Medicolegal Corner

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REQUEST OF HCFI FOR FORMULATION OF LAW RELATING TO NATIONAL ESSENTIAL DEVICES AND DISPOSABLES IN INDIA HAS BEEN ACCEPTED BY THE CENTRAL GOVERNMENT

Heart Care Foundation of India (HCFI) had filed one RTI Application dated 22.01.2018 with National Pharmaceutical Pricing Authority, Department of Pharmaceuticals and also with Drug Controller General of India, Ministry of Health and Family Welfare asking them to provide following information:

- Is there any law relating to National Essential Medicine in India? If yes, please provide the details of the said law.
- Is there any policy of Ministry of Health relating to National Essential Medicine? If yes, please provide the copy of the said policy.
- Is there any list of National Essential Medicine in India? If yes, please provide the copy of the said list.

In response to the said RTI application dated 22.01.2018, the Ministry of Health and Family Welfare had given its reply dated 09.02.2018 wherein the Ministry of Health and Family Welfare had specifically stated that there is no separate list of National Essential Devices and Disposables and that the Ministry of Health and Family Welfare only issues the National List of Essential Medicines. The relevant portion of the reply dated 09.02.2018 is reproduced hereunder:

"*Reference is invited to your RTI application dated 22.01.2018 forwarded by Shri Arun Kumar Diwan, CPIO, NPPA vide letter No. 23011/07(1)/16-Admn/NPPA-RTI/Pt.-I dated 24.01.2018 (received on 31.01.2018) and it is informed that there is no separate list of National Essential Devices and Disposables. Ministry of Health and Family Welfare issues only the National List of Essential Medicines (NLEM).*"

Thereafter, the Directorate General of Health Services, Office of DCG (I) had also sent a reply dated 20.02.2018 thereby informing that they do not have any information relating to National Essential Devices and Disposables.

Thereafter, HCFI submitted one representation dated 08.06.2018 to Mr. Narendra Modi, Hon'ble Prime Minister of India, Mr. Jagat Prakash Nadda, Hon'ble Minister, Ministry of Health and Family Welfare and also to Mr. Ravi Shankar, Hon'ble Minister, Ministry of Law and Justice thereby **requesting them to recognize and prepare the List of National Essential Devices and Disposables in the same manner as National List of Essential Medicines is being recognized and prepared.**

The request of HCFI of formulation of law relating to National Essential Devices and Disposables in India is duly accepted by Hon'ble Ministers and accordingly, vide letter dated 07.08.2018, the Drug Controller General, Central Drugs Standard Control Organization, DGHS informed HCFI that Ministry of Health and Family Welfare has constituted a committee for preparing detailed guidelines and procedures for revision of National List of Essential Medicines and inclusion of Medical Devices, Medical Disposables and Medical Consumables and other products used for Health and Hygiene of general public in NLEM. The relevant portion of the letter dated 07.08.2018 is reproduced hereunder:

"This office has received a representation vide PMO ID No. PMOPG/D/2018/021845 enclosing your letter dated 08.06.2018 for taking appropriate action on the subject mentioned above.

In this regard, it is pertinent to mention here that Ministry of Health and Family Welfare vide F. No. 11053/923/2017-DRS dated 03.07.2018 has constituted a Standing National Committee on Medicines (SNCM) under the Chairmanship of Secretary, DHR and DG, ICMR.

As per the Term of reference of the SNCM, the committee will prepare detailed guidelines and procedures for revision of National List of Essential Medicines and suggest additions and deletion in the NLEM, Revision of NLEM 2-15, ***Inclusion of Medical Devices, Medical Disposables, Medical Consumables and other product used for Health and Hygiene of general public in NLEM****.*

It is important to mention herein that across the world, the National Essential Devices and Disposables is being recognized by law and are as important as a National List of Essential Medicines. Now, after the constitution of the said Standing National Committee on Medicines,

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in India also there will be National List of Essential Medical Devices, Medical Disposables, Medical Consumables and other product used for Health and Hygiene of general public in NLEM.

The National List of Medical Devices, Medical Disposables, Medical Consumables and other products used for Health and Hygiene will be beneficial for the general public for the following reasons:

- Guide safe and effective treatment of priority disease conditions of a population.
- Promote the rational use of Medical Devices, Medical Disposables, Medical Consumables and other products used for health and hygiene.
- Optimize the available health resources of a country.
- State governments can use this national list as a guide to prepare their list of essential Medical Devices, Medical Disposables, Medical Consumables and other products used for health and hygiene.
- There will be uniformity in prices of Medical Devices, Medical Disposables, Medical Consumables and other products used for health and hygiene included in the national list.

DELHI HIGH COURT: ADVISORY DATED 28.08.2018 OF CENTRAL GOVERNMENT BANNING ENDS IS NOT BINDING ON STATES/UT

In the matter titled as "*Piush* Ahluwalia versus Union of India" the Hon'ble High Court of Delhi vide order dated 14.11.2018 has held that the advisory dated 28.08.2018 issued by the Central Government is not binding and it would be open to the respective states and union territories to take an informed decision in this regard. The Hon'ble Court has further held that the petitioner is at liberty to challenge any action that may be taken by the State Governments/Union Territories in accordance with law.

The said case was filed by the petitioner impugning an advisory dated 28.08.2018 issued by the respondent, whereby the States/Union Territories have been advised to ensure that electronic nicotine delivery systems (ENDS) including e-Cigarettes, Head-Not-Burn Devices, Vape, e-Sheesha, e-Nicotine Flavored Hookah and the like devices that enable nicotine delivery are not sold, manufactured, distributed, traded, imported and advertised in their jurisdiction for the purpose and the manner as may be approved in. The said advisory also indicates that certain states have prohibited manufacture, distribution and import and sale of ENDS.

In the said case, the petitioner had contended that the said advisory is violative of the petitioner's fundamental rights under Article 14, 19 and 21 of the Constitution of India inasmuch as it deprives the petitioner from exercising its discretion to use the aforesaid products. According to the petitioner, the said products are less harmful than cigarettes and are used by smokers to quit the habit of smoking. The petitioner has also referred to the study carried out by Executive Agency of the Department of Health and Social Care, Public Health England, which indicates that e-cigarettes are 95% safer than smoking paper rolled cigarettes (PRCs).

After hearing the arguments from both the parties the court had held that:

> *6. This Court does not consider that any interference with the said advisory is warranted, as the same is an advisory which is required to be considered by the State Governments/Union Territories. The said advisory is not binding and it would be open to the respective states and Union Territories to take an informed decision in this regard. In any event, the petitioner is at liberty to challenge any action that may be taken by the State Governments/Union Territories in accordance with law.*

WHAT ARE THE MCI GUIDELINES FOR CLINICAL RESEARCH?

Regulation 6.8 "Code of conduct for doctors in their relationship with pharmaceutical and allied health sector industry" of the MCI Code of Ethics Regulations 2002 has issued the following guidelines regarding clinical research or trials:

6.8.1 (e) Medical Research: A medical practitioner may carry out, participate in, work in research projects funded by pharmaceutical and allied healthcare industries. A medical practitioner is obliged to know that the fulfillment of the following items (i) to (vii) will be an imperative for undertaking any research assignment/project funded by industry - for being proper and ethical. Thus, in accepting such a position a medical practitioner shall:

(i) Ensure that the particular research proposal(s) has the due permission from the competent concerned authorities.

(ii) Ensure that such a research project(s) has the clearance of National/State/Institutional Ethics Committees/Bodies.

(iii) Ensure that it fulfils all the legal requirements prescribed for medical research.

(iv) Ensure that the source and amount of funding is publicly disclosed at the beginning itself.

(v) Ensure that proper care and facilities are provided to human volunteers, if they are necessary for the research project(s).

(vi) Ensure that undue animal experimentations are not done and when these are necessary they are done in a scientific and a humane way.

(vii) Ensure that while accepting such an assignment a medical practitioner shall have the freedom to publish the results of the research in the greater interest of the society by inserting such a clause in the MoU or any other document/agreement for any such assignment.

IS THE CONSENT GIVEN FOR A DIAGNOSTIC PROCEDURE ALSO VALID AS CONSENT FOR THERAPEUTIC TREATMENT?

Consent given for a diagnostic procedure is not a valid consent for therapeutic treatment as the diagnostic procedure and therapeutic treatment are different and separate consent for both are required. The registered medical practitioner, hospital should always inform the patient and his/her relatives about the diagnostic procedure as well as therapeutic treatment separately and should take informed written consent for both separately.

The **3 Judges Constitution Bench of Hon'ble Supreme Court of India** in the landmark judgment titled as "**Samira Kohli versus Prabha Manchanda, AIR 2008 SC 1385** has held that:

> *"32 We may now summarize principles relating to consent as follows:*
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> *(iii) Consent given only for a diagnostic procedure, cannot be considered as consent for therapeutic treatment. Consent given for a specific treatment procedure will not be valid for conducting some other treatment procedure. The fact that the unauthorized additional surgery is beneficial to the patient, or that it would save considerable time and expense to the patient, or would relieve the patient from pain and suffering in future, are not grounds of defence in an action in tort for negligence or assault and battery. The only exception to this rule is where the additional procedure though unauthorized, is necessary in order to save the life or preserve the health of the patient and it would be unreasonable to delay such unauthorized procedure until patient regains consciousness and takes a decision."*

WHEN IS IT A CASE OF NEGLIGENCE?

If no inquiry or experts are required, then it is a clear case of negligence. In such cases, medical negligence is established based on the doctrine of *res ipsa loquitur* (the thing speaks for itself).

- If there is any evidence of *prima facie* case, never events or *mens rea* (criminal intent).
- If there is violation of any of the following SCI recommendations (Martin F. D'Souza vs. Mohd. Ishfaq, 3541 of 2002, dated 17.02.2009)
  - Current practices, infrastructure, paramedical and other staff, hygiene and sterility
  - No prescription should ordinarily be given without actual examination
  - The tendency to give prescription over the telephone, except in an acute emergency, should be avoided
  - A doctor should not merely go by the version of the patient regarding his symptoms, but should also make his own analysis including tests and investigations where necessary
  - A doctor should not experiment unless necessary and even then he should ordinarily get a written consent from the patient
  - An expert should be consulted in case of any doubt; Full record of the diagnosis, treatment, etc. should be maintained.
  - Not maintaining complete records of diagnosis, treatment, etc.
- If there is any violation of established treatment guidelines with no consent.
- If informed consent was not taken.
- If a copy of medical records were not given in time despite request by the patient or authorized person.
- If the act in question is a willful act.
- If the patient was neglected at any time or not attended to in an emergency.

CAN AN INSTITUTION RUN BY A PHYSICIAN BE ADVERTISED? SHOULD YOU ADVERTISE YOUR MEDICAL PRACTICE?

As per the provisions of **Clause 6.1.1 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002,** soliciting of patients directly or indirectly by the physician or group of physicians or by institution or organization is unethical.

Further, as per the provisions of Clause 6.1.1 of Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, the medical practitioner is allowed to make formal announcement in the press about his starting practice, change of type of practice, change in address, etc. The provisions of Clause 6.1.1 are reproduced hereunder:

> *"6.1.1 Soliciting of patients directly or indirectly, by a physician, by a group of physicians or by institutions or organizations is unethical. A physician shall not make use of him/her (or his/her name) as subject of any form or manner of advertising or publicity through any mode either alone or in conjunction with others which is of such a character as to invite attention to him or to his professional position, skill, qualification, achievements, attainments, specialties, appointments, associations, affiliations or honors and/or of such character as would ordinarily result in his self-aggrandizement. A physician shall not give to any person, whether for compensation or otherwise, any approval, recommendation, endorsement, certificate, report or statement with respect of any drug, medicine, nostrum remedy, surgical, or therapeutic article, apparatus or appliance or any commercial product or article with respect of any property, quality or use thereof or any test, demonstration or trial thereof, for use in connection with his name, signature, or photograph in any form or manner of advertising through any mode nor shall he boast of cases, operations, cures or remedies or permit the publication of report thereof through any mode. A medical practitioner is however permitted to make a formal announcement in press regarding the following:*
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> - *On starting practice.*
> - *On change of type of practice.*
> - *On changing address.*
> - *On temporary absence from duty.*
> - *On resumption of another practice.*
> - *On succeeding to another practice.*
> - *Public declaration of charges."*

Also, as per the provisions of **Clause 6.1.2 of Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002**, printing of self-photograph, or any such material of publicity in the letterhead or on sign board of the consulting room or any such clinical establishment shall be regarded as acts of self-advertisement and unethical conduct on the part of the physician. However, printing of sketches, diagrams, picture of human system shall not be treated as unethical.

Further as per the provisions of **Clause 7.11 of Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002**, the physician is not allowed to contribute to lay press articles and give interviews regarding diseases and treatments which may have the effect of advertising himself or soliciting practices; but is open to write to the lay press under his own name on matters of public health, hygienic living or to deliver public lectures, give talks on the radio/TV/internet chat for the same purpose and send announcement of the same to lay press.

The provisions of **Clause 7.12 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002** allows an institution run by a physician for a particular purpose to be advertised but with some restrictions. The provision of Clause 7.12 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 is reproduced hereunder:

> *"7.12: An institution run by a physician for a particular purpose such as a maternity home, nursing home, private hospital, rehabilitation centre or any type of training institution, etc. may be advertised in the lay press, but such advertisements should not contain anything more than the name of the institution, type of patients admitted, type of training and other facilities offered and the fees."*

Further, **vide judgment dated 10.01.2014 as passed by the Hon'ble High Court of Delhi** in the matter titled as **"Max Hospital, Pitampura vs. MCI,"** it has been categorically observed by the Hon'ble High Court that MCI has no jurisdiction to pass any order against the hospital under the provisions of 2002 regulations. Thus, as hospitals are not covered under MCI Act and the provisions of Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 are not applicable on hospitals, so the hospitals can advertise themselves.

In view of the above, it is opined that an institution run by a physician for a particular purpose like maternity home, nursing home, private hospital can be advertised but such advertisement should not contain anything more than the name of the institution, type of patients admitted, type of training and other facilities offered and fees.

The physician or the medical practitioner cannot advertise his medical practice which has the effect of advertising himself or soliciting practices.

ARE LIFE-SAVING MACHINES, DEVICES AND EQUIPMENTS LIKE CPAP MACHINE COVERED UNDER INSURANCE POLICY?

Life-saving machines and devices such as pacemaker, CPAP, BiPAP, orthopedic implants, intracardiac valve

replacements, vascular stents, relevant laboratory diagnostic tests, X-ray and such similar implants and machines are often prescribed by registered medical practitioners to their patients.

Such machines are duly covered under the insurance policy/Mediclaim policy.

If any patient is advised to use CPAP machine for his treatment and such patient has an insurance policy/ Mediclaim policy in his/her name, then the insurance company has to make the payment of the cost of CPAP machine to such patient as the same is covered by the insurance policy. Even if there is no specific clause in insurance policy/mediclaim policy stating that the CPAP machine is covered under the insurance policy, then also the insurance company has to pay the patient for the cost of CPAP machine as the same is life-saving machine and without it, the treatment of the patient is not complete.

All the doctors, registered medical practitioners, hospitals, nursing homes, etc. should educate their patient that the CPAP machine being a life-saving machine is duly covered by the insurance policy/Mediclaim policy obtained by them and they should immediately contact their insurance company for claiming the reimbursement of the cost of the said machine.

In numerous cases, the National Consumer Dispute Redressal Commission and State Consumer Dispute Redressal Commission of Delhi have held that the CPAP machine being a life-saving machine is completely covered by the insurance policy and the claim of the patient for the same has to be paid by the insurance company:

- "New India Assurance Co. Ltd. versus Ghanshyamdas A. Thakur," order and judgment dated 07.02.2014 passed by Hon'ble National Consumer Disputes Redressal Commission.
- Narender Kumar Jain versus United India Insurance Company Limited, Hon'ble State Consumer Dispute Redressal Commission of Delhi.
- "The New India Assurance Co. Ltd. & Anr. versus Mrs. Sonali Sareen & Anr." Delhi State Consumer Disputes Redressal Commission order dated 09.12.2014.

THE PATIENT WAS NOT GETTING CURED. CAN THIS BE TERMED AS MEDICAL NEGLIGENCE?

No doctor can give 100% guarantee about the treatment or surgery. The only assurance which a doctor can give or can be understood to have given by implication is that he is possessed of the requisite skill in that branch of profession which he is practicing and while undertaking the performance of the task entrusted to him he would be exercising his skill with reasonable competence.

The Hon'ble Apex Court in various judgments has duly held that no guarantee is given by any doctor or surgeon that the patient would be cured.

1. In the matter titled as "**P. B. Desai versus State of Maharashtra, AIR 2014 SC 795**, the Hon'ble Apex Court has held that:

> *"39. It is not necessary for us to divulge this theoretical approach to the doctor-patient relationship, as that may be based on model foundation. Fact remains that when a physician agrees to attend a patient, there is an unwritten contract between the two. The patient entrusts himself to the doctor and that doctor agrees to do his best, at all times, for the patient. Such doctor-patient contract is almost always an implied contract, except when written informed consent is obtained. While a doctor cannot be forced to treat any person, he/she has certain responsibilities for those whom he/she accepts as patients. Some of these responsibilities may be recapitulated, in brief:*
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> *a. to continue to treat, except under certain circumstances when doctor can abandon his patient;*
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> *b. to take reasonable care of his patient;*
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> *c. to exhibit reasonable skill: The degree of skill a doctor undertakes is the average degree of skill possessed by his professional brethren of the same standing as himself. The best form of treatment may differ when different choices are available. There is an implied contract between the doctor and patient where the patient is told, in effect, "Medicine is not an exact science. I shall use my experience and best judgment and you take the risk that I may be wrong. I guarantee nothing.*
>
> *d. Not to undertake any procedure beyond his control: This depends on his qualifications, special training and experience. The doctor must always ensure that he is reasonably skilled before undertaking any special procedure/ treating a complicated case.*
>
> *e. Professional secrets: A doctor is under a moral and legal obligation not to divulge the information/knowledge which he comes to learn in confidence from his patient and such a communication is privileged communication."*

2. In the matter **Malay Kumar Ganguly vs. Sukumar Mukherjee & Ors. AIR 2010 SC 1162, the Hon'ble Supreme Court of India** has held that:

   "INDIVIDUAL LIABILITY OF THE DOCTORS: There cannot be, however, by any doubt or dispute that for establishing medical negligence or deficiency in service, the courts would determine the following:

   i. No guarantee is given by any doctor or surgeon that the patient would be cured.

   ii. The doctor, however, must undertake a fair, reasonable and competent degree of skill, which may not be the highest skill.

   iii. Adoption of one of the modes of treatment, if there are many, and treating the patient with due care and caution would not constitute any negligence.

   iv. Failure to act in accordance with the standard, reasonable, competent medical means at the time would not constitute a negligence. However, a medical practitioner must exercise the reasonable degree of care and skill and knowledge which he possesses. Failure to use due skill in diagnosis with the result that wrong treatment is given would be negligence.

   v. In a complicated case, the court would be slow in contributing negligence on the part of the doctor, if he is performing his duties to be best of his ability.

   Bearing in mind the aforementioned principles, the individual liability of the doctors and hospital must be judged."

3. In the landmark judgment of **Jacob Mathew Petitioner vs. State of Punjab & Anr. 2005 (3) CPR 70 (SC) the Hon'ble Supreme Court** has held that:

   "Para 28: No sensible professional would intentionally commit an act or omission which would result in loss or injury to the patient as the professional reputation of the person is at stake. A single failure may cost him dear in his career. Even in civil jurisdiction, the rule of res ipsa loquitur is not of universal application and has to be applied with extreme care and caution to the cases of professional negligence and in particular that of the doctors. Else it would be counterproductive. ***Simply because a patient has not favourably responded to a treatment given by a physician or a surgery has failed, the doctor cannot be held liable per se by applying the doctrine of res ipsa loquitur."***

4. In the matter titled as **"Martin F. D'Souza versus Mohd. Ishfaq, 2009(3) SCC 1"** the Hon'ble Supreme Court has held that:

   "Para 124: "It must be remembered that sometimes despite their best efforts the treatment of a doctor fails. For instance, sometimes despite the best effort of a surgeon, the patient dies. That does not mean that the doctor or the surgeon must be held to be guilty of medical negligence, unless there is some strong evidence to suggest that he is."

5. In the matter titled as **"Lok Nayak Hospital versus Prema, RFA No. 56/2006"** the Hon'ble High Court of Delhi vide judgment dated 06.08.2018 has held that:

   "8. Firstly, it is to be noted that the only allegation of negligence alleged by the respondent/plaintiff against the appellant/defendant is that the tubectomy/ sterilization operation failed. ***Since medically there is never a 100% chance of success in sterilization operations, the mere fact that the operation was not successful, that by itself cannot be a reason to hold the appellant/defendant and its doctors guilty of negligence.*** *This aspect is no longer res integra and is so held by a Division Bench of this Court in the case of Smt. Madhubala Vs. Govt. of NCT of Delhi, 118 (2005) DLT 515 (DB).*

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Abdominal Aortic Aneurysm: The Number 5

- Aortic flow should be 50 cm/s slower than flow in the peripheral arteries.
- AAA surgery when the diameter is >5 cm or there is progression of >0.5 cm/year
- Aneurysm size is one of the strongest predictors of the risk of rupture, with risk increasing markedly at aneurysm diameter >5.5 cm.
  - Diameter between 4.0-4.9 cm: Less than 5% risk of rupture
  - Diameter >5 cm: 5% risk.