GOVERNMENT OF INDIA MINISTRY OF HEALTH AND FAMILY WELFARE DEPARTMENT OF HEALTH AND FAMILY WELFARE

LOK SABHA STARRED QUESTION NO. 336 TO BE ANSWERED ON THE 24TH MARCH. 2017

ORGAN TRANSPLANTATION

*336. SHRI JYOTIRADITYA M. SCINDIA: SHRI KAMAL NATH:

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) whether there exists a mismatch between demand and supply of various human organs and tissues and if so, the details thereof;
- (b) the details of existing guidelines, protocols for organ transplantation;
- (c) whether the Government has decided to come out with new rules, regulations and protocols for facilitating organ donation and transplantation in the country and if so, the details thereof;
- (d) whether the views of eminent doctors, health experts and other stakeholders have been/are being considered before bringing new rules, regulations and protocols for facilitating organ donation, etc. and if so, the details thereof; and
- (e) the rules that exist in developed countries in this regard?

ANSWER THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA)

(a) to (e): A Statement is laid on the table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 336* FOR 24TH MARCH, 2017

- (a) The demand for organs for transplantation is far more than the availability of organs.
- (b) and (c) The Transplantation of Human Organs in India is regulated as per the Transplantation of Human Organs and Tissues Act, 1994 (as amended in 2011) and rules made thereunder. Further, the following guidelines/regulations have been issued in recent past for facilitating organ donation and transplantation in the country:
- (i) Highlights of National Organ and Tissue Transplant Programme and operational Guidelines for its implementation, in 2015.
- (ii) Allocation Criteria for Kidney, Liver, Heart, Lung, Heart-Lung and Cornea in 2016
- (iii) Draft Standard Operating Procedures (SOPs)/protocols for management of brain stem dead donors and retrieval of different Organs.

These are available in public domain on the website of National Organ and Tissue Transplant Organization (NOTTO) namely www.notto.gov.in:

- (d) It is a standard practice to obtain expert advice of eminent doctors, health experts and other stakeholders before finalizing any rules, guidelines or protocols. The Allocation Criteria in respect of Kidney, Liver, Heart, Lung, Heart-Lung and Cornea has been prepared after taking the views of eminent doctors, health experts and other stakeholders into account.
- (e) The details of the law governing organ donation in world as different countries of the world accessed on 22.03.2017 at 5:00 PM from website link https://dash.harvard.edu/bitstream/handle/1/8963882/Arthur%20Chern%20%20 Food%20%20Drug%20Law%20Final%20Paper%20%20Regulation%20of%20 Organ%20Transplants.pdf?sequence=1 are annexed.

TABLE 2: ORGAN DONATION LAWS IN 34 COUNTRIES

Country	Informed Consent Law	Presumed Consent Law
Australia	Law of 1982	
Austria		Law of 1982
Belgium		Law of 1986 (Families could potentially object)
Bulgaria		Law of 1996 (In practice consent is sought from the next-of-kin)
Canada	Law of 1980	une near or min)
Croatia		Law of 2000 (In practice consent is sought from the next-of-kin)
Cyprus		Law of 1987
Czech Republic		Law of 1984
Denmark	Current Law of 1990	(Previous Law of 1967)
Finland		Law of 1985
France		Law of 1976 (In practice consent is sought from
		the next-of-kin)
Germany	Law of 1997	
Greece		Law of 1999
Hungary		Law of 1972
Ireland	No law, follows UK guidelines	
Israel	,	Law of 1953
Italy		Law of 1967
Japan	Law of 1997 (Before 1997, brain death not accepted) (Family can veto)	Dan of 1907
Luxemburg		Law of 1982
The Netherlands	Law of 1996	
New Zealand	Law of 1964	
Norway		Law of 1973 (Family consulted and can potentially object)
Poland		Law of 1990
Portugal		Law of 1993
Romania	Law of 1998	
Singapore		Law of 1987 (Only Asian country with a presumed consent law)
Slovak		,
Republic		Law of 1994
Slovenia Spain		Law of 2000 Law of 1979 (In practice consent is sought from the next-of-kin)
Sweden		Law of 1996 (Family can potentially veto)
Swedell		Law of 1770 (Failing Can potentially veto)
Switzerland	Law of 1996	

Turkey		Law of 1979 (Only Muslim-dominated country with a presumed consent law; in practice consent is sought from the next-of-kin)
United	If 1061 1 1000	
Kingdom	Laws of 1961 and 1989	
United States	Uniform Anatomical Gift Act of 1968,	
	revised in 1987	
	National Organ Transplant Act of	
	1984	

Source: Alberto Abadie and Sebastien Gay (June 2004). The Impact of Presumed Consent Legislation on Cadaveric Organ Donation: A Cross Country Study. Kennedy School of Government Working Paper No. RWP04-024.