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INDIAN LEGAL IMPETUS®

EDITORIAL

Manoj K. Singh
Founding Partner

Dear Friends,

It gives us immense pleasure to present this October 2018 edition of *Indian Legal Impetus*.

In this issue, we first discuss if an arbitrator can award escalated charges in the absence of any clause in the concerned contract for such escalation; followed by an analysis of the rule laid down in the *Hardy Exploration case* wherein the court decided upon the question whether designation of place ipso facto will assume the nature of 'seat'?

Going forward, we scrutinize various aspects, issues, legal framework and status of the food industry in India. This article also throws light on the relevant compliances, offences and penalties as applicable under related laws.

This issue also have brief write-ups on recent bills & policies which will have a far reaching effect in coming times; these include the Personal Data Protection Bill, Consumer Protection Bill, National Digital Communications Policy and National Policy on Electronics. It can very well be noted that these bills & policies when made effective as per their respective mandate will create a huge impact in the functioning of the governmental instrumentalities as well as the general public at large.

In a brief article, we analyze a recent judgment by the Hon'ble Supreme Court, which reaffirmed the Bolam's Test laid in the case of *Bolam* v. *Friern Hospital Management Committee*; including deliberation on fastening medical negligence and validity of consent forms signed by the patients and/or their representatives.

In the last leg, we discuss in detail two interesting topics, i.e. rules that are applicable qua drones / remotely piloted aircrafts in India and pharmacovigilance regime in India. These two write-ups will touch upon all key characteristics of the said two domains and provide comprehensive insights thereto.

Trust you enjoy reading this issue as well. Please feel free to send your valuable inputs / comments at newsletter@singhassociates.in

Thank you.

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CAN AN ARBITRATOR AWARD ESCALATION CHARGES IN THE ABSENCE OF ANY CLAUSE FOR ESCALATION IN THE CONTRACT?

Parth Rawal

In a commercial contract, a tender is procured upon estimation of prices of material and labor to be incurred in future. However, these prices are susceptible to change due to reasons beyond the control of either party. Such unforeseen change in prices, which may shake the very foundation of the bargain, which parties entered into, may lead to frustration of contract, which in turn leads to termination of contract. To avoid such a situation, an escalation clause is added into the contract, which takes into account any future changes in prices of labor and material.

It is a cardinal principle of arbitration, that the arbitrator derives his authority from the terms of the contract and an award passed in contravention of such terms of contract is without jurisdiction and is liable to be set aside. However, there are several instances where contract does not provide for escalation clause and the contract is extended beyond completion period because of no fault of contractor. Thus, contractor suffers losses because of extension of contract and becomes entitled to damages, which include escalation in cost of material and labor. In such a situation, the question that crops up is whether arbitrator can award escalation in cost of material and labor in absence of any clause for escalation in the contract. In a recent case of *Union of India (UOI) vs. Varindera Constructions Ltd. and Ors.,*[1] the Supreme Court, in a special leave petition overturned the decision of division bench, Single Judge and arbitral tribunal and held that in presence of a clause expressly prohibiting escalation charges, arbitrator cannot award escalation charges. However, since there are many aspects of interpretation of escalation charges in varying circumstances, the author in this article expounds upon other situations dealing with interpretation of escalation charges in contract.

WHERE THERE IS ABSENCE OF ESCALATION CLAUSE IN CONTRACT

In absence of an escalation clause in contract, the arbitrator is within his jurisdiction to award escalation charges if the delay is not attributable to the contractor himself. This was dealt by Supreme Court in case of *Food Corporation of India vs. A.M. Ahmed and Co. and Ors*.[2] It was held in this case:

"*Escalation, in our view, is normal and routine incident arising out of gap of time in this inflationary age in performing any contract of any type. In this case, the arbitrator has found that there was escalation by way of statutory wage revision and, therefore, he came to the conclusion that it was reasonable to allow escalation under the claim. Once it was found that the arbitrator had jurisdiction to find that there was delay in execution of the contract due to the conduct of the FCI, the Corporation was liable for the consequences of the delay, namely, increase in statutory wages. Therefore, the arbitrator, in our opinion, had jurisdiction to go into this question.*" This has been reiterated by court in case of *Assam State Electricity Board and Ors. vs. Buildworth Pvt. Ltd.*[3]

In case of *Ramachandra Reddy and Co*, the court has held that escalation can be granted only either when contract provides for it or when competent authority has agreed to provide for escalation charges by correspondence[4]. In case of Food Corporation of India, the contractor had made several correspondences with regards to escalation charges, however, the authority never replied to them and kept silent as to whether escalation charges will be paid to contractor.

WHERE THERE IS A CAP ON AMOUNT THAT CAN BE CLAIMED AS ESCALATION CHARGES

The court in case of *N.J. Devani Builders P. Ltd. vs. Indian Farmers Fertilizer Cooperative Ltd*, held that in case there is a cap on escalation clause, irrespective of the actual amount of loss suffered, arbitrator cannot award escalation charges more than the amount stipulated in the contract. The court stated that:

1 SC) AIR2018SC2961

2 AIR2007SC82

3 AIR2017SC3336

4 Ramachandra Reddy and Co. vs. State of Andhra Pradesh and Ors. (27.02.2001 - SC) AIR 2001 SC 1523

"The imposition of limitation on the amount of escalation that the Contractor may claim by a contractual term cannot be said to be a term which offends public policy or to be forbidden by law. In contractual matters, the promisee may desire that the promisor should make a definite promise with regard to the costs to be incurred by the promisee for getting the work done. It is for the promisor to make his own estimation and evaluation on the basis of his experience and to make his offer on that basis, keeping in view the contractual terms"[5]

WHERE THERE IS CAP ON TOTAL AMOUNT OF DAMAGES THAT CAN BE CLAIMED IN CONTRACT

Where there are clauses in contracts which place limit on total amount of damages which can be claimed irrespective of total loss, the question that surfaces is whether escalation can be asked over and above the damages paid by authority under the clause. An illustration of such clause is given in case of *Pt. Munshi Ram and Associates (P) Ltd. vs. Delhi Development Authority and Ors.*[6]

"Clause 22 is also the relevant clause which reads as under:

"All sums payable by way of compensations under any of these conditions shall be considered as reasonable compensation to be applied to this use of Delhi Development Authority without reference to the actual loss or damage sustained, and whether or not any damage shall have been sustained."

While giving interpretation of such clause in terms of escalation, the court held that in such cases also if the contractor has suffered actual loss because of no fault of his own then he is liable to be compensated for the same.

CONCLUSION

Escalation clause takes care of the rise and fall in price but the parties can always agree that the contractor would not be entitled to any escalation whatsoever or that the contractor would be entitled to escalation limited to a certain amount or a certain percentage of the contract. Such a stipulation is not illegal or inconsistent.[7] However, in absence of such stipulation, court will always rule in favor of equity and will not allow party to be unjustly enriched at cost of other.

5 *N.J. Devani Builders P. Ltd. vs. Indian Farmers Fertilizer Cooperative Ltd. (05.12.2012 - DELHC) 2013IAD(Delhi)205*

6 *Pt. Munshi Ram and Associates (P) Ltd. vs. Delhi Development Authority and Ors. (07.12.2001 - DELHC) 96(2002)DLT597*

7 *Supra n 4*

SEAT, VENUE OR PLACE OF ARBITRATION: ANALYSIS OF HARDY EXPLORATION AND PRODUCTION (INDIA) INC

Prashant Daga

Every International Commercial Arbitration (**ICA**) or International Arbitration (**IA**) deals with the multiple interactions of laws. These laws may be municipal laws of more than one country or general principles of Public International Law. The interaction between multiple laws in an ICA or IA arises from the concept of separability of an arbitration agreement. It is a settled law that an arbitration agreement is a separate agreement than the main or matrix contract.[8] Thus, in a contract the parties can have two different set of laws - one, governing the main contract which will determine the respective rights and liabilities of the parties and another, related to arbitration. However, the law governing arbitration is further sub divided into two aspects - law governing the procedural aspects and law governing the substantive aspects of arbitration.[9] For the sake of brevity the same is illustrated below:

1.	**Governing law**	It is the law governing the main contract. It determines the respective rights and obligations between the parties. (Governing law)
2.	**Substantive Law governing arbitration**	Substantive law governs the validity of arbitration agreement, answers the questions on whether dispute lies within the ambit of arbitration agreement, validity of notice of arbitration, constitution of arbitral tribunal, whether the award lies within the jurisdiction of arbitral tribunal, parties have discharged their obligation to arbitration future dispute. (**Substantive Law**)
3.	**Curial (or procedural) law governing arbitral proceedings**	It governs the manner of individual reference, procedural powers and duties of arbitrator, questions of evidence.[2] ("**Curial Law**") Such law is generally the same as Substantive Law; however, the parties can opt out and subject themselves to other laws such as the rules of an institution governing arbitration to determine the conduct of arbitral proceedings to the extent it is permissible to deviate from under the Substantive Law. In case of contradiction between Substantive Law and Curial Law it is the Substantive Law that will prevail.

Substantive Law and Curial Law are collectively known as '*Lex arbitri*' or the law applicable to arbitration and Governing Law is the law applicable in arbitration.[10] The parties are free to determine which set of national laws (subject to the limitation for e.g. two Indian parties cannot make a foreign law as the governing law of their contract[11]) will apply to all the aforementioned laws in an arbitration agreement. For instance - Parties in a contract can agree upon Governing Law to be Indian Law, and Arbitration may be subject to English Law, however, the Curial Law can be SIAC Rules or Singaporean Law.

The determination of *lex arbitri* will determine which court(s) will have the supervisory jurisdiction before, during and post arbitration in relation to the arbitral proceedings or arbitration agreement, although

8 *National Agriculture Coopr Marketing v. Gains Trading co, AIR 2007 SC 2327*

9 *Naviera Amazonica Peruana SA v Cia Internacional de Seguros del Peru [1988] 1 Lloyd's Rep 116.*

10 *Alastair Henderson, Lex Arbitri, Procedural Law and the Seat of Arbitration, 26 SAcLJ 886 (2014).*

11 *TDM Infrastructure Pvt. Ltd. v. UE Development Pvt Ltd, (2008) 14 SCC 271.*

parties can expressly mention the law applicable to arbitral proceedings in their arbitral clause say for e.g. the arbitration shall be governed by English Law. In such a situation the courts in England will have the supervisory jurisdiction over the arbitration or arbitral proceedings.[12] However in addition to this, parties may provide for place/seat of arbitration, say, arbitration shall take place in London or the place of arbitration shall be London or the seat of Arbitration shall be London or the venue of arbitration is London. It is important that arbitral clause be drafted properly as the moment the parties designate a place as 'seat' the same tantamount to the designation of an exclusive jurisdiction clause (contrary to designating a venue which is merely a convenient place of hearing) and later on parties cannot wriggle out of the agreed terms.[13]

Therefore, the moot question is how to determine whether the place mentioned in an arbitral clause is a "juridical seat" or "venue".

The aforementioned moot question came before the consideration of the three-Judge bench of Hon'ble Supreme Court (by the way of reference from DB) in *Union of India* v. *Hardy Exploration and Production (India) Inc*. (**Hardy Case**)[14]. In the aforementioned case, the agreement provided:

- Governing law of the Contract: Laws of India
- Governing law of Arbitration: UNCITRAL Model Law on International Commercial Arbitration
- Venue of arbitration or conciliation: Kuala Lumpur or as decided by the Parties.

Thus, the question before the court was whether designation of place, ipso facto, will assume the nature of 'seat'. The court answered the question in negative and held that place will not ipso facto assume the status of seat unless one of the following conditions precedents is satisfied. Thus, a place mentioned in an arbitral clause will be deemed to be the 'juridical seat' if:

- *Law governing arbitration agreement is same as the law of the place mentioned as venue*.[15] For e.g. if the governing law of arbitration agreement in the aforementioned case provided that law in Malaysia shall apply then the seat Kuala Lumpur would have been deemed to be seat of Arbitration.
- *Law of the Matrix Contract and law of the venue/ place of arbitration are same*.[16] For e.g. if the law governing the contract in abovementioned case is Law of Malaysia rather than Law of India then Kuala Lumpur would have been the seat of Arbitration.
- *If the parties provide for an Institutional Rules*.[17] It is settled law that the *lex arbitri* determines the seat of arbitration and consequently, which court will have the supervisory jurisdiction.[18] The question is what if the '*lex arbitri*' is not a national law and is merely an Institutional Rules, then which court will have the supervisory jurisdiction. The Hon'ble Supreme Court in *Roger Shashoua* v. *Mukesh Sharma*[19] (Roger Shashoua) held that since the parties provided for ICC rules, Paris for arbitration and place of arbitration was London, hence London will be deemed to be seat of Arbitration. The Arbitral Clause in *Hardy Case* and *Roger Shashoua* Case were identically worded:

12 *Reliance India Limited v. Union of India, (2014) 7 SCC 603 where in court held that law which would apply to the filing of the award, to its enforcement and to its setting aside would be the law governing the agreement to arbitrate and the performance of that agreement will be Law in England and hence the English Court will have the supervisory jurisdiction over the arbitration.*

Also see, Enercon (India) v. Enercon GMBH, (2014) 5 SCC 1 ('Enercon'), where in parties have agreed that governing law of the contract shall be Indian law, Law governing arbitration was Indian Arbitration and Conciliation Act, 1996 and place of arbitration was mentioned to be London. In that case court held that it India which the seat of arbitration not London.

13 *Bharat Aluminium v. Kaiser Aluminium, (2012) 9 SCC 552 ("BALCO").*

14 *Civil Appeal no. 4628 of 2018 decided on 25.09.2018 (Supreme Court).*

15 *Harmony Innovation Shipping Ltd v. Gupta Coal India Limited and anr, (2015) 9 SCC 172.*

16 *Dozco India v. Doosan Infrastructure, (2011) 6 SCC 179 wherein Law governing Matrix Contract was Korean Law and Place of Arbitration was Seoul.*

17 *See for e.g. Yograj Infrastructure v. Ssang Yograj Engineer, (2011) 9 SCC 735. However, in that case parties also designated Singapore as the place of Arbitration.*

18 *See, Videocon Industries v. Union of India, (2011) 6 SCC 161, in that case Law governing matrix contract was Indian Law, Governing Law of Arbitration Agreement was English Law and Venue of Arbitration was Kuala Lumpur. The Court held that Seat of Arbitration was London not Kuala Lumpur.*

19 *Roger Shashoua* v. *Mukesh Sharma*, (2017) 14 SCC 722.

Criteria	Hardy Case	Roger Shashoua
Governing Law of Matrix Contract	India	India
Law Governing Arbitration	UNCITRAL Model Law. Article 20 provides that Parties or Arbitral Tribunal shall decide the Seat	ICC, Rules. Article 18 provides for similar provision as in Article 20, UNCITRAL Model Law.
Venue of Arbitration **Courts which will have jurisdiction (as decided by Hon'ble Supreme Court)**	Kuala Lumpur India	London London

It is pertinent to note that in the *Hardy case*, as noted above, court has held that Kuala Lumpur is not the seat of arbitration and courts in India will have the jurisdiction. However, in *Roger Shashoua* case the fact that ICC Rules, Paris was provided, the Court held that London was the seat of arbitration. Unlike MCIA Rules which provides for Mumbai as default Seat of Arbitration, ICC rules doesn't provide for a default seat.[20] Thus, contradiction in the reasoning of the Court is evident. However, the same can be explained that it was the intention of parties which is evident in *Roger Shashoua* case that they didn't intend to submit themselves to the supervisory jurisdiction of Indian Courts when they opted for ICC rules, Paris. However, the same was missing in *Hardy Case* as UNCITRAL Model Law is a delocalized law and doesn't refer to any particular National law.

20 *Naviera Amazonica Peruana v Cornpania Internacional De Seguros Del Peru [1988] 1 Lloyd's Rep 116, wherein Court held that: [T]he relevant rules of such bodies are incorporated by reference into the contract between the parties, and their binding effect will be respected and enforced by the Courts of the forum except in so far as they may conflict with the public policy or any mandatory provisions of the lex fori.*

The above mentioned are just a few surrounding circumstances which give an impression that place/ venue used in arbitration agreement is intended by the parties as 'seat' in an arbitral agreement.

Second contention which was raised before the court was whether the fact that arbitral award was signed in Kuala Lumpur will designate Kuala Lumpur as the seat of Arbitration and will exclude the jurisdiction of Indian Courts over the subject matter of arbitration. The Court held that the word 'determine' in Article 20(1), UNCITRAL Model Law (or its corollary Section 20(2), Arbitration and Conciliation Act, 1996) means a positive determination and an expressive opinion by the Arbitral Tribunal. The mere signing of an award at a place will not be construed as the determination of that place as seat by an arbitral tribunal under Article 20(1).

CONCLUSION

Aftermath of *Hardy Case* is that the Supreme Court has now settled the law that venue or place can be termed as seat of arbitration if something else is added to it as concomitant. The Court in *Hardy Case* didn't lay down the condition precedent(s)/situations in which 'place' in an arbitral clause can be construed as the Seat of arbitration as there are no exhaustive situations in which place can be construed as a seat and it depends on the facts and circumstances of each case. As noted above, the same can be construed only by holistic reading of an arbitral clause in the light of surrounding circumstances. Thus, the Court has allowed the place to be used interchangeably with seat keeping intact the sanctity and concept of 'juridical seat'. However, it is suggested that the exercise of determination of 'seat' shall be done in initial stages of arbitration and such determination should be left for arbitral tribunal. The court should refrain from encroaching upon such powers of arbitral tribunal keeping in mind the mandate of Section 5 read with Section 20 of the Act.

Further, the parties should aim at drafting an 'exhaustive' arbitral clause through mutual negotiation to avoid unnecessary and prolong litigation as the proper determination of seat and '*lex arbitri*' are of prime significance and consequence to any arbitration.

FOOD INDUSTRY IN INDIA: AN OUTLINE OF LEGAL REGIME, COMPLIANCES AND PENAL PROVISIONS

Kumar Deep

INTRODUCTION

Food[21] means any substance, whether processed, partially processed or unprocessed, which is intended for human consumption; and includes primary food, genetically modified or engineered food or food containing such ingredients, infant food, packaged drinking water, alcoholic drink, chewing gum, and any substance, including water used into the food during its manufacture, preparation or treatment but does not include any animal feed, live animals unless they are prepared or processed for placing on the market for human consumption, plants prior to harvesting.

LEGAL FRAMEWORK

In India, the food industry was earlier governed by various laws and regulations. The first legislation which dealt with food safety in India was the Prevention of Food Adulteration Act, 1954. It regulated the laws of the food industry along with other laws and regulations viz. the Fruit Product Order of 1955, the Meat Food Products Order of 1973, the Vegetable Oil Products (Control) Order of 1947, the Edible Oils Packaging (Regulation) Order of 1998, the Solvent Extracted Oil, De oiled Meal, and Edible Flour (Control) Order of 1967 and the Milk and Milk Products Order of 1992. Different laws relating to food were enacted under different Ministries, GOI, each having its own rules and regulations. This created many confusions in the minds of consumers, traders, manufactures and investors. There was a strong need for a comprehensive law to deal with such confusions and complexities in laws governing food industry in India. Accordingly, in order to bring uniformity and a single reference point for all issues in relation to food industry, the Food Safety and Standards Act, 2006 (FSS Act) was enacted in the same year. The FSS Act overrides all existing laws relating to food industry which were in force prior to 2006.

The FSS Act has been enacted with a purpose to consolidate the laws relating to food and to establish the Food Safety and Standards Authority of India (FSSAI) with primary objective of laying down science-based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import, in order to ensure availability of safe and wholesome food for human consumption.

In addition to the FSS Act, the Food Safety and Standards Rules, 2011, and several Regulations as listed below, are also applicable to food industry in India:

(i) Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011

(ii) Food Safety and Standards (Packaging and Labelling) Regulations, 2011

(iii) Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011

(iv) Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011

(v) Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011

(vi) Food Safety and Standards (Laboratory and Sample Analysis) Regulations, 2011

COMPLIANCES UNDER THE FSS ACT AND RULES & REGULATIONS MADE THEREUNDER

Any person carrying on the business of manufacture, packing, sale, storage or transport of food is called as Food Business Operator (FBO). Such FBOs are responsible for ensuring the compliances of the FSS Act, rules and regulations made thereunder. The summary of such compliances under the FSS Act are as under:

1) Compliance with respect to Licensing and

21 As per definition provided under the Food Safety and Standards Act, 2006

Registration:

- Any person carrying on the business of manufacture, packing, sale, storage or transport of food i.e. Food Business Operators require either a Registration or a License under the FSS Act to carry on the business of manufacture, packing, sale, storage or transport of food.

2) Food Business Operators need to comply with the following conditions at all times during the course of Food Business:

- To display a true copy of the license granted in Form C at a prominent place in the premises where Food Business is carried on.
- To give necessary access to licensing authorities and/or their authorized personnel to the premises.
- To inform authorities about any change or modifications in activities relating to Food Business.
- To employ at least one technical person to supervise the production process.
- To furnish periodic annual return i.e. for the period 1st April to 31st March, on or before 31st May of each year.
- To ensure that no product other than the product indicated in the license /registration is produced in the unit.
- To maintain factory's sanitary and hygienic standards as prescribed.
- To maintain daily records of production, raw materials utilization and sales separately.
- To ensure that the source and standards of raw material used are of best quality.
- To ensure clean-in-place system (whatever necessary) for regular cleaning of machines & equipments.
- To ensure testing of relevant chemical and/ or microbiological contaminants in food products in accordance with the regulation to ensure production and delivery of safe food through own or NABL accredited /FSSAI recognized laboratories at least once in every six month.
- To ensure that as much as possible the required temperature shall be maintained throughout the supply chain from the place of procurement or sourcing until it reaches the end consumer including chilling, transportation, storage etc.

3) Compliances with respect to Sanitary & Hygiene Requirements:

- Premises to be clean, adequately lighted, ventilated
- Floor, walls, ceiling to be in sound condition
- Floor and skirted walls to be washed daily with disinfectant
- Lay-out of the premises should be such that there is no cross-contamination
- Floor, walls to be made of impervious, non-absorbent, washable material
- Premises to be kept free from all insects
- Water used in manufacturing (food handling, washing, processing, cooking) to be potable, meeting BIS standards
- Workers in processing and preparation to use clean aprons, hand gloves, head wears
- No person employed should be suffering from infectious disease
- Workers to have finger nails trimmed, clean.
- Vehicles used to transport food must be kept in good repair and kept clean.
- Display board mentioning do's and don'ts to be displayed
- Segregation of raw material, processed, rejected, recalled products – suitable marking
- FIFO norms to be followed for raw material, ingredients, WIP, finished products

- Detailed SOP to be developed for proper management

4) Ensuring Compliance that the food is Not

- Unsafe;
- Misbranded; or
- Substandard.

5) Compliance with respect to Label Declaration.

- Every FBO to ensure that the labelling of foods should conform to the regulations and does not mislead the consumers.

OFFENCES AND PENALTIES

Where an offence under the FSS Act has been committed by a company and/or every person (who at the time the offence was committed) in charge of and responsible to the company for the conduct of the business of the company, such persons and the company shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly as per provisions of the FSSA. However, in case it is proved that the offence has been committed without the consent or connivance of or is not attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall not be deemed to be guilty of that offence and shall not be liable to be proceeded against and punished accordingly.

PENALTIES AND PUNISHMENTS UNDER THE FSS ACT ARE PRESENTED BELOW:

Penalty for selling food not of the nature or substance or quality demanded	Upto Rs. 2 Lakhs
Penalty for sub-standard food	Upto Rs. 5 Lakhs
Penalty for misbranded food	Upto Rs. 3 lakhs
Penalty for misleading advertising	Upto Rs. 10 Lakhs
Penalty for food containing extraneous matter	Upto Rs. 1 Lakh
Penalty for failure to comply with the directions of Food Safety Officer	Upto Rs. 2 Lakhs
Penalty for unhygienic or unsanitary processing or manufacturing of food	Upto Rs. 1 Lakh
Penalty for possessing adulterant	Upto Rs. 2 Lakhs (in case adulterant is not injurious to health) Upto Rs. 10 Lakhs (in case adulterant is injurious to health)
Penalty for contraventions for which no specific penalty is provided	Upto Rs. 2 Lakhs
Punishment for unsafe food	Imprisonment upto 6 months and fine upto Rs. 1 lakh (for non-injurious) Imprisonment upto 1 year and fine upto Rs. 3 lakh (for non-grievous injury) Imprisonment upto 6 years and fine upto Rs. 5 lakh (for grievous injury) Imprisonment for term not less than 7 years but can extend to imprisonment for life and fine not less than Rs. 10 lakh (in case such failure or contravention results in death)
Punishment for interfering with seized items	Imprisonment upto 6 months and fine upto Rs. 2 lakh
Punishment for false information	Imprisonment upto 3 months and fine upto Rs. 2 lakh

Punishment for obstructing or impersonating a Food Safety Officer	Imprisonment upto 3 months and fine upto Rs. 1 lakh
Punishment for carrying out a business without license	Imprisonment upto 3 months and fine upto Rs. 1 lakh
Punishment for subsequent offences	twice the punishment which might have been imposed on a first conviction; and a further fine on daily basis which may extend upto Rs. 1 Lakh where the offence is continuing one; and cancellation of license.

In addition to the punishment and penalties provided under the FSS Act, Section 272 of the Indian Penal Code also provides penalties for Adulteration of food or drink intended for sale. Accordingly, if any person who adulterates any article of food or drink, so as to make such article noxious as food or drink, intending to sell such article as food or drink, or knowing it to be likely that the same will be sold as food or drink, shall be punished with imprisonment of either description for a term which may extend to 6 months, or with fine which may extend to Rs.1000/-, or with both.

THE PERSONAL DATA PROTECTION BILL, 2018

Anjani Soni Wadhwa

With the advancement in technology, personal data created and stored in hard disk cloud, database, memory disk, internet, computer, etc., continues to grow at limitless rates, thereby leading the data to enter the Public Domain. This data is then subjected to maxim threats, which are classified into two categories - external threats to information security such as threats from hackers, network security threats, denial-of-service attacks, software threats, etc. and internal threats which are often associated with misuse or misrepresentation of information, data breaches and leaks.

The term Data Protection means legal control over access to and use of data stored. In other words, it refers to a series of continuous and repetitive processes, sound policies and privacy laws to reduce intrusion in one's privacy.

On August 24, 2017, a nine-judge bench of the Supreme Court, in the landmark case of ***Justice K.S. Puttaswamy and Anr. v. Union of India and Ors***[22]**,** has ruled "Privacy" as a Fundamental Right essential to life and liberty, and thereby, it has been put under the ambit of Article 21 of the Indian Constitution. The bench comprised Chief Justice Khehar and Justices J. Chelameswar, S.A. Bobde, R.K. Agrawal, Rohinton Nariman, A.M. Sapre, D.Y. Chandrachud, Sanjay Kishan Kaul and S. Abdul Nazeer.

The Judgement was delivered by Justice D.Y. Chandrachud, wherein he stated *"Ours is an age of information. Information is knowledge. The old adage that 'knowledge is power' has stark implications for the position of the individual where data is ubiquitous, an all-encompassing presence. The internet has become all pervasive as individuals spend more and more time online each day of their lives… the internet is used to carry on business and to buy goods and services."*

It was further stated, *"Informational privacy is a facet of the right to privacy. The dangers to privacy in an age of information can originate not only from the state but from non-state actors as well. We commend to the Union Government the need to examine and put into place a robust regime for data protection. The creation of such a regime requires a careful and sensitive balance between individual interests and legitimate concerns of the state."*

In order to have an effective and efficient data protection mechanism in India, Justice BN Srikrishna Committee was formed, which has submitted the draft bill on *personal data protection* to the Ministry of Electronic and Information Technology on July 27, 2018. As per the draft bill, **"Personal Data"** means data about or relating to a natural person who is directly or indirectly identifiable, having regard to any characteristic, trait, attribute or any other feature of the identity of such natural person, or any combination of such features, or any combination of such features with any other information.

1. THE DRAFT BILL AIMS TO ESTABLISH THE FOLLOWING:

- Fiduciary relationship and obligations on the part of the fiduciaries
- The manner in which personal and sensitive data is to be processed
- Establish safeguards for transparency and accountability
- Establishment of Data Protection Authority
- Imposition of penalties

2. THE DRAFT BILL HAS INTRODUCED CONCEPTS WHICH ARE THE ESSENCE OF DATA PROTECTION, SUCH AS:

- **Data fiduciary:** Any person, including the State, a company, any juristic entity or any individual who alone or in conjunction with others determines the purpose and means of processing of personal data.
- **Data principal:** Refers to the natural person, such as an individual, a Hindu undivided family, a company, a firm, the state, an association of

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persons or a body of individuals and every artificial judicial person.

- **Data processor:** Means any person, including the State, a company, any juristic entity or any individual who processes personal data on behalf of a data fiduciary, but does not include an employee of the data fiduciary.

3. THE KEY ASPECTS OF THE PERSONAL DATA PROTECTION BILL ARE:

DATA PROTECTION OBLIGATIONS

- The bill imposes duty on the person processing the personal data of data principal to process such personal data in a fair and reasonable manner that respects the privacy of the data principal. Collection of personal data to be limited to the purpose of processing. The data fiduciary shall be responsible for complying with the obligations in respect of any processing undertaken by it or on its behalf.

GROUNDS FOR PROCESSING PERSONAL DATA

The Bill makes consent an essential part of processing data. No data shall be processed without the consent of the data principal. However, the data shall be processed without consent only on certain grounds specified in the draft bill, such as:

- If processing is necessary for any function of Parliament or any State Legislature or for any service or benefit to the data principal.
- For compliance with any order or judgement of any Court or Tribunal in India.
- To respond to any medical emergency involving a threat to the life, a severe threat to the health or outbreak of disease.
- Recruitment or termination of employment of a data principal by data fiduciary.
- Prevention and detection of any unlawful activity, mergers and acquisition, credit scoring, recovery of debt and whistle blowing.

GROUNDS FOR PROCESSING SENSITIVE PERSONAL DATA

The term 'Sensitive Personal Data' includes passwords, financial data, health data, biometric data, genetic data, and data on caste or tribe or religious and political beliefs. The sensitive personal data may be processed on the basis of explicit consent for:

- Any function of Parliament or any State Legislature,
- For any service or benefit to the data principal.
- For compliance with any order or judgement of any Court or Tribunal in India.
- To respond to any medical emergency involving a threat to the life, a severe threat to the health or outbreak of disease.

RIGHTS OF DATA PRINCIPAL

The Data Principal are granted certain rights such as:

- Right to confirmation whether the data fiduciary is processing or has processed the personal data and access to the data.
- Right to correction of inaccurate, misleading or incomplete personal data.
- Right to data portability.
- Right to be forgotten, i.e., the right to restrict or prevent continuing disclosure of personal data by a data fiduciary.

TRANSFER OF PERSONAL DATA OUTSIDE INDIA

Personal data other than those categorized as sensitive personal data may be transferred outside the territory of India under the following conditions:

- Transfer is made subject to standard contractual clauses or inter-group schemes that have been approved by the Authority.
- The Central Government has prescribed that transfers to a particular country or sector within a country is permissible.

- The Authority approves a particular transfer or set of transfers as permissible.
- In furtherance to the above, the data principal has consented to such transfer of personal data.

EXEMPTIONS

Processing of personal data in the interests of prevention, detection, investigation and prosecution of any offence or any other contravention of law be permitted, provided it is authorized by a law made by Parliament and State Legislature.

CONCLUSION

The Ministry of Electronics and Information Technology has announced that before the Draft Bill is passed by the Parliament, it will undergo intensive parliamentary consultation. The Ministry **solicits comments from General Public on the Draft Bill in o**rder to ensure that it is indeed the need of the hour and beneficial to the interests of the individuals. The Draft Bill, when enacted will give way to new data privacy regime, which is based on trust and efficient mechanism between the Data Fiduciary and Data Principal. The Draft Bill imposes series of obligations on the State and makes it accountable for processing the personal data of an individual, thereby protecting both - the personal data and the constitutionally guaranteed right to privacy.

"A PHYSICIAN CANNOT ASSURE THE PATIENT OF FULL RECOVERY IN EVERY CASE" – REAFFIRMED BY THE SUPREME COURT

Ruchika Darira

The Bench comprising of Justice Abhay Manohar Sapre and Justice Vineet Saran, in the case titled *S.K. Jhunjhunwala* v. *Dhanwanti Kumar*[23], reaffirmed the Bolam's Test laid in the case of *Bolam* v. *Friern Hospital Management Committee*[24].

FACTS OF THE CASE

The present appeal before the Supreme Court was filed by the Appellant against the final judgment and order dated 01.09.2009, passed by the National Consumer Disputes Redressal Commission (hereinafter referred to as "*the National Commission*").

In the present case, the appellant was a doctor with expertise in gall bladder surgery and it was alleged by the respondent to have conducted a gall bladder surgery on the respondent without obtaining her consent. Respondent No.1 alleged that she had only given her consent for a Laparoscopic surgery. Respondent No.1 approached the State Commission alleging negligence on the part of the appellant (doctor). The respondent alleged that she suffered from various ailments which occurred due to the negligence on the part of appellant giving reference to the conventional gall bladder surgery which she had not agreed/consented to. The appellant denied all the allegations of the respondent and stated that he had examined the respondent and accordingly advised her to go for surgery of gall bladder, which may even include removal of the gall bladder. The appellant stated that consent of respondent for performing the laparoscopic cholecystectomy was duly obtained before performing the surgery. The appellant further pleaded that after starting the laparoscopic surgery, he noticed swelling, inflammation and adhesion on respondent's gall bladder and consequently, he came out of the Operation Theater and disclosed the said facts to respondent's husband and told him that in such a situation it would not be possible to perform the laparoscopic surgery and only the conventional procedure of surgery was the option to remove the malady. The husband of respondent agreed for the option suggested by the appellant and the appellant accordingly performed conventional surgery.

Respondent was discharged after spending few days in the hospital for post-operative care. The appellant, therefore, denied any kind of negligence or carelessness or inefficiency on his part in performing the surgery on respondent and stated that all kinds of precautions to the best of his ability and capacity, which were necessary to perform the surgery were taken by him and by the team of doctors that worked with him in all such operational cases.

After hearing both the parties, the State Commission refused any compensation to the respondent and therefore, the respondent approached the National Commission and the National Commission awarded compensation to the respondent by setting aside the State Commission's order vide order dated 01.09.2009.

OBSERVATION MADE BY THE SUPREME COURT

The Supreme Court, on perusal of the facts, evidence and placing reliance on the Bolam's Test reiterated the principle that a "*physician would not assure the patient of full recovery in every case. A surgeon cannot and does not guarantee that the result of surgery would invariably be beneficial, much less to the extent of 100% for the person operated on.*"

The Hon'ble Supreme Court in the present appeal held that the appellant i.e. the doctor was a qualified senior doctor with requisite knowledge and skill to perform the surgery of gall bladder. The said step of conducting the gall bladder surgery while conducting the laparoscopic surgery was taken due to the condition observed while doing the latter. The Court further held that on the occurrence of such an emergent situation, the appellant still took the consent of the respondent's

23 2018 SCC OnLine SC 1721

24 [1957] 1 WLR 582

husband by explaining to him the whole situation. Further, the Court also observed that Clause 4 of the Consent Form which was duly signed by the respondent, empowered the doctor to perform additional operation or procedure in the event of an emergency.

The Court also observed that no medical evidence of any expert was adduced to prove the allegation of negligence by respondent.

Therefore, the Hon'ble Court concluded that the act of the appellant was not an unauthorized act and he could legally perform the said surgery based on Clause 4 of the Consent Form which the respondent had duly signed. Hence, the appeal was allowed by restoring the State Commission's order and setting aside the National Commission's order on finding no merit in that decision.

OVERVIEW OF THE CONSUMER PROTECTION BILL, 2018

Manish Gopal Singh Lakhawat

The Government recently introduced the Consumer Protection Bill, 2018, in the Lok Sabha to replace the Consumer Protection Act, 1986. The Bill proposes to safeguard the consumer rights on account of rapid changes that have taken place due to advancements in e-commerce.

The Statement of Objects and Reasons of the Bill states that *"the emergence of global supply chains, rise in international trade and the rapid development of e-commerce have led to new delivery systems for goods and services and have provided new options and opportunities for consumers. Equally, this has rendered the consumer vulnerable to new forms of unfair trade and unethical business practices. Misleading advertisements, telemarketing, multilevel marketing, direct selling and e-commerce pose new challenges to consumer protection and will require appropriate and swift executive interventions to prevent consumer detriment."*

The Bill empowers the Centre to formulate measures to prevent unfair trade practices in e-commerce. As per the draft Bill, the e-commerce entities would be: (1) mandated to share with consumers the main features of their terms and conditions in a simplified and an easily understandable form; and (2) required to disclose to consumers the terms and conditions governing their arrangement with vendors.

Both the Bill and the draft e-commerce policy will need to consider the issue of variety of products that are available through e-commerce. For example, the definition of 'product' under the Bill pertains to tangible physical products that would obviously not include financial products (insurance policies sold online) or services (housekeeping, pest control, etc).

Another positive step is the introduction of the concept of 'product liability'. As per the Bill, a consumer can initiate product liability action against a manufacturer or a service provider or a seller (as the case may be) as per the provisions of the Bill, for any harm caused on account of a defective product or deficiency in services.

E-commerce and online purchasing in India have grown by leaps and bounds, and are set to record unprecedented growth owing to increasing penetration of internet. We are living in the times where disruption and novel ideas pour in almost on a daily basis. It is often said that law always plays catch-up to novel business ideas, and e-commerce is no exception. The present time is perhaps the most challenging yet interesting, where the law (and lawmakers) has to play catch-up faster than ever to make sure that the aspirations of the industry and consumers are met evenly.

TELECOM SECTOR IN INDIA: APPROVAL OF NATIONAL DIGITAL COMMUNICATIONS POLICY 2018

Rupesh Gupta

India has been witnessing tremendous growth in telecom sector on account of its vast subscriber list. Keeping in mind the importance of digitalization, the Union Cabinet, on September 26, 2018, approved the National Digital Communications Policy-2018 (NDCP-2018).

The key objectives of NDCP-2018 are:

1) Broadband for all;

2) Creating four million additional jobs in the Digital Communications sector;

3) Enhancing the contribution of the Digital Communications sector to 8% of India's GDP from ~ 6% in 2017;

4) Propelling India to the Top 50 Nations in the ICT Development Index of ITU[25] (India is ranked at 134 in the year 2017);

5) Enhancing India's contribution to Global Value Chains; and

6) Ensuring Digital Sovereignty.

NDPC-2018 aims to attract USD 100 billion in the telecommunication sector. In the last three years, the Foreign Direct Investment (FDI) in the telecom sector has jumped nearly five times from USD 1.3 billion in 2015-16 to USD 6.2 billion in 2017-18. Recently, the Department of Telecommunications (DoT) cleared 100% FDI in Idea Cellular, paving the way for its merger with Vodafone India.

In a press release issued on September 25, 2018, the Government of India has significantly stated that it is keen on facilitating roll out of 5G services by 2020 in India at par with the world which will play key role in harnessing new emerging technologies like machine-to-machine communications, internet of things, artificial intelligence, etc.

India has announced plans to launch 5G service by 2020 which provides big investment opportunity in the country.

NDPC-2018 aims to:

- Provide universal broadband connectivity at 50 Mbps to every citizen;
- Provide 1 Gbps connectivity to all Gram Panchayats by 2020 and 10 Gbps by 2022;
- Ensure connectivity to all uncovered areas;
- Attract investments of USD 100 billion in the Digital Communications Sector;
- Train one million manpower for building New Age Skills;
- Expand Internet of Things (IoT) ecosystem to 5 billion connected devices;
- Establish a comprehensive data protection regime for digital communications that safeguards the privacy, autonomy and choice of individuals;
- Facilitate India's effective participation in the global digital economy;
- Enforce accountability through appropriate institutional mechanisms to assure citizens of safe and secure digital communications infrastructure and services.

NDCP-2018 looks promising and a game changer for telecom sector in India. The target to train one million people in new-age skills and sectors such as 5G LTE and artificial intelligence is commendable. The intent to increase digitalization in rural areas in India will further boost the telecom sector. NDCP-2018 will create colossal infrastructure as the same is vital for the existing bleeding telecom sector in India. The government is dedicated to achieve its Digital India plan and we hope that the implementation of NDCP-2018 will bring more smiles to the foreign investors as well as domestic players in the telecom sector.

25 *International Telecommunication Union (ITU) is a specialized agency of the United Nations that is responsible for issues that concern information and communication technologies.*

DRAFT NATIONAL POLICY ON ELECTRONICS 2018

Harsimran Singh

On October 10 2018, the Ministry of Electronics and Information Technology (MeitY), Government of India, issued the "*National Policy on Electronics 2018*" (NPE 2018) for the Electronics System Design and Manufacturing (ESDM) Sector of India.[26] NPE 2018 aims to position India as a global hub for Electronics System Design and Manufacturing (ESDM) by creating an enabling environment for the industry to compete globally.

NPE 2018 is the result of the roadmap devised under NPE 2012, which recognized the electronics sector's unique dynamics, significant opportunity and structural challenges, and laid the way forward for the development of electronics sector in the country. NPE 2018 policy is holistic, investor-friendly and market-driven, and focused on upgradation of infrastructure, providing incentives to offset disabilities, promoting innovation and human resource development.

As stated in NPE 2018, the global electronics production is estimated to be USD 1,740 Billion in 2017, growing at a Compound Annual Growth Rate (CAGR) of 5%. Indian electronics hardware production has increased from INR 1,90,366 crore in 2014-15 to an estimated INR 3,87,525 crore (USD 59 Billion) in 2017-18, registering a CAGR of 26.7%, as against a growth rate of 5.5% in 2014-15. India's share in the global hardware electronics production is 3.4%. The share of domestic electronics production in India's GDP is 2.3%. The import of electronic goods was of the order of USD 53 Billion in 2017-18. With the demand for electronics hardware expected to rise rapidly to about USD 400 Billion by 2023-24, India cannot afford to bear a huge foreign exchange outgo on import of electronics alone. Accordingly, NPE 2018's endeavor for promoting domestic electronics hardware manufacturing, for a high value addition is of critical importance.

NPE 2018 aims to push the startup ecosystem in emerging technology areas such as 5G, Internet of Things, artificial intelligence and machine learning, and their applications in areas such as defense, agriculture, health, smart cities and automation. Being export-led, it is also targeting to develop core competencies in all the sub-sectors of electronics, including electronic components and semiconductors, telecommunication equipment, medical electronics, defense electronics, automotive etc.

MeitY will coordinate with the concerned Ministries/ Departments to provide incentives to industry for rapid and robust expansion of electronics hardware manufacturing within the country. As per NPE 2018, MeitY shall work out details and facilitate decisions by the Government on the measures indicated hereunder:

1. Create eco-system for globally competitive ESDM sector by incentivizing domestic manufacturing and compensating for disabilities;

2. Establish a body in MeitY for developing and setting standards for Electronics (including Components as well as Fabless Industry), IT, e-Governance, etc.

3. Set up an institutional mechanism within MeitY for mandating compliance to standards for electronics products;

4. Create/ upgrade Lab infrastructure/ capacity for testing of electronic goods, including cyber security;

5. Ease of Doing Business: Strengthen and leverage Invest India, the National Investment Promotion and Facilitation Agency, which was established as a single window for global investors, for facilitation of investment in ESDM sector as a one-stop shop for facilitation of investments / businesses, coordination with the State Governments, establishment of Joint Ventures, obtaining speedy approvals by coordinating with the concerned Government agencies on behalf of the investors, and hand-holding them till the manufacturing unit becomes functional;

6. Encourage industry-led R&D and innovation in all sub-sectors of Electronics;

26 http://meity.gov.in/writereaddata/files/Draft_NPE_2018_10thOct2018.pdf

7. Provide support for significantly enhancing availability of skilled manpower in the ESDM sector;

8. Export promotion: Provide attractive package of incentives for promotion of indigenization and export of electronics, and hence empowering Indian ESDM exporters by facilitating global market access;

9. Enhance understanding of cyber security issues/ concerns, risks and mitigation measures thereof pertaining to electronic products;

10. For the requirements of Government Sector, an exclusive Government owned testing and evaluation facility to be set up;

11. Promote the use of secure chips by design and systems to reduce cyber security risks;

12. Promote Start-up eco-system for development of photonics, nano-based devices and cyber security products;

13. Provide special package of incentives for Mega Projects which are extremely high-tech and entail huge investments, such as Fabrication (FAB) units (Semiconductors, Display, LED, Solar Cells), including granting infrastructure status to these units;

14. Promote investment in mega facilities abroad, such as an existing FAB facility, including support for setting up of R&D units abroad, where eco-system exists for a particular technology;

15. Preferential Market Access: Encourage the State Governments to adopt the Public Procurement (Preference to Make in India) Order 2017 (PPO 2017), in procurement of electronic products. Leverage Government eMarket Place (GeM) to create/ expand the market for domestically manufactured electronic products;

16. Provide special support for developing core competencies in the relevant subsectors.

From the governance structure perspective, NPE 2018 provides for creating institutional mechanism for implementation of various schemes/programmes under the Policy, such as constituting a High-Level Advisory Committee to review the implementation status and provide strategic recommendations/ decisions from time to time. With NPE 2018, it is apparent that the Government now seeks to build on that foundation to propel the growth of ESDM industry in the country. The NPE 2018 is conceived as a comprehensive plan of action with deliverables and will provide the requisite framework for the same.

RULES GOVERNING FLYING OF DRONES / REMOTELY PILOTED AIRCRAFTS IN INDIA

Rupesh Gupta

The Office of the Director General of Civil Aviation ('DGCA'), Government of India, has issued the much-awaited Civil Aviation Requirements ('CAR') considering the use of Remotely Piloted Aircraft ('RPA') by civilians for several purposes including but not limited to surveys for infrastructure monitoring. A remotely piloted aircraft, its associated remote pilot station(s), command and control links and related components form a Remotely Piloted Aircraft System (RPAS). CAR is issued under the provisions of Rule 15A and Rule 133A of the Aircraft Rules, 1937.

RPA is defined as an unmanned aircraft, which is piloted from a remote pilot station. Looking at the definition, a **drone** (commonly known term) will be an RPA under the provisions of CAR.

RPA is also deployed for multifarious imminent needs in technologically advanced world such as aerial surveys, commercial goods delivery, commercial photography, traffic monitoring, aerial damage assessment etc. DGCA recognized the need to encourage as well as regulate the use of UAS in India and accordingly formulated the CAR. CAR is scheduled to be effective from December 1, 2018.

Key features of CAR that will enable the companies, authorities and civilians to legally use drone/RPA in India are as follows:

CATEGORIES OF RPA

Civil RPA is categorized in accordance with Maximum All-Up-Weight (including payload) as indicated below:

i) Nano: Less than or equal to 250 grams.

ii) Micro: Greater than 250 grams and less than or equal to 2 kg.

iii) Small: Greater than 2 kg and less than or equal to 25 kg.

iv) Medium: Greater than 25 kg and less than or equal to 150 kg.

v) Large: Greater than 150 kg.

APPLICATION PROCESS

FOR RPA IMPORTED IN INDIA

Any entity intending to import RPAs in India will be required to obtain Equipment Type Approval (ETA) from WPC Wing, Department of Telecommunication ('DoT') for operating in de-licensed frequency band(s). Such approval shall be valid for a particular make and model.

The applicant shall apply to DGCA for import clearance as per the form provided with the CAR. This rule will not apply to Nano category RPAs. Based upon the import clearance issued by DGCA, Directorate General of Foreign Trade ('DGFT') shall issue license for import of RPAS.

Upon receipt of import license, the applicant shall apply to DGCA for Unique Identification Number ('UIN') or Unmanned Aircraft Operator Permit ('UOAP'), as applicable.

FOR RPAS LOCALLY PURCHASED IN INDIA

The applicant shall obtain ETA from WPC Wing, DoT for operating in de-licensed frequency band(s). Such approval shall be valid for a particular make and model.

The applicant shall submit information as per the format given with CAR along with application for issue of UIN / Unmanned Aircraft Operator Permit (**'**UAOP'), as applicable.

All applications will be processed on case-to-case basis through "Digital Sky Platform".

REQUIREMENTS FOR ISSUE OF UNIQUE IDENTIFICATION NUMBER (UIN)

A Civil RPA shall require Unique Identification Number (UIN) from DGCA. UIN will be granted where the RPA is wholly owned either:

a) By a citizen of India; or

b) By the Central Government or any State Government or any company or corporation owned or controlled by either of the said Governments; or

c) By a company or a body corporate provided that:

(i). it is registered and has its principal place of business within India;

(ii). its chairman and at least two-thirds of its directors are citizens of India; and,

(iii). its substantial ownership and effective control are vested in Indian nationals; or

d) By a company or corporation registered elsewhere than in India, provided that such company or corporation has leased the RPAs to any organization mentioned in (b) or (c) above.

In order to obtain UNI, documents that are listed in Rule 6.2 will be required to be submitted by the applicant to DGCA along with duly filled application (through Digital Sky Platform), as per Annexure IV provided with CAR and a fee of INR 1000/-. Besides general and equipment related documents, security clearance from MHA is mandatory in case of above mentioned (a), (c) & Indian company or corporate leasing RPAs from a company or corporate registered elsewhere than in India under 6.1, (d) not earlier than five years from date of application for UIN.

FAQ issued by DGCA points out that foreigners are currently not allowed to fly drones in India. For commercial purpose, they need to lease RPAs to an Indian entity who in-turn will obtain Unique Identification Number (UIN) and UAOP from DGCA.

A citizen of India shall either obtain security clearance from MHA or submit self-attested copies of at least two out of three valid identity proofs viz. Passport, Driving License or Aadhar Card. The requisite form for security clearance has been provided with CAR.

In case the documents are in order, the UIN shall be issued in 02 working days.

EXEMPTION OF REQUIREMENT TO OBTAIN UIN WILL APPLY TO:

1. RPAs in Nano category intended to fly upto 50 feet (15 m) above ground level in uncontrolled airspace/ enclosed premises for commercial / recreational / R&D purposes.

2. RPAs owned / operated by National Technical Research Organization, Aviation Research Centre and Central Intelligence Agencies.

REQUIREMENTS FOR ISSUE OF UNMANNED AIRCRAFT OPERATOR PERMIT (UAOP)

In addition to obtaining UIN, all Civil RPA operators, other than those mentioned herein below, shall require UAOP from DGCA:

1. A Nano RPA operating below 50 feet (15 m) above ground level in uncontrolled airspace/ enclosed premises.

2. Micro RPA operating below 200 feet (60 m) above ground level in uncontrolled airspace / enclosed premises. However, the user shall intimate to local police office 24 hours prior to the conduct of actual operations.

3. RPA owned and operated by National Technical Research Organization, Aviation Research Centre and Central Intelligence Agencies. However, the agency shall intimate local police office and concerned ATS Units prior to the conduct of actual operations.

APPLICATION FOR ISSUANCE OF UAOP

A duly filled application as per the format provided with CAR along with requisite fees of INR 25,000/- has to be submitted to DGCA, through Digital Sky Platform, at least 7 working days prior to actual commencement of operations. The documents to be annexed will include:

a) A Standard Operating Procedure detailing the procedure and mandates enumerated in CAR;

b) Permission of the land/property owner (only for area used for take-off and landing of RPA);

c) Details of remote pilot(s) along with security clearance from MHA or self-attested copies of at least two out of three valid identity proofs viz. Passport, Driving License or Aadhar Card and copies of training records;

d) Insurance details (as applicable);

e) Security programme as approved by Bureau of Civil Aviation Security ('BCAS').

In case the documents are in order, the UAOP shall be issued in 07 working days.

A UAOP is valid for a period of five years from the date of issue, non-transferrable and renewal shall be subject to fresh security clearance from MHA.

SECURITY/ SAFETY REQUIREMENTS

The operator shall be responsible for the safe custody, security and access control of the RPAs and in case of loss of RPA, the operator shall report immediately to the local police office, BCAS and DGCA.

The operator of all RPA categories (except Nano RPA) shall be responsible for notifying any incident/ accident involving RPA to the Director of Air Safety, DGCA as per format made available with CAR.

In case, the RPA is damaged and cannot be restored to original condition, the same shall be notified to DGCA by the owner/ operator for cancellation of UIN.

The RPAs operator shall ensure that all security measures as enumerated in the Security Programme (approved by BCAS) are in place before the operation of each flight.

The ground control station (while in use or in store) shall be secured from sabotage or unlawful interference.

The RPAs (issued with UIN) shall not be sold or disposed-off in any way to any person or firm without permission from DGCA.

Any changes in the contact details specified in UIN shall be immediately notified to DGCA and all other concerned agencies.

REMOTE PILOT TRAINING REQUIREMENTS

Remote pilot should have attained 18 years of age, passed 10th exam in English, and should have undergone ground/ practical training. Ground training can be obtained through any DGCA approved Flying Training Organization (FTO). The practical training shall comprise of RPA in flight having live component, and/ or simulated flight training to demonstrate control of RPA throughout its operating conditions, including safe recovery during emergencies and system malfunction.

EXEMPTION

The requirements for Remote Pilot Training Requirements are not applicable for Nano and Micro category RPA pilots intending to operate in uncontrolled airspace. However, the owner and user shall be fully aware of responsibilities for all aspects of flight safety during such operations.

RPAS MAINTENANCE REQUIREMENTS

Besides maintaining and repairing RPAs as per manufacturer's approved procedures, a UAOP holder is also required to maintain records of each RPA flight as per format provided with CAR and make such records available to the DGCA on demand.

EQUIPMENT REQUIREMENTS

All RPAs (except for Nano category intending to operate up to 50 feet (15 m) above ground level in uncontrolled airspace/ enclosed premises), are required to be equipped with specified serviceable components/ equipment. Indian Air Force will monitor movements of RPAs in the country in coordination with Airports Authority of India.

OPERATING REQUIREMENTS

A Standard Operating Procedure as per the relevant sections of Aeronautical Information Publication has to be prepared by an RPA Operator. All RPA operations shall be restricted to day only, within Visual Line of Sight (VLOS), subject to following conditions:

(i) RPA operations, except those in enclosed premises, shall be conducted only when the following meteorological conditions exist:

a) During daylight (between sunrise and sunset).

b) In Visual Meteorological Conditions (VMC) with a minimum ground visibility of 5 km and cloud ceiling not less than 1500 feet (450 m).

c) Surface winds of not more than 10 knots or as specified by the manufacturer.

d) No precipitation (rain, hail or snow) or thunderstorm activities, or exceeding those specified by the manufacturer.

(ii) The RPA operator [except Nano category intending to operate up to 50 feet (15 m) above ground level in uncontrolled airspace/ enclosed premises] shall obtain permission before undertaking flight through 'Digital Sky Platform'.

(iii) All RPA operators [except Nano and Micro category intending to operate up to 50 feet (15 m) above ground level and 200 feet (60 m) above ground level respectively in uncontrolled airspace/ enclosed premises] are required to file flight plan at least 24 hours before actual operations and obtain following:

a) ATC briefing, Meteorological (MET) briefing, and ATC clearance from the nearest ATC Unit

b) Air Defense Clearance (ADC) from the nearest IAF Unit

c) FIC Number from the Flight Information Centre (FIC) concerned.

(iv) All RPA operators (except Nano RPA operating below 50 feet), shall inform the concerned local police office in writing prior to commencing the operations.

OPERATING RESTRICTIONS

CAR further specifies the areas within which an RPA shall be flown keeping in mind the security and safety protocols. It cannot be flown from a mobile platform such as a moving vehicle, ship or aircraft and over eco-sensitive zones around National Parks and Wildlife Sanctuaries notified by Ministry of Environment, Forests and Climate Change without prior permission. RPAs are restricted from carrying out aerial photography/remote sensing survey over restricted areas specified in CAR. Although DGCA may authorize such operations on case-to-case basis subject to approval of Ministry of Defense. In such a case, application shall be submitted to the Director Regulations & Information, DGCA (seven copies) in the prescribed format as indicated at Annexure-XI.

MINIMUM STANDARDS FOR MANUFACTURING OF RPAS (BOTH INDIAN & FOREIGN)

CAR further stipulates the minimum standards for manufacturing of Small and above categories of RPAs. For all categories of RPAs, except Nano, the manufacturer has to provide a Certificate of Compliance along with No Permission-No Takeoff compliance to DGCA.

LEGAL OBLIGATIONS

CAR clarifies that the issuance of UIN and/ or UAOP by DGCA shall not confer any right on RPAs operator against the owner or resident of any land or building or over which the operations are conducted, or prejudice in any way the rights and remedies which a person may have in respect of any injury to persons or damage to property caused directly or indirectly by the RPA. Further, it shall not absolve the operator/ remote pilot from compliance with any other regulatory requirement, which may exist under the State or local law.

INSURANCE

It is mandatory for all civil RPA operators to have insurance with the liability that they might incur for any damage to third party resulting from the accident/ incident.

ENFORCEMENT ACTION

In case of violation of provisions of this CAR/ approved operating conditions, the UIN/ UAOP issued by DGCA shall be suspended/ cancelled. Breach of compliance to any of the requirements and falsification of records/ documents shall attract penal action including imposition of penalties as per applicable provisions of the Indian Penal Code, 1860 (IPC) (such as sections 287, 336, 337, 338). Necessary actions will be taken as per

relevant sections of the Aircraft Act 1934 / the Aircraft Rules 1937 or any statutory provisions.

ANALYSIS

While CAR is set to come into effect from December 1, 2018, it is likely to create doubts in the mind of RPA/ Drone users as to the complete understanding and compliance of the CAR to avoid Enforcement Action against them. Use of Drones is an important aspect in today's world and almost all major business entities require it for a purpose.

For infrastructure and real estate entities, use of drone is crucial at all times, especially during pre-tender survey in greenfield areas and due-diligence stage. Drones are also required to carry out and capture aerial survey of the progress of the works. While CAR makes it amply clear that there are no restrictions on Nano RPAs intended to fly upto 50 feet (15 m) above ground level in uncontrolled airspace/ enclosed premises for commercial / recreational / R&D purposes, Nano RPAs may not be sufficient enough to carry out all the requisite heavy duty recording and allied activities.

FAQs published by DGCA states that delivery of items is not allowed as of now under CAR even if flying below 50 feet. Another FAQ states that RPAs can be used for agricultural purpose except for the purpose of spraying pesticides until specifically cleared. RPAs if issued with UIN, cannot be transferred or disposed-off without permission from DGCA. It will be required to undergo process of cancellation of UIN and the subsequent buyer will have to apply for fresh UIN through Digital Sky Platform.

Several grey areas and doubts remain to be answered by DGCA and clearly, all entities will have to cautious and careful while using or engaging any entity to use drone facility for them. DGCA has imposed strict enforcement action in case of violation of CAR as well as penal action, as may be applicable.

We look forward for further updates on the subject from DGCA and shall update our esteemed readers in our upcoming newsletters.

INDIA'S PHARMACOVIGILANCE REGIME

Aishani Das & Prashant Daga

INTRODUCTION

The Pharmacovigilance Programme of India (PvPI) is an administrative mechanism that has been developed for monitoring the safety of authorized medicinal products (for human use) and to detect any deviation in their risk-benefit balance.[27]

The PvPI mechanism rests on continuous communication to stakeholders and risk management of Adverse Drug Reactions (ADRs). Stakeholders in the PvPI system include healthcare bodies and professionals, manufacturers of drugs (i.e. Market Authorization Holders/MAHs), Adverse Drug Reaction (ADR) Monitoring Centres (AMCs), regulatory bodies such as the Central Drugs Standard Control Organization (CDSCO) and ADR reporting-cum-analysis bodies within the National Coordinating Centre (NCC)-Indian Pharmacopeia Commission (IPC).

This article attempts to provide an outline of the system of pharmacovigilance in India.

AUTHORITIES AND THEIR RESPECTIVE ROLES

A. **CDSCO**

a. Taking regulatory decision on the basis of recommendations of Signal Review Panel (SRP)[28] and the Steering Committee of NCC –PvPI at IPC,

b. Decisions on the basis of *scientific evaluation* of Periodic Safety Update Report (PSUR) data, and

c. Utilization of evidence-based information to initiate appropriate regulatory decision such as changing/ updating package-insert[29], issuance of Drug Alerts[30], banning of drug, etc.

B. **State Drug Regulatory Authority**

a. Monitor ADRs as per Para 28, Schedule M[31] of the Act (based on information received from MAHs) and the same is also forwarded to NCC-PvPI.[32]

C. **Indian Pharmacopoeia Commission**

IPC is the nodal agency which is functioning as NCC of PvPI program, supervising and regulating the PvPI programme (*see, for details Ch. 1 Guidance Document*). It is also responsible for coordinating with WHO-Uppasla Monitoring Centre, Sweden. The following bodies work under NCC:

i. AMCs are responsible for collection and reporting of ADRs.

ii. The *Steering Committee* supervises and provides overall guidance for the PvPI programme. Further, the decisions of the Steering Committee are presented to the Drugs Technical Advisory Board (DTAB) by CDSCO.[33]

iii. *Working group* reviews and monitors major technical issues related to establishment

27 http://www.ipc.gov.in/PvPI/about.html

28 A 'signal', as defined by the World Health Organization, is reported information of preliminary nature that seeks to establish a causal relationship between an adverse reaction and the use of a drug, in the document titled 'Signal Review Panel under PvPI' published by IPC.

29 DCGI letter to State Drug Controllers dated 12th May, 2015 directing manufacturers of the drug Carbamezepine to effect changes in safety label based on recommendations of the SRP and Subject Expert Committee.

30 PvPI releases monthly drug alerts based on preliminary assessment of ADRs to direct healthcare professionals and consumers to closely study the effect of such drugs and report further ADRs, if any.

31 This provision makes it an obligation of the MAH to report ADRs to the State Licensing Authority as a part of 'Good Manufacturing Practices'.

32 Pharmacovigilance Guidance Document for Market Authorization Holders of Pharmaceutical Products published by IPC, January 2018, p. 2-3 (Guidance Document). Also see, PvPI Newsletter, Vol. 6 Issue 16 available at: http://www.ipc.gov.in/PvPI/newsletter/Newsletter%20Vol%206%20Issue%2016%202016%20PDF.pdf

33 Process and Procedures as per the 'Standard Operating Procedure for Communications in Pharmacovigilance Programme of India' dated 22nd February, 2011, p. 4-5

and implementation of the programme. It also provides technical inputs to CDSCO for appropriate regulatory intervention/actions.

iv. *Quality Review Panel* reviews quality, prepares causality assessment reports and ensures completeness of Individual Case Safety Reports (ICSRs).

v. *Signal Review Panel* is responsible to assess the database for the occurrence of 'signals' of possible repercussions on public health, drug regulation and science.

Steps in PvPI programme

Step 1: *ADR Reporting*

a. *Who can report*: All healthcare professionals (clinicians, dentists, pharmacists and nurses) and consumers may report ADRs. Pharmaceutical companies can also report ICSRs/ PSURs-specifics for their products. AMCs (which are basically hospitals or medical colleges) are responsible for continuous monitoring of drugs; all reports received through AMCs are entered into a digital software known as 'Vigiflow' which is maintained by the World Health Organisation (WHO).

b. *How to Report:* Different ADR forms are available at http://www.ipc.gov.in/PvPI/adr.html for reporting adverse drug reactions.

c. *Whom to report:* Such ADR forms can be submitted to AMCs or directly to NCC. One can also report through NCC-PvPI helpline - 1800 180 3024.

d. The above data collected is used for signal generation, risk management, drug regulation and educational purposes.

Step 2: *Assessment of Adverse Event*

a. *Causality Assessment* involves the evaluation of likelihood that a medicine was the causative agent of an observed adverse event. AMCs are responsible for causality assessment reports which shall be reviewed at NCC. NCC may further route these communications to CDSCO. (*For details see, Ch. 6 Guidance Document*)

b. *Signal Detection*: If there is any causal relationship between an adverse event and a drug and such relationship was previously unknown or incompletely documented, a 'signal' is generated.[34] More than a single report is required to generate the signal depending upon the seriousness of event and the quality of information.

c. NCC performs the identification and initial review of a signal, the results of which are submitted to the SRP. SRP reviews the report against the following parameters - quality, content and completeness of data.[35]

d. The information generated by NCC on the basis of ADR reports assists in continuous assessment of the benefit-risk ratio of medicines. The information is submitted to the Steering Committee of PvPI constituted by the Ministry of Health & Family Welfare (MOHFW). The Committee is entrusted with the responsibility to review the data and suggest any intervention that may be required.[36]

e. NCC will *communicate* the findings of aforementioned review and also the metrics related to ADR data to CDSCO through a monthly report.

34 *See Generally, Ch. 7, Guidance Document, supra note 6.*

35 *Generally see, PvPI performance report available at: http://www.ipc.gov.in/PvPI/pub/Pharmacovigilance%20Programme%20of%20India%20Annual%20performance%20Report%202014-2015.pdf*

36 *Advice on Reporting as stipulated in the Suspected Adverse Drug Reaction Reporting Form, Version 1.2, IPC (available at https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzAz)*

Step 3: *Risk Management and Communication*

a. The scientific data collected and analysed in Step 2 is forwarded by NCC to the CDSCO for appropriate regulatory actions.[37]

b. CDSCO is also responsible for giving directions to the concerned state Licensing Authorities for taking appropriate actions in the form of change in label/package inserts or recall in relation to the drugs which have been identified as spurious, sub-standard and injurious to human health by NCC in Step 2.[38] The flow of aforementioned regulatory directives is illustrated below:

c. Communications to all PvPI stakeholders will be the primary responsibility of the CDSCO-HQ. The linkages outlined in the flowchart below[39] ensure that pharmacovigilance information is well-circulated and all stakeholders are kept in the loop.

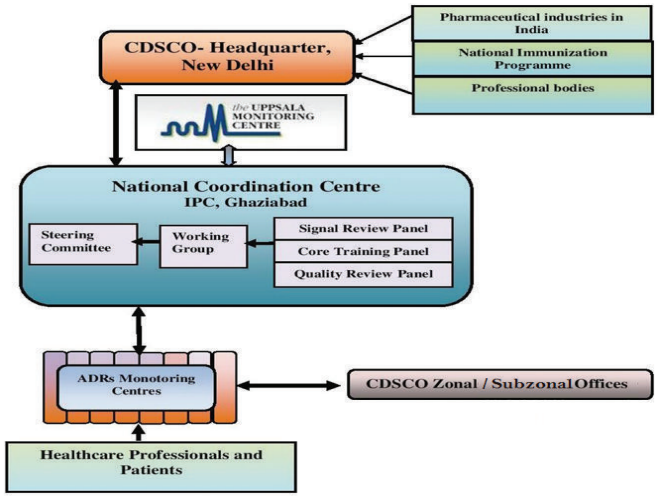

Figure 1: Communication Flow in PvPI Programme

CONCLUSION

Having commenced in 2010, the PvPI programme now has 250 AMCs working across India.[40] During the period 2011-2016[41], it received 1,81,656 ADR reports from all sources.[42] In the period 2015-16, the SRP made eleven recommendations regarding change in label for investigational drugs to CDSCO - out of which three recommendations got approved.[43] The work of PvPI has been duly recognised by WHO. It has been made WHO-Collaborating Centre for Public Health Programmes and Regulatory Services.[44] The WHO-NRA assessment awarded highest maturity level – 4 out of 5, to PvPI.[45]

Every drug has benefits and risks associated with its use. It is only when the benefits outweigh the risk that the drug is considered safe for human use. The process of benefit-risk analysis is a continuous process. The current PvPI system is an attempt to bring uniformity in post-marketing surveillance of a drug, creating a single-window collection and analysis of ADRs and bringing the current regime at par with global WHO standards.

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37 *See generally, Indian Pharmacopoeia notification ref no.: IPC/NCC-PvPI/SRP/2016-17 dated 14.12.2016 in which PVPI recommend that regulatory actions be undertaken for 24 drugs. The copy of the said notification is available at: http://www.cdsco.nic.in/writereaddata/PvPI%20recommendations.pdf*

38 *See generally, CDSCO notification ref. no. File no. 4-01/2015-DC (Misc.82) dated 23.12.2015 CDSCO available at: http://www.ipc.gov.in/PvPI/das/Regulatory%20Pharmacovigilance%20-Potential%20signal%20and%20Recommendation%20for%20the%20label%20change%20of%20certain%20medicinal%20product%20marketed%20in%20India%20-%20Reg.pdf*

39 *This diagram has been taken from the Guidance Document for Spontaneous Adverse Drug Reaction Reporting of May, 2014 pblished by the IPC, p. 6*

40 *www.ipc.gov.in/PvPi/adr/ADR.pdf*

41 *Data for 2016-17, 2017-18 is not been available.*

42 *PvPI, Annual Performance Report, 2015-16 http://www.ipc.gov.in/PvPI/pub/Pharmacovigilance%20Programme%20of%20India%20Annual%20performance%20Report%202015-2016.pdf*

43 *Id.*

44 *http://www.ipc.gov.in/PvPI/newsletter/Newsletter%20Vol%207%20Issue%2021%202017%20PDF.pdf*

45 *Id.*

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