



Appendix E — Correspondence from the Embassy of the People's Republic of China

1. Letter received from Embassy of the People's Republic of China
2. English translation of letter received from Embassy of the People's Republic of China

澳大利亚联邦议会外交、国防和贸易联委会人权分委会：

中国政府对器官移植工作态度是一贯和明确的，我们坚定遵循国际上公认的关于器官移植的伦理学原则，坚持中国公民逝世后器官捐献自愿、无偿的原则，使用符合伦理学原则的器官，严格控制活体器官移植，禁止旅游移植，保障器官捐献者和接受者权利，实现人体器官科学、公正的分配，推动中国器官移植工作在法治的框架内规范发展。自 2007 年《人体器官移植条例》（以下简称《条例》）颁布实施以来，中国已建立了符合中国国情、文化和社会治理结构的人体器官捐献与移植工作体系（包括捐献体系、获取与分配体系、移植临床服务体系、移植后科学注册体系以及移植服务监管体系），成立了中国人体器官捐献与移植委员会，有力地推动了中国人体器官捐献与移植事业的发展。

一、人体器官捐献与移植法制建设方面

2007 年，国务院颁布实施《条例》，对器官捐献与器官移植各方的法律责任进行了详细规定，标志着中国人体器官捐献与移植工作进一步走上了法制化和规范化的轨道。2011 年，《中华人民共和国刑法修正案（八）》中，进一步对器官捐献知情同意及器官买卖进行严格界定，将“组织出卖人

体器官”作为严重的刑事犯罪予以严厉打击。同时，国家卫生健康委和中国红十字会出台 30 余个配套文件进一步规范人体器官捐献与移植行为。中国人体器官捐献与移植工作遵循以下原则：

（一）自愿无偿原则。《条例》对人体器官捐献有明确规定：人体器官捐献应当遵循自愿、无偿的原则，禁止器官买卖，《刑法修正案八》已将器官买卖罪入刑。

（二）知情同意（明确同意）的原则。公民享有捐献或不捐献其人体器官的权利；任何组织或者个人不得强迫、欺骗或者利诱他人捐献人体器官。捐献人体器官的公民应当具有完全民事行为能力。公民捐献其人体器官应当有书面形式的捐献意愿，对已经表示捐献其人体器官的意愿，有权予以撤销。公民生前表示不同意捐献其人体器官的，任何组织或者个人不得捐献、摘取该公民的人体器官；公民生前未表示不同意捐献其人体器官的，该公民死亡后，其配偶、成年子女、父母可以以书面形式共同表示同意捐献该公民人体器官的意愿。

（三）回避的原则。《条例》及其配套文件明确规定：获取捐献器官，应当在捐献人死亡后进行。从事人体器官移植的医务人员和人体器官获取组织（OPO）工作人员不得参与捐献人的死亡判定。

（四）伦理审查的原则。明确要求各器官移植医院必须

成立人体器官移植技术临床应用与伦理委员会，对每一例器官移植进行伦理审查。未通过审查的，不得获取器官进行器官移植手术。

（五）活体器官移植管理的原则。活体器官移植是在公民逝世后器官捐献无法满足需要的一种不得已而为之的补充措施，在管理上中国采取了较国际上其他国家（如美国等）更为严格的活体器官移植监管措施，维护器官捐献者与接受者合法权益，确保活体器官移植在法律的框架内规范开展。在政策层面，中国在《刑法修正案（八）》、《人体器官移植条例》及其配套文件的框架下，形成了活体器官移植管理的政策体系并付诸实施。明确规定将活体器官捐献严格限定在亲属间，不得摘取不满 18 周岁公民的器官用于移植。所有活体器官移植手术必须经主诊医生、医院伦理委员会及省级卫生计生行政部门三级审核同意后方可实施。目前，中国活体器官捐献主要以父母向子女捐献为主，其余为配偶间捐献，子女向父母捐献，以及兄弟姐妹间的捐献。

（六）器官科学公平分配的原则。《条例》及《中国人体器官分配与共享基本原则和核心政策》明确规定：申请人体器官移植手术患者的排序，应当符合医疗需要，遵循公平、公正和公开的原则。

基于此政策，中国已建立了中国人体器官分配与共享计算机系统（以下简称 COTRS）。要求所有捐献器官必须通过

COTRS 进行分配，确保捐献器官的分配科学、高效、公平。

（七）可溯源管理的原则。中国已搭建了以 COTRS 和各器官移植登记中心为核心的大数据信息化监管平台，实现了器官可溯源管理。

（八）违法必究的原则。对于违反中国人体器官移植相关法律的行为。一经查实，我们将依据法律规定，对涉案医务人员和医疗机构给予暂停直至吊销执业证书或取消器官移植资质的处罚。涉及违反《刑法》等法律法规的，移交司法机关查处。

综上所述，中国对器官移植管理的法规和政策与世界卫生组织（WHO）《人体细胞、组织和器官移植指导原则》完全一致，在活体器官移植管理等方面甚至采取了更加严格的管理措施。

二、人体器官捐献方面

自 2010 年起，国家卫生健康委与中国红十字会密切协作，依据《条例》及两部门配套文件，立足于中国社会结构特点，建立了由中国红十字会作为第三方参与的人体器官捐献体系。中国在 2015 年实现器官来源的根本性转型，公民自愿捐献器官成为器官移植的唯一合法来源。器官捐献的理念得到社会广泛认同。中办、国办在《关于党员干部带头推进殡葬改革的意见》中，鼓励党员干部逝世后捐献器官和遗体。部分省份还通过地方立法，完善人体器官捐献法律保障

体系。

截至 2018 年 8 月底，我国已累计完成公民逝世后器官捐献达 1.9 余万例，捐献大器官突破 5.4 万个，其中，2017 年度，我国完成公民逝世后器官捐献 5146 例，捐献与数量均居世界第 2 位。

三、人体器官获取与分配方面

中国建立起了一支 2000 余名经过规范培训与考核的器官捐献协调员队伍。出台了《中国人体器官分配与共享基本原则和核心政策》，明确了器官分配的原则和政策，同时使用中国人体器官分配与共享计算机系统（以下简称 COTRS）分配捐献器官，确保捐献器官的分配科学、高效、公平。2016 年，建立了多部门协作的、以民航与高铁为核心的、低成本高效率的器官转运“绿色通道”，体现了政府对器官捐献与移植事业和保障人民群众健康安全的高度重视，彰显了“以人为本、生命优先”的理念。

四、人体器官移植服务能力方面

目前，中国有 178 所器官移植资质医院，有肝脏、肾脏、心脏、肺脏移植资质的医院数量分别为 136 所、97 所、46 所、32 所。2017 年共实施器官移植手术 16687 例。其中，86%来源于公民逝世后捐献，14%来源于亲属间活体捐献。

五、人体器官捐献与移植管理方面

国家卫生健康委成立了肝脏、肾脏、心脏、肺脏 4 个移

植数据中心（质控中心），分别独立承担肝脏、肾脏、心脏和肺脏移植数据注册登记、统计分析和移植质量控制等工作。目前，各数据中心与 COTRS 共同构成了中国器官移植管理的核心信息系统，开展了趋势预警分析、日常动态监测与重点监测，实现了移植器官的可溯源管理，形成了大数据信息化监管与点对点飞行检查紧密结合的监管机制。同时，国家卫生健康委员会联合国家公安部建立数据资源共享机制，严厉防范打击器官买卖犯罪行为。

六、国际交流方面

中国人体器官捐献与移植事业也得到了国际社会的大力支持。世界卫生组织（WHO）、国际移植协会（TTS）和国际器官捐献与获取协会（ISODP）等国际组织和相关国际专家（包括澳大利亚著名器官移植专家、TTS 前任主席 Philip O'Connell）多次来华并全程参与、见证了中国人人体器官捐献体系的构建，在器官获取组织（OPO）建立、人体器官捐献协调员培训、器官分配政策研究、人体器官捐献与移植的各种技术标准制定，以及人体器官捐献与移植管理等方面开展了广泛而又深入的合作和交流。

2016 年 8 月，在香港举办的第 26 届国际器官移植大会上，举办了“中国器官移植的新时代”专场会议，中国人人体器官捐献与移植委员会黄洁夫主任委员作为唯一受邀嘉宾在大会主论坛作主旨发言，向世界展示了中国人人体器官捐献

与移植工作改革发展取得的成就，得到了包括 WHO 和 TTS 在内的国际组织和专家的高度评价。WHO 代表表示中国目前的人体器官捐献与移植体系与 WHO 的指导原则完全一致。2016 年 10 月，在北京人民大会堂举办的中国-国际器官捐献大会上，时任世卫组织总干事陈冯富珍女士在视频讲话中高度赞扬中国在器官捐献与移植领域的进展，她表示中国的改革方向正确，行动迅速，许多成功经验可以作为样板，供其他国家学习借鉴。2017 年 2 月，在梵蒂冈举办的反对器官贩卖全球峰会上，展示了中国政府反对器官贩卖的坚决态度并倡议成立 WHO 器官捐献与移植特别委员会，统筹协调器官捐献与移植全球治理。2018 年 3 月，在梵蒂冈教皇科学院举办的全球践行伦理道德峰会上，与会各国专家一致认可中国在预防和打击器官贩卖工作中作出的重要贡献。会后发布《梵蒂冈教皇科学院践行伦理道德会议宣言》中，认为预防和打击器官贩卖的“中国模式”体现了世界卫生组织关于公正、透明和公平的指导原则，可供他国学习借鉴。2018 年 7 月，在中国倡议和积极推动下，WHO 器官捐献与移植工作委员会正式成立，中国和美国成为唯一拥有两位委员的国家。中国将在未来几年的国际器官移植全球治理的格局中贡献更多力量。

中国器官移植发展基金会

Joint Standing Committee on Foreign Affairs, Defence and Trade's Human Rights Sub-Committee:

The Chinese government has a consistent and clear attitude towards human organ transplantation. By firmly following the internationally-acknowledged ethical principles of organ transplantation, we insist that Chinese citizens voluntarily donate their organs after death. The organs being transplanted are in line with ethical principles. Living organ transplants are strictly monitored and transplant tourism is forbidden. We make sure that the rights of both organ donors and recipients are protected, human organ allocation is scientific and fair, and organ transplantation practices in China are developing legally. Since the introduction of the *Regulation on Human Organ Transplantation* (RHOT) in 2007, China has developed a system of human organ donation and transplantation which reflects China's identity, culture and governance of the society, including donation system, procurement and allocation system, clinical transplant service, post-transplantation registry system and transplantation service regulation system. Another achievement is the establishment of the National Organ Donation and Transplantation Committee. The development of human organ donation and transplantation in China has been promoted in the following areas:

1. Legislation of Human Organ Donation and Transplantation

The RHOT was introduced by the State Council in 2007, which stipulates in detail the legal responsibilities of all parties involved in organ donation and transplantation. This marked the legalization and standardization of human organ donation and transplantation practices in China. In 2011, the Eighth Amendment to the Criminal Law of the People's Republic of China came into effect, which strictly distinguishes organ donation with informed consent from organ trafficking, stating that "whoever organizes others to sell human organs shall be convicted and punished." Since then, the National Health Commission and the Red Cross Society of China has introduced more than 30 supporting documents which further regulates human organ donation and transplantation practices. The following principles are observed in the area of human organ donation and transplantation in China:

(1) **Voluntariness:** The RHOT stipulates clearly that all kinds of human organ donation should be voluntary and without payment, and that organ trafficking is forbidden. The Eighth Amendment to the Criminal Law defines organ trafficking as a crime.

(2) **Informed Consent:** It is a Chinese citizen's right to donate or not donate their organs. Any

organization or individual shall not make others donate their organs by coercion, deception or temptation. Organ donors should have full capacity for civil conduct and written consent is required for organ donation. Donors who already gave consent have the right to withdraw. If a citizen has refused to donate their organs, any organization or individual shall not donate or procure their organs. If a citizen has not refused to donate, their organ can be donated after their death with the joint written consent of their spouse, children over the age of 18 and parents.

(3) Evasion: The RHOT and its supporting documents stipulate clearly that organ procurement should be conducted after death. Doctors and medical staff working in human organ transplant and staff of organ procurement organizations shall not be involved in the death determination of donors.

(4) Ethics Review: In all hospitals performing organ transplants, committees on the clinical application of technologies and ethics of human organ transplantation are required to establish to conduct ethics review on every case of organ transplant. For cases that could not pass the ethics review, organ procurement and organ transplant surgery are not allowed.

(5) Regulation of Living Organ Transplant: Living organ transplant is a last resort when organ donation fail to meet the demand. Living organ transplant regulations in China are stricter than other countries including the US. Under such regulations, the legal rights of organ donors and recipients are protected, and living organ transplants are performed legally. In the area of policy, the Eighth Amendment to the Criminal Law, the RHOT and the supporting documents have contributed to a system of living organ transplant regulation policies. It is clearly stipulated that living organ donor and recipient have to be genetically or maritally related, living organs of citizens under the age of 18 shall not be procured for transplant, and each living organ transplant surgery has to be reviewed and approved by the attending doctor, the ethics committee of the hospital and the provincial health department. Currently, the majority of living organ donors in China are parents of the recipients, and other donors include spouse, children and siblings of the recipients.

(6) Scientific And Fair Allocation of Organs: The RHOT and the Basic Principles and Core Policy of Human Organ Allocation and Sharing in China clearly stipulate that the arrangement of human organ transplant surgery applicants should be fair and transparent, and medical requirements need to be considered. A computer-based organ allocation and sharing system called the China Organ Transplant Response System (COTRS) has been developed. Every organ is allocated through this system to ensure scientific, efficient and fair allocation.

(7) Traceability Management: China has developed a big data digital regulation platform based on COTRS and organ transplant registries to improve traceability of organs allocation.

(8) Prosecution of Lawbreakers: Any confirmed violation of human organ transplant regulations

in China will be punished. The certificates of the doctors and medical staff involved will be suspended or revoked. For medical organizations involved, their qualification of organ transplant will be revoked. Those who violate the Criminal Law will be investigated by the judicial branch.

In conclusion, the law and policies regarding organ transplant regulations in China are perfectly in line with the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation. In the area of living organ transplant regulation, China has taken stricter measures.

2. Human Organ Donation

Since 2010, the National Health Commission and the Red Cross Society of China has worked together to build an organ donation system in which the Red Cross Society takes part as a third party. This system is based on the RHOT and supporting documents drafted by these two departments, and reflects the social structure of China. The source of organs was fundamentally changed in 2015 when voluntary donation became the only legitimate source for organ transplant. The concept of organ donation is widely accepted. General Office of the Communist Party of China and General Office of the State Council has jointly released the Opinion on Party Member and Cadre Leading Funeral Reform, in which party members and cadres are encouraged to donate their organs and bodies. Some provinces has improved legal protection for human organ donation by local legislation.

By August 2018, the amount of after-death organ donors in China has accumulated to more than 19,000 people, while donation of major organs has reached 54,000 cases. In 2017, 5146 Chinese citizens donated their organs after death, which was the second largest number in the world.

3. Human Organ Procurement and Allocation

China has more than 2,000 organ donation coordinators who have received training and assessments. Meanwhile, the Basic Principles and Core Policy of Human Organ Allocation and Sharing in China states the principles and policy of organ allocation; COTRS is used to allocate organs to make sure the allocation is scientific, efficient and fair. In 2016, different departments worked together to introduce an organ transport “fast track” with low cost and high efficiency using civil aviation and high speed railway. This effort proves that the government attaches great

importance to the course of organ donation and transplantation as well as the health and safety of its people; it reflects the concept of "putting people first".

4. Capacity of Human Organ Transplant Service

Currently, China has 178 hospitals which are qualified for organ transplant, including 136 qualified for liver transplant, 97 for kidney transplant, 46 for heart transplant and 32 for lung transplant. In 2007, China saw 16,687 organ transplant surgeries, among which 86% were after-death donation and 14% were living donation from recipients' family members.

5. Human Organ Donation and Transplant Regulation

The National Health Commission has established 4 transplant data centres (quality control centres) targeting liver, kidney, heart and lung transplant respectively. They are responsible for organ transplant data registration, analysis and transplant quality control. These centres and COTRS form a core information system of organ transplant regulation, which performs trend analysis, daily monitoring and intensive monitoring. It makes traceability of organs allocation possible, and helps to develop a regulation system which uses combined methods of digital monitoring and unannounced field audits. The National Health Commission has worked with Ministry of Public Security to build an information integration platform to prevent and combat criminal behaviors like organ trafficking.

6. International Communication

The course of human organ donation and transplant in China has received substantial support from all over the world. Many international organizations such as WHO, The Transplantation Society (TTS) and the International Society for Donation and Procurement and international experts (including famous Australian organ transplant expert, former TTS president Philip O'Connell) have come to China to participate in and witness the establishment of human organ donation system. They took part in extensive cooperation and communication with the Chinese in areas like the establishment of organ procurement organizations, organ donation coordinator training, organ allocation policy research, standard-setting for organ donation and

transplantation, and organ donation and transplantation regulation.

In August 2016, the 26th International Congress of the Transplantation Society was held in Hong Kong. A dedicated session titled "The New Era of Organ Transplantation in China" was held. Dr. Jiefu Huang, the Chair of the China Organ Donation and Transplant Committee gave the keynote speech as the only invited guest. He presented the achievements of human organ donation and transplantation reform to the world, which received praises from international organizations including WHO and TTS and experts. WHO representatives said that the current organ donation and transplantation system in China is in line with the WHO Guiding Principles. In October 2016, at the China International Organ Donation Conference held in the Great Hall of the People in Beijing, Margaret Chan Fung Fu-chun, former director-general of the WHO, spoke highly of China's development in the area of organ donation and transplantation. She said that the reform in China was not only fast but also on the right track, and China's success could serve as a model for other countries to learn from. In February 2017, the Summit on Organ Trafficking and Transplant Tourism was held in Vatican. During the summit, the Chinese government showed its resolve to combat organ trafficking and proposed the establishment of a WHO task force on organ donation and transplantation which arranges and coordinates global governance of organ donation and transplantation. In March 2018, the Ethics in Action Meeting on Modern Slavery, Human Trafficking, and Access to Justice For The Poor and Vulnerable was held at the Pontifical Academy of Sciences in Vatican. Experts from all over the world acknowledged the important contribution China made to preventing and combating organ trafficking. The Final Declaration of the Ethics in Action Meeting states that the "China model" is illustrative of the WHO Guiding Principles of equity, transparency, and fairness and may serve as an example of an operational mechanism to combat organ trafficking for the rest of the world. In July 2018, thanks to China's initiative and promotion, the WHO Task Force on Donation and transplantation of Human Organs and Tissues was formally established. China and the US are the only two member states to have two members in the task force. China will continue to contribute to global governance of organ transplantation in the near future.

China Organ Transplant Development Foundation



