanation when applying for the licence for a private health care service and it will be subject to the decision of the relevant authority.</p> <p>Medical practitioners providing services at a private special clinic must have a Medical Practitioner Licence issued by the Myanmar Medical Council. Foreign specialists who wants to practice in Myanmar would need to obtain a Limited Special Medical Practitioner Licence.</p> <p>Medical practitioners can only practice the medical treatment that is contained in their licence.</p>
Regulatory authority	<p>Ministry of Health and Sports</p>
Regulatory Framework	
Egg Freezing	<p>There are no specific laws, regulations, notifications, orders and directive regulating egg freezing services. Nonetheless, there are private hospitals and clinics in Myanmar providing egg freezing services only for married couples.</p>

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Laws and Regulations on IVF	<p>There are no specific laws and regulations on IVF in Laos.</p> <p>Medical services are governed under Law on Health Care No. 58 dated 24 December 2014 (“the Health Care Law”) which provides principles, regulations and measures relating to the organisation, activities, management and control of health care activities in Lao PDR.</p> <p>Under the Decree on the Approval of Controlled and Concession Business Lists of Lao PDR No. 03/PMO dated 10 January 2019 both private hospital business and medical, dental, and public health services (specialised clinic) are controlled businesses, which are subject to approval by the Ministry of Planning and Investment (MPI). A business operation license from the Ministry of Health must also be secured.</p>
Regulatory authority	<p>Ministry of Health</p>

Regulatory Framework

General	<p>Current Lao legislation does not appear to provide specialised regulation for reproductive medicine and particularly for fertility treatments such as intrauterine insemination, preimplantation genetic diagnosis and screening, intracytoplasmic sperm injection, single embryo transfer, frozen embryo transfer, gender selection, non-surgical sperm retrieval, egg freezing, endoscopic surgery, germinal vesicle transfer.</p> <p>Nonetheless, the Health Care Law contains prohibitions and restrictions that may impact some treatment or procedures:</p> <ul style="list-style-type: none"> • Prohibition against trafficking in any product or organ from the human body • Prohibition against unauthorised care • Prohibition against health care that is not in conformity with medical professional rule • Amongst others, no health-care professional shall engage in trafficking in any product or organ from any part of the human body. <p>Article 21 of the Decree on Private Hospitals No. 151/GOV dated 28 April 2014 contains further prohibitions for private hospitals, such as:</p> <ul style="list-style-type: none"> • to engage in in trade of products or organs of live or dead human bodies. • to misleadingly advertise in any form that lead patients to their hospitals. • to import equipment (including second hand medical equipment), medicine and medical products that has not received approval for use in healthcare services of private hospitals. • to operate healthcare services and issue medical licences that are not compliant with the Healthcare Law and other relevant laws.
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Laws and Regulations on IVF	<p>There are no specific laws and regulations on IVF in Brunei.</p> <p>Currently the Ministry of Health does not provide any laws, regulations, or guidelines on IVF business or procedures. Government/public hospitals also do not provide any IVF procedures or facilities.</p> <p>There is one private hospital that offers IVF (and other assisted reproductive services such as Intracytoplasmic Sperm Injection (ICSI), Sperm Aspiration (TESA, PESA), and Preimplantation Genetic Screening (PGS)) at their Reproductive Medicine Unit. The unit and their services are not regulated by any strict laws except for the general Code of Conduct (good medical practice).</p> <p>While there is no legal framework governing IVF practice in Brunei, the only requirement, while not stipulated in law but as a self-implemented safeguarding practice by hospital to ensure that they are “Syariah-compliant”, is that only married couples are permitted to utilise IVF and other assisted reproductive services. They must produce proof of marriage by way of a marriage certificate. Sperms and eggs must only be extracted and collected from the married couple themselves.</p> <p>As a standard prerequisite, all medical practitioners in Brunei Darussalam, including those practicing assisted reproduction such as IVF, must be registered with the Brunei Medical Board and Brunei’s Ministry of Health. In addition, those in private practice require an Annual Practicing Certificate.</p>
Regulatory authority	Ministry of Health
Regulatory Framework	
Egg Freezing	There are no specific laws, regulations, notifications, orders, and directives regulating egg freezing and egg donation services.
Surrogacy	<p>There are no specific laws, regulations, notifications, orders, and directives regulating surrogacy services.</p> <p>It is useful to note that Brunei Darussalam is Syariah-compliant and assisted conception between unmarried individuals may be prohibited. Thus surrogacy, though not explicitly unlawful, could be deemed an infraction of religious sensibilities.</p>

Rozaiman Abdul Rahman

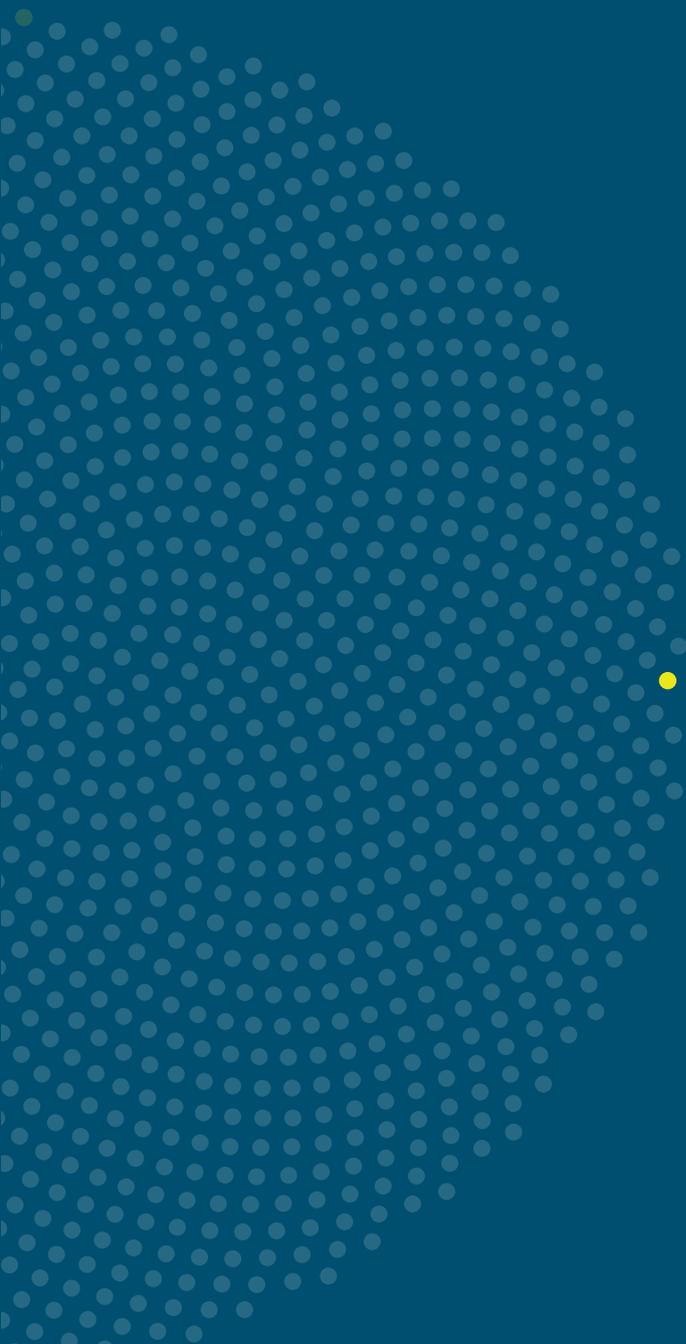
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