



Mysuru Chapter e-Magazine

November 2020
199th Edition



Vision

"To be a global leader in promoting good corporate governance"

Motto

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From the Desk of Chairman

CS Parvathi K R
Chairperson
Mysuru Chapter

Dear Professional colleagues,

Greetings from the Mysuru Chapter of ICSI.

On behalf of Mysore Chapter of ICSI, I wish you all a happy Deepavali !

May this festival of lights fill your life with lots of light, brightness, cheer, and colour

Institute is working hard to conduct the examinations by taking all precautionary measures and complying with SOP standards. As the Examination is around the corner, I am sure the students have started preparing for the exams. I recall the words of an American writer William A Ward-

“Study while others are sleeping; work while others are loafing; prepare while others are playing; and dream while others are wishing. This is the recipe for success”

It is a time to sing a song again

“One more river,

And that’s the river to cross…….”

We are just a step away from reaching a great milestone. The 200th edition of the e-Magazine. I know you all are eagerly waiting as much as I am.

Feel free to share inputs, feedback and suggestions to continue this journey of growing together!



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Company Secretaries of India**

भारतीय कम्पनी सचिव संस्थान

IN PURSUIT OF PROFESSIONAL EXCELLENCE

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Chapter Activities

Career Awareness Program

Chapter organized three Career Awareness Programs during the month through online mode. The details are as follows

S. No	Date	College Name	Speaker	No of Participants
1	05.10.2020	SDM &MMK Mahila Maha Vidayala Studnets, Mysuru	CS Vijaya Rao N. Dhanabal	150
2	17.10.2020	JSS College for Women, Mysuru	CS Madhwesh K N. Dhanabal	75
3	19.10.2020	JSS College for Women, Mysuru	CS Phani Datta D N	75

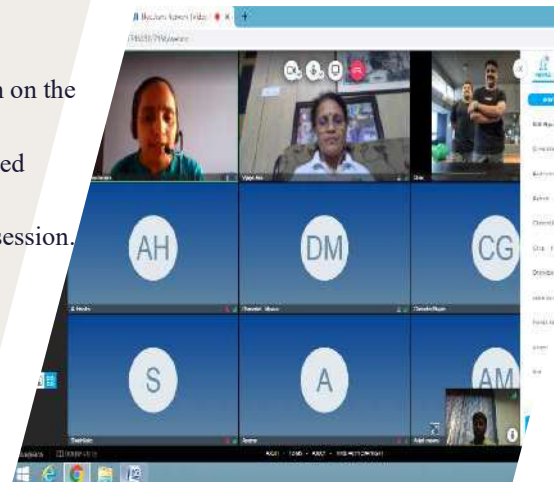
Foundation Day Celebration

a. FIT India – FIT ICSI : Zumbathon

On the occasion of 52nd Foundation Day of ICSI, Chapter organized the Fit India – Fit ICSI session on the topic “Fitness First” on 2nd October, 2020 from 5.00 pm to 6.00 pm through online.

CS Parvati K R., Chairperson of the Chapter welcomed the participants for the session and explained the motive of the Institute’s initiative & the importance of maintaining healthy body & mind. CS Vijaya Rao, Vice Chairperson introduced the resource persons of the session & moderated the session. Mr. Christopher, Mr. Raju & Ms. Shilpa from Team Synergy (Certified Trainers from Mysuru) trained the participants in the following areas. Warm Up, Surya Namaskara, Strengthening, Abs workout & Aerobics. Fitness pledge also has been administered during the event.

CS Harsha A., Secretary of the Chapter proposed the vote of thanks. Members & Students of the Chapter participated in the session and got benefitted.



b. Sprawling Governance in Grassroots - Code for Charity Governance

On the occasion of 52nd Foundation Day of ICSI, Chapter organized the Sprawling Governance in Grassroots session on the topic “Code for Charity Governance” on 3rd October 2020 from 7.00 pm to 8.00 pm through online.

CS Parvati K R., Chairperson of Mysuru Chapter welcomed the participants for the session and appreciated the efforts of the Institute in making this code. CS Vijaya Rao, Vice Chairperson Introduced the resource person of the session & moderated the session. CS Alok, Practicing Company Secretary from Mysuru was the speaker for the session. CS Parvati K R., Chairperson Proposed the vote of thanks.

Around 20 Members, Students of the Chapter & members from various charitable organizations participated in the session and got benefitted.



3. Students Study Circle Meeting

Chapter organized a Study Circle Meeting for students on 02.10.2020 in the topic “Related Party Transactions under Companies Act 2013” through online. CS Anuj Mehta, Company Secretary, S3V Vascular Technologies Private Limited moderated the session. CS Phani Datta D N., Treasurer welcomed the gathering & introduce the speaker. Around 15 students from Executive & Foundation stage participated in the session and discussed.



*Watch Out for
Mysuru Chapter e-Magazine
special 200th edition
Dec 15th 2020
With thought provoking articles and
columns*

To File or not to File Softex Forms and Legal Implications



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There are many Software exporting companies operating outside an export oriented scheme (STP, SEZ, EOU etc.) and they are always confused whether they need to comply with the erstwhile STPI guidelines and RBI regulations of filing Softex forms, sometimes they are also advised, that there is no need for them to file SOFTEX forms anymore as the STPI and IT benefits are over, due to the sun set clause in the Income Tax Act. Many young entrepreneurs feel that STPI should have been closed when the income tax exemption scheme expired half a decade ago and Verification of invoices serves absolutely no purpose, lately Even without STPI verification it is legal money coming in via legal banking channels for a legal purpose without any scope of tax evasion

Many Start-ups obviously get confused and, in some cases, companies stopped getting SOFTEX certification done, after complying with the STPI and RBI guidelines in past when they moved out of STP/SEZ schemes.

There are always two parts to deal with regulatory compliance. One, the policy aspect and second, the procedural aspect. Procedural are explained in plenty but no proper explanation on the policy is available, hence the confusion continues.

In general exports means sending 'goods and service' to clients in foreign country (outside territorial borders of India) for purpose of sale. The value of the goods declared is accepted & recorded and certified by the customs office called "valuation of export". Once the valuation of export is complete, the value is accepted both by RBI and its authorised dealer (the exporter's bank). RBI then monitors, the remittance of an equivalent value in exporter's bank account, the purpose of this process is that the person exporting the goods does not undervalue the goods or overvalue the goods thereby resulting in money laundering, this is the answer to the question of many entrepreneurs that Verification or valuation of invoices serves absolutely no purpose, and Even without verification it is legal money coming in via legal banking channels for a legal purpose without any scope of tax evasion, how can money be legal when the export value is X and the exporter receives foreign currency for X PLUS , thereby resulting in illegal money travelling into the country, not only that this may also result in tax evasion

Software as Goods - The Apex Court in the case of Tata Consultancy Services vs State of Andhra Pradesh on 5 November, 2004, held that Computer programs are the product of an intellectual process, but once implanted in a medium are widely distributed to computer owners and are goods. Similarly, when a professor delivers a lecture, it is not a good, but, when transcribed as a book, it becomes a goods. This how SOFTEX came into existence, therefore all software exports are classified as GOODS, Software (IT and ITeS) was given a special status in international trade equivalent to 'goods'.

Coming to the valuation of Software Invoices we first need to understand that the export process of Software can be physical on a media (CD/DVD, magnetic tapes etc.) OR exported through data communication links. There is a difference, when exported through data communication links, there are no physical goods, therefore government has

announced SOFTEX form as an alternative to the GR/PP forms (Physical exports), to suit the export of Software, through data communication links.

The RBI circulars on SOFTEX mentions exports of 'Software', there are multiple interpretations stating that software covers both Software services and Software products and Software services include a whole lot of things from consulting to design, development, implementation, maintenance, re-engineering of Software or a Software product and 'ITeS' covers all those services that are delivered to clients across borders of India using an IT driven system and process over a telecom/internet link (include BPO, KPOs, Digitization, Call centres, Data processing etc.) Seriously mistaken in its interpretation of software and the things Softex applies to, many entrepreneurs are confused as to what is included as software. The FEMA (export of goods and services) regulations 2000 - Notification No. FEMA 23 /2000-RB clearly defines Software as follows:

"includes transmission through any electronic media and 'software' means any computer programme, database, drawing, design, audio/video signals, any information by whatever name called in or on any medium other than in or on any physical medium ;

Therefore, we first need to determine whether services rendered by a company falls under Softex process or not, on proper interpretation a lot of consulting won't fall under Softex. As another proof point, the RBI incoming remittance classification includes a code category for "Computer, electronic, telecommunication ... consultancy services other than those covered in the SOFTEX form".

Had all software services fallen under Softex, why would that category exist?!! Therefore, proper interpretation is necessary, as Non filing of SOFTEX will result in the exports proceed realized and the remittance received treated as either 'general services' or not as an export proceed or illegal.

For general services such as management consulting, technical services there is no declaration form required to be filed.

For Software exporting companies not operating under STPI, it is possible to bypass and get remittances without filing SOFTEX , under the guise of a 'service' export. There is no immediate threat of non-compliance, However, not getting classified as 'software' can create problems in future. First problem created is your exports are not 'Software exports'. The other problems can erupt from regulations in other areas of taxation etc. Complex GST rules can create a lot of problem. Any situation, where an exporter will need to prove and protect itself can end up in to a nightmare of non-compliance.

In terms of Regulation 3 ibid, the exporters of goods and services are required to declare the value of exports to the specified authority viz. Commissioner of Customs in case of goods and Director of STPI in case of software. RBI requires the certification of the value of exports by the specified authority in order to monitor their realization and the specified authority is made responsible for this certification, the declaration of the value of exported software and its certification is a post facto exercise which would be undertaken after export performance.

Regulation 3(3) ibid has clarified that in situations where there are no prescribed declarations are specified to be made for any services, the exporter may export such services without furnishing any declaration, but shall be liable to realize the amount of foreign exchange which becomes due or accrues on account of such export and repatriate in accordance

with FEMA regulations. The above is applicable only when the regulations do not prescribe any declaration for the services which are exported.

However, as stated earlier, for export of software a declaration in the manner of SOFTEX has to be filed as the same is prescribed. Hence, every exporter of software is obliged to file a declaration in SOFTEX.

In case where the DTA (Domestic Tariff Area) units engaged in export of software services, has failed to declare their software exports and get them certified in SOFTEX forms, the same amounts to violation of Foreign Exchange Management (Export of Goods and Services) Regulations, 2015. This will attract penal proceedings under Section 13(1) FEMA . Further, entities engaged in exports are entitled to claim refund of the input GST paid on inputs and input services received for undertaking exports. In order to process these refund claims, the concerned tax authorities insist the business entities engaged in software exports to submit SOFTEX forms for the purpose of processing of such refund claims. Non-submission of said forms may lead to rejection of the refund claims.

Further, in the absence of certified SOFTEX forms, the banks will process the inward foreign exchange remittances as proceeds realized towards exports of services and accordingly BRCs (Bank Reconciliation Statements) will be issued certifying that the proceeds are received against export of services but not towards export of software. This will act as deterrent to the business entities in claiming that they have previous export performance for participation in tenders related to software projects.

Therefore, for export of software a declaration in the manner of SOFTEX has to be filed as the law exists today, Coming to the view that STPI must be abolished & Softex Discontinued there are several opinion on this aspect stating that the STPI as a regulation/process are the worst form of red tape that should be scrapped.

When there are no benefits under the STPI scheme and with ever growing e governance & central government facilitating ease of doing business, should STPI exist?



Code of conduct – An Instrument for Self-Governance



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What is a Code of conduct?

The code of conduct describes the expectations that we have of ourselves and our stakeholders. Code of conduct consists of all the obligations that professionals must respect while carrying out their duties. It includes core values of the profession and the behaviour which should be adopted. People who breach their code of conduct incur disciplinary actions that can range from a warning or reprimand to dismissal or expulsion from their professional order.

A code of professional conduct is a necessary component to any profession to maintain standards for the individuals within that profession to adhere. It brings about accountability, responsibility and trust to the individuals that the profession serves. Code of conduct is adopted to assist members in understanding the difference between right and wrong and in applying that understanding to their decisions. Code of conduct refers to the principles, values, standards or rules of behaviour that guide the decisions, procedures and systems of a profession in a way that contributes to the welfare of its key stakeholders and respects the rights of all constituents affected by its operations. a warning or reprimand to dismissal or expulsion from their professional order.

The Code of Conduct outlines specific behaviours that are required or prohibited. Codes of conduct are written to guide behaviour. It is probably quite obvious that codes of conduct are not made for circumstances where it is easy to do what is right, but rather for when immediate factors might otherwise render the proper move unclear or obscured by ideas of expediency. These are made to guide us towards consistently proper or ethical choices so that we habitually avoid difficult and ambiguous situations. However, we have to accept that despite rules, constraints, training, or promises, human beings act in accordance with their morality.

Professional codes of conduct draw on professional ethical principles viz. honesty, trustworthiness, loyalty, respect for others, adherence to the law, doing good and avoiding harm to others, accountability, as the basis for prescribing required standards of behaviour for members of a profession. They also seek to set out the expectations that the profession and society have of its members. Most professionals have internally enforced codes of conduct that members of the profession must follow to preserve the integrity of the profession. This is not only for the benefit of the client but also for the benefit of those belonging to that profession. Disciplinary codes allow the profession to define a standard of conduct and professional responsibility and ensure that individual practitioners meet this standard, by disciplining them through a professional body if they do not practice accordingly. It also maintains the public's trust in the profession, encouraging the public to continue seeking their services.

Purpose of the Code of conduct

The intention of code of conduct is to provide guidelines for the minimum standard of appropriate behaviour in a professional context. Codes of conduct sit alongside the general law of the land and the personal values of members of the profession. The primary value of a professional code of conduct is not as a checklist for disciplining non-conforming members, although breaches of a code of conduct usually do carry a professional disciplinary consequence. Rather, its primary value is to act as a prompt sheet for the promotion of ethical decision-making by members of that profession.

Benefits of the Code of conduct

Professional codes of conduct provide benefits to:

- the public, as they build confidence in the profession's trustworthiness
- clients, as they provide greater transparency and certainty about how their affairs will be handled
- Members of the profession, as they provide a supporting framework for resisting pressure to act inappropriately, and for making acceptable decisions in what may be 'grey areas'
- The profession as a whole, as they provide a common understanding of acceptable practice which builds collegiality and allows for fairer disciplinary procedures
- Others dealing with the profession, as the profession will be seen as more reliable and easier to deal with.

Living the Code of conduct

In order to be of use or relevant to a professional, a code of conduct requires internalization and habitual reference. Specifically, it requires a strong, consistent internal standard; quantifiable, integrated into every element of practice, and each component related to the others. The result of this standard put into practice is known as professionalism which means behaving in an ethical manner while assuming and fulfilling your rightful responsibilities in every situation every time, without fail. It means, in part, conducting your affairs in such a way as to garner trust and confidence in every aspect of your work. It means having the requisite ability to be worthy of the confidence others place in you.

Professionalism connotes "Professional responsibility" which implies obligations and standards in the performance of services. Characteristically, there are three elements in the concept "professional responsibility. One element concerns the effective use of that body of knowledge that the profession has developed. A second concerns the suitability of the professional's attitudes and actions in dealing with the client when viewed in terms of regard for public standards and ethics in behaviour. The third element focuses on the propriety of the professional's conduct in view of the professional's self-image. Typically, all three perspectives are commingled and may be presented as a "code of professional conduct. A professional Code of conduct is a rational construct built upon a foundation of values. Those in the habit of moral discrimination—the practice of automatically comparing issues to their own core values and deciding and/or acting accordingly—are people of integrity. But not everyone is practiced at or has disciplined themselves to evaluate and make decisions in this manner. There are many who approach each situation afresh and evaluate based merely on immediate factors and/or emotional primacy.

Professional decisions which are compatible with the professional Code of conduct therefore require of individuals three qualities that can be identified and developed. The first is competence to recognize issues and to think through the

consequences of alternative resolutions. The second is self-confidence to seek out different points of view and then to decide what is right at a given time and place, in a particular set of relationships and circumstances. The third is what William James called tough-mindedness, which is the willingness to make decisions when all that needs to be known cannot be known and when the questions that press for answers have no established and incontrovertible solutions. At times, under pressures to get ahead, the professional (of whose native integrity we are hopeful) is tempted to pursue advancement at the expense of others, to cut corners, to seek to win at all cost, to make things seem better than they are. We often make small ethical compromises for "good" reasons. Minor ethical lapses can seem harmless, but they instill in us a hard-to-break habit of distorted thinking. Rationalizations drown out our inner voice, and we make up the rules as we go. We lose control of our decisions, fall victim to the temptations and pressures of our situations, taint our characters, and sour business and personal relationships. The professional practice requires a prolonged play of judgment. Professionals must find in their own will, experience, and intelligence the principles and practice of conduct they apply in balancing conflicting claims.

Code of conduct in practice is only as strong as the individual's moral base. When one's core morality is based on relativism, any ethical constraints become impotent because then any behavior or practice can be justified according to its relative value and appropriateness. As should be obvious, such behavior contradicts ethical constraint. It is probably quite obvious that rules and codes of conduct are not made for circumstances where it is easy to do what is right, but rather for when immediate factors might otherwise render the proper move unclear or obscured by ideas of expediency. More to the point, codes of conduct are made to guide us toward consistently proper or ethical choices so that we habitually avoid difficult and ambiguous situations. However, despite rules, constraints, training, or promises, human beings can only be trusted to act in accordance with their morality. Since a professional must unfailingly adhere to the rules of professional ethics, perhaps you can perceive the potential for problems presented by any allowance for relativism.

Living the Code of conduct - live examples

I was invited to deliver a lecture on the occasion of the founders' day of a company. I decided to talk on Code of Conduct. I raised a question - is there a Code of conduct in the company? Many hands went up (though not all), then I asked, have you read it? Fewer hands were up now, I then asked - have you understood it, still fewer hands went up. Finally, I asked - do you live by it? Only two hands went up in a gathering of about 350 people. It is good thing for a company to have a code of conduct, but more importantly people must also live by it.

I was a speaker at one of the seminars at Chennai organized by the Institute of Cost Accountants of India. Sitting on the dais alongside was a senior professional lady from a company based in Noida. As is customary after the presentations by the speakers a memento was offered to all the dignitaries sitting on the dais. When the gift packed memento was handed over to this lady she whispered in my ears "what is the cost of this?" I was surprised, I said 'Madam why are you bothered ..this is just a token of appreciation for your having come all the way to participate as a speaker at the seminar " she said ' No, Dr. Gupta my company has a gift policy. If whatever is there inside the box exceeds that threshold amount, then sorry I would not be able to accept it "I was startled. Here was a lady who was living the code of conduct of the company in true sense.

Conclusion

In order to be of use or relevant to a professional, a Code of conduct requires internalization and habitual reference. Specifically, it requires a strong, consistent internal standard; integrated into every element and various dimensions of practice. A professional need to live the Code of conduct and manifest the same in all his professional actions, duties and responsibilities. A professional code of conduct articulates both expected and unacceptable standards of behavior. However, a code without discipline lacks substance and impact. Desirable behavior results from training, ensuring professionals comprehend the code through written acknowledgements and reinforcing the standards in practice every day.

Labour Codes and Opportunities for PCS



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The Government's decision to amalgamate various labour acts into 4 Labour codes is a welcome step. Let us have brief overview of the new Labour Codes.

1. Wage Code (69 Sections and 9 Chapters)

The historic wage code got the Presidential assent on 08th August 2019, which was a major boost to the labour reforms in India.

It subsumes 4 Acts.

- a. The minimum wages Act,
- b. Payment of wages Act
- c. Payment of Bonus Act, and
- d. The equal remuneration Act.

Further, three other labour Codes, being Code on Social Security, Occupational Safety and Health Working Conditions Code (OSHC) and the Code on Industrial Relations received Presidential assent on 28th September 2020

2. Social Security Code 2020,

It subsumes nine labour acts relating to social security, retirement and employee benefits, such as (i) The Employees Compensation Act, 1923, (ii) The Employees State Insurance Act, 1948, (iii) The Employees Provident Fund and Miscellaneous Provisions Act, 1952, (iv) The Employees Exchange (Compulsory Notification of Vacancies) Act, 1959, (v) The Maternity Benefit Act, 1961, (vi) The Payment of Gratuity Act, 1972, (vii) The Cine Workers Welfare Fund Act, 1981, (viii) The Building and Other Construction Workers Cess Act, 1996, and (ix) The Unorganized Workers' Social Security

Act, 2008). The Social Security Code shall give a new dimension to the existing labour laws and shall ensure uniformity across labour legislations. The code, among other things, provides for

1. Aadhar is basis for identification
2. Stringent penalties
3. The definition of wages has changed. Now wages include basic, DA and retaining allowance if any but does not include HRA and other allowances to be excluded for the purpose of wages.

3. Occupational, Safety, Health and working conditions Code (OSH Code 2020)

It subsumes 13 Acts into one single code with 143 provisions.

1. The Factories Act, 1948
2. The Contract Labour (Regulation and Abolition) Act, 1970
3. The Mines Act, 1952
4. The Dock Workers (Safety, Health and Welfare) Act, 1986
5. The Building & Other Construction Workers (Regulation of Employment and Conditions of Service) Act, 1996
6. The Plantations Labour Act, 1951
7. The Inter-State Migrant Workmen (Regulation of Employment and Conditions of Service) Act, 1979
8. The Working Journalist and other News Paper Employees (Conditions of Service and Miscellaneous Provision) Act, 1955
9. The Working Journalist (Fixation of rates of wages) Act, 1958
10. The Cine Workers and Cinema Theatre Workers Act, 1981
11. The Motor Transport Workers Act, 1961
12. The Sales Promotion Employees (Conditions of Service) Act, 1976
13. The Beedi and Cigar Workers (Conditions of Employment) Act, 1966

Some establishments such as factories and mines, and those hiring workers such as Beedi and Cigar workers, may be required to obtain additional licenses to operate.

- The Code aims at lessening the burden of the employers as it would replace multiple registrations under various enactments to one common registration, one licence and one return which will ultimately create a consolidated database centrally and will be helpful under ease of doing business.
- The workplace should be kept free from hazards that cause or likely to cause injury or occupational disease to the employees
- Employers are required to conduct free annual health check-up for their employees.

4. Industrial Relations Code 2020

It subsumes 3 labour Acts

1. The industrial Disputes Act
2. The Industries Employment Standing Orders Act
3. The Trade Unions Act

The Code introduces 'fixed term employment', giving employers the flexibility to hire workers based on requirement through a written contract. Fixed term employees should be treated on par with permanent workers in terms of hours of work, wages, allowances and other benefits, including statutory benefits such as gratuity.

The Code says any establishment that employs 300 or more workers must prepare standing orders relating to classification of workers, manner of intimating to them periods and hours of work, holidays, pay days etc, shifts, attendance, conditions for leave, termination of employment, or suspension, besides the means available for redress of grievances.

Salient features of Labour Codes

It is indeed needless to say that the four codes aim to simplify, rationalize and amalgamate 29 existing central labour enactments for ease of doing business. The salient features of Labour Codes are as follows.

1. Social security is provided now informal sector workers, gig workers and platform employees.
2. Various expressions and definitions are introduced in the Codes.
3. For example, a) Career Centres b) Home based worker c) Platform worker d) Self-employed worker and e) Aggregator.
4. The code provides for eight hours work excluding lunch time
5. Compounding of offences is introduced.
6. To electronically upload the data and to maintain the Registers in electronic mode.
7. Establishments covered by the Code are required to register within 60 days (of the commencement of the Code) electronically to the registering officers appointed by the Central or State government. under the Code by the establishment within such time as may be notified.
8. Govt to frame schemes for self-employment persons
9. Gratuity for fixed term employee on pro rata basis but normal employees after 5 years of service.
10. 9.The role of inspector under the Code is now facilitator.
11. 10.To appeal against the order of authority 25% of the penalty amount has to be paid first.

The Central Govt is formulating Rules and thereafter it will be notified. It is expected that Rules will be notified in the end of 2020 or in the beginning of 2021.

Opportunities for PCS

The door of Opportunity is opened for PCS. Plenty of professional opportunities are available to PCS to facilitate compliances under Labour Codes and Rules made thereunder. Many companies are not having separate HR department or Hr Manager. PCS can act as Labour consultant for those companies and help in registration, obtaining licence, keeping the electronic registers, filing annual returns, interpretation of codes and appearing before labour authorities etc.,

Conclusion

Any transformation will initially have teething issues and in the course of time everything will become normal. It is certain that the labour codes when implemented would achieve the purpose of ease of doing the business and would offer enough opportunities for PCS.

Clinical Trial of Vaccines: A Legal Perspective



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The outbreak of the coronavirus pandemic has devastated the entire world. “Positive” has become the most “negative” word of the year 2020 and every person has a story of their struggle. While we salute the services of each and every corona-warrior, the pharma companies/governments are making their best efforts to discover the vaccine which is not expected to be released in market until the first half of 2021. With the second wave in sight and governments imposing further lockdowns around the globe, the need for vaccine has become the desperate need of the hour. With more and more companies coming forward to conduct trials and few stepping back in light of side effects and unknown illness, many trials have stopped, and discovery of the vaccine is further prolonged. Hence under the complex legal ecosystem, it becomes all the more important for obtaining approvals for vaccine trials. Some of the important aspects of such regulatory and legal procedures behind the vaccine trails are explained below.

Clinical trials are an arrangement of practices performed to confirm and guarantee the security of a new drug. As defined under Rule 2(j) of the New Drugs and Clinical Trials Rules, 2019 “clinical trial” in relation to a new drug or investigational new drug means any systematic study of such new drug or investigational new drug in human subjects to generate data for discovering or verifying its,-

- i. clinical or;
- ii. pharmacological including pharmacodynamics, pharmacokinetics or;
- iii. adverse effects,

Laws governing the clinical trials in India:

- Drugs and Cosmetics Act - 1940
- Medical Council of India Act - 1956, (as amended in the year 2002)
- Central Council for Indian Medicine Act - 1970
- Guidelines for Exchange of Biological Material (MOH order, 1997)
- Right to Information Act - 2005
- Ethical Guidelines of the Indian Council of Medical Research (2006)
- Indian Good Clinical Practice Guideline (2001)
- New Drugs and Clinical Trial Rules, 2019



Regulatory bodies:

The Central Drugs Standard Control Organisation (CDSCO)

CDSCO is the National Regulatory Authority in India set under the Ministry of Health and Family Welfare, Government of India. Its mission is to safeguard and enhance public health by assuring the safety, efficacy and quality of drugs, cosmetics and medical devices.

Drugs Controller General of India (DCGI)

DCGI is an official of the CDSCO is the ultimate regulatory authority for the approval of clinical trials in the country. Jurisdiction of the office of DCGI, also extends to inspections of trial sites, inspections of sponsors of clinical research and manufacturing facilities in the country, oversight of the Central Drugs Testing Laboratory (Mumbai) and the Regional Drugs Testing Laboratory, heading the Indian Pharmacopoeia Commission among various other roles, responsibilities and functions.

Indian Council of Medical Research (ICMR)

ICMR is responsible for the formulation, coordination and promotion of biomedical research in the country. Ministry of Health and Family Welfare and the Department of Health Research, Government of India provides funding to ICMR for carrying out their functions.

The Medical Council of India (MCI) Act states that all clinical trials in India should follow the ICMR guidelines of 2000. Further, Schedule Y along with rules 122A, 122B, 122D, 122DA, 122DAC and 122E of the Medical Council of India Act governs clinical research in the country. There are also 12 appendices, formats for clinical trial protocols, informed consent forms, Ethics Committee (EC) approval templates and format for Serious Adverse Event (SAE) reporting.

An online clinical registry has been initiated by the Indian Council of Medical Research (ICMR) for the registration of any interventional trial to ensure the following goals:

- Transparency and accountability of clinical research
- Internal validity of clinical trials
- To oversee the ethical conduct of clinical trials
- Reporting of results of clinical trials

Stages of clinical trials:

Clinical trials are carried out in four phases. Clinical trials of drugs developed in India must undergo all four phases of trials in India

Phase I or clinical pharmacology trials or “first in man” study

A small number, a minimum of 2 healthy, informed volunteers are identified for each dose under the close supervision of a doctor. The purpose is to identify if the volunteers develop any tolerance and their behaviour to the medicine in the body.

Phase II or exploratory trials

The medicine is administered to a group of approximately 10-12 informed patients in 3 to 4 centers to determine its effect and also to check for any unacceptable side effects.

Phase III or confirmatory trials

The group is between 1000-3000 subjects. If the results are positive, the data is presented to the licensing authorities for a commercial license to market the drug for use by the patient population for the specified and approved indication.

Phase IV trials or post-marketing phase

Phase of surveillance after the medicine is made available to doctors, who start prescribing it. The effects are monitored on thousands of patients to help identify any unforeseen side effects.

Parties involved in the trials

Sponsor: includes a person, a company or an institution or an organization responsible for initiation and management of a clinical trial;

Contract Research Organization: an entity that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis;

Trial Subjects (Volunteers): means a person who is either a patient or a healthy person to whom investigational product is administered for the purposes of a clinical trial.

The trials can be conducted for either Indian (indigenous) or a global drug before the DCGI. Hence application can be classified as:

1. Approval of trials of a global drug (whether new drug or an existing drug whose trials are approved outside India)
2. Approval of trials of an Indian drug (provided that the new drug or investigational new drug as part of discovery or research are discovered in India, research and development of the drug are being done in India and also the drug is proposed to be manufactured and marketed in India).

Compensation for clinical trials

Rule 42 of the New Drugs and Clinical Trial Rules 2019 provides that the independent Committee setup by the DCGI shall examine the cases and make its recommendations for arriving at the cause of death or any serious ailments and the quantum of compensation to be paid to the heirs of the trial subjects (volunteers), in case of clinical trial related death and accordingly, the sponsor or its representative shall be liable to pay the compensation.

Documents required for application for conducting clinical trials

1. Application Form in CT-04 format
2. Details/documents as specified in Second Schedule of the New Drugs and Clinical Trials Rules, 2019
3. Fees prescribed under Sixth Schedule ibid Rs. 3,00,000 for 1st Phase and Rs. 2,00,000 respectively for the remaining phases.

Patents of medicines

The Patents Act 1970 does not recognize the product-based patent for medicines. Only the process i.e., technique of making the medicine is patentable in the country. However, pursuant to becoming a member country to the World Trade Organization (WTO) - TRIPS (Trade Related Aspects of Intellectual Property Rights) Agreement in 1995 which prescribed the minimum standards of IP laws to be followed by each of its member nations, India was under a contractual obligation to amend its Patents law to make it compliant with the provisions of the agreement. The first amendment in compliance of the same was made to the Patents (Amendment) Act, 1999 which enabled pipeline protection till product patents are recognized. This was especially important in the pharma sector. The said amendment enabled filing of applications for product patents for drugs with effect from 1st January 1995 as mailbox applications and introduced the grant of Exclusive Marketing Rights (EMRs).

Under the second set of TRIPS obligations, the Patents Act, 1970 was further amended vide Patents (Amendment) Act, 2002 through which a provision of 20 years uniform term of patent for all categories of invention was introduced.

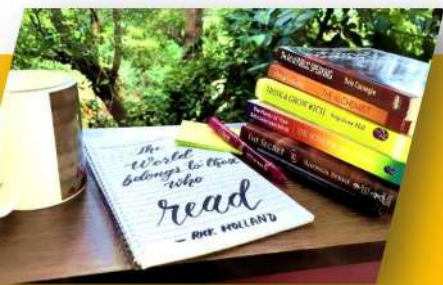
The third set of amendments in the patent law was introduced as the Patents (Amendment) Act, 2005. Under this, product patent regime was introduced in India. Mere discovery of new form, new property or new use of a known substance was made patentable subject to certain conditions, provisions related to pre grant and post grant oppositions were modified and provision for the grant of compulsory license for export of patented pharmaceutical products in certain conditions was introduced.

Therefore, once the vaccine trials pass Stage - 3, it is cleared for patenting and further manufacturing & marketing and so on.

Conclusion

With the New Drugs and Clinical Trials Rules, 2019 in place and few trials being stopped for unknown illness & side effects and many other vaccines currently progressing well, the door is now open for entrepreneurs and pharma companies to grab the opportunity for manufacturing vaccines and make India a global leader in vaccine manufacturing as it has huge manufacturing capabilities and skilled manpower.





HELP YOURSELF

Food for Thought



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The Art of Public Speaking

- By Dale Carnegie

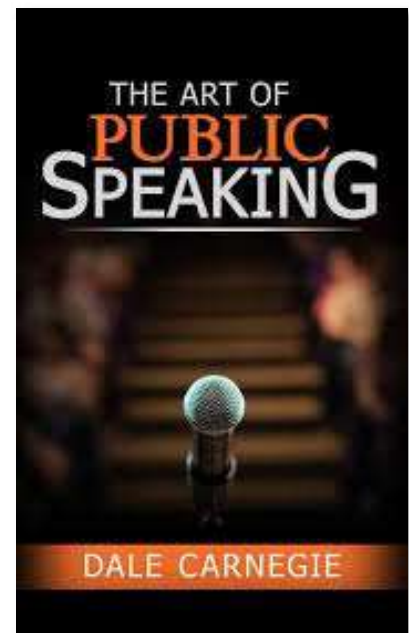
Public Speaking is often dreaded by people. Specifically, for a Company Secretary, speaking can never be escaped. From speaking before the Board of Directors or stakeholders, to appearing before the National Company Law Tribunal, public speaking as a skill for a CS is quintessential.

This book is a great start for a beginner, of any sphere of life, at public speaking. The book has so much knowledge to shower on you, public speaking will no more be a dread to you, if at all it is. If you already like this art, then this book will certainly help you master it. Personally, I used to have butterflies in my stomach whenever I had to speak up to someone new. Well, merely reading this book gave me confidence and helped me bid farewell to the butterflies.

Dale Carnegie's books are loved by many across the globe, for their timeless wisdom. This book explains everything about public speaking, at length. Facts, examples, instructions, suggestions, and principles - this book has them all. Reading this book will give you insights on preparation, voice, pitch, pause, pace, methods of delivery, fluency, growing a vocabulary, gesture, narration, persuasion, argument and so many more. The book also helps you overcome stage fright, avoiding the 'sin of monotony,' and self-consciousness while speaking. The book even talks about the importance of feeling and enthusiasm, right thinking and personality reflection in speeches. The book doesn't miss out on any aspect essential for you to know in order to be great at public speaking.

The very first chapter of the book is 'Acquiring Confidence before an Audience.' The emphasis on practice in this chapter and also at various other parts of the book is immense. The author points out "No philosopher's stone has ever been found as a substitute to laborious practice."

Here's an instance to give you a glimpse of how effectively the author explains aspects in the book. The chapter 'Pause and Power' explains the importance of pausing while speaking. The author explains that riding on a train for several hours will make you accustomed to its roar and thus, it loses its attention value. Similar is the attention of your audience. Adding pauses is the solution. The author also gives an example of gas wells- when a stronger flow is wanted, they are not tapped continually, a pause is made, Nature has time to gather her reserve forces and a stronger flow is the result. Further, pausing is intended not just to break the monotony, but also to prepare the minds of the audience to receive



something important. The book also has example sentences to help you understand which word to stress on, in what pitch and where to pause in order to make your speech most appealing and effective.

With an intent to improve your public speaking skills, grabbing this book and reading it well coupled with implementing your learning through practicing well will not just level you up at speaking, but also your overall personality.



Tech news

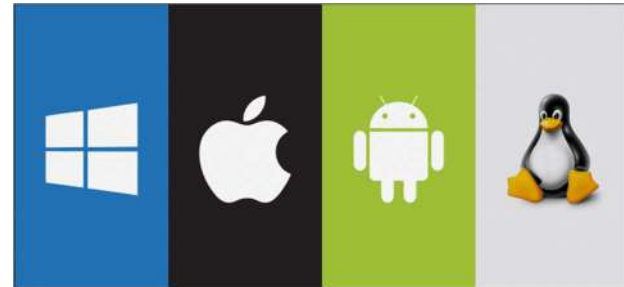


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Operating system

The face of the Computer

Operating system is the face of the computer because it is the reason for which your computer is operating by using the hardware resources which is in the computer. The operating system is the one which controls the hardware for the best operating and enhances the hardware performance. It also allows you to communicate with the computer without knowing how to speak the computer's language. Without an operating system, a computer is useless.



Your computer's operating system (OS) manages all of the software and hardware on the computer. Most of the time, there are several different computer programs running at the same time, and they all need to access your computer's central processing unit (CPU), memory, and storage. The operating system coordinates all of this to make sure each program gets what it needs.

Just a hardware is not useful without a proper operating system. So, it should be carefully selected by keeping the type of usages in mind.

There are 2 major operating systems which everyone comes across at any given point of time, one is by Microsoft "Windows" and another one is by Apple Inc.'s "Mac OS. Windows are widely used when compared to Mac because we can install the windows on any pc which we can build. The operating system is what one experiences while using a computer. It controls each hardware in a computer, even if your computer hardware is performing at its max, you cannot use the computer without the help of the operating system.

Sources: GCFlearning.org-----



Exam Preparation Quiz

Question: Two Joint Hindu Families carry on a business as joint owners. The first family consists of 3 brothers and their respective sons being 12 in number. The second family consists of the father, 4 major sons and 2 minor sons. Is the association illegal as per the provisions of Companies Act, 2013?

Ans.: As per Section 464, no association or partnership consisting of more than prescribed persons shall be formed for the purpose of carrying on any business, unless it is registered as a company or is formed under any other law for the time being in force. The number of persons which may be prescribed under this section shall not exceed 100.

Rule 10 of Companies (Miscellaneous) Rules, 2014 prescribes 50 persons in this regard.

The effect of non-registration of an association which falls within the terms of Section 464 is that such association is illegal and has no existence in the eyes of law. The law does not recognize it, so no relief can be granted either to the association or to any of its members, as the contractual relationship on which it is founded is illegal. In computing the number, minor members of joint families are to be ignored.

In given case number of adult members of the two families does not exceeds 50 and as such it is not illegal association.

However, Section 464 shall not apply to (a) a Hindu undivided family carrying on any business; or

(b) An association or partnership, if it is formed by professionals who are governed by special Acts.

Question: State the provision under the Companies Act, 2013 regulating transfer of securities. What is 'transfer of shares'? CS (Inter) - June 2000 (2 Marks)

Ans.: Transfer of securities [Section 58(2)]: The securities or other interest of any member in a public company shall be freely transferable. The Board of directors or the concerned depository has no discretion to refuse or withhold transfer of any security. The transfer has to be effected automatically and immediately.

Any contract or arrangement between two or more persons in respect of transfer of securities shall be enforceable as a contract.

Instruments of transfer to be presented to the company [Section 56(1)]: A company, shall not register a transfer of securities unless a proper instrument of transfer in Form No. SH. 4 duly stamped, dated and executed by on behalf of the transferor and the transferee has been delivered to the company by the transferor or transferee within a period of 60 days from the date of execution along with the certificate relating to the securities or letter of allotment of securities.

Registration of partly paid up shares - Notice to the transferee [Section 56(3)]: Where an application is made by the transferor for transfer of partly paid shares, the company shall give the notice of the application, in Form No. SH. 5 to the transferee. Such partly paid shares can be transferred if the transferee gives no objection to the transfer within 2 weeks from the receipt of notice.

Time limit for delivery of certificates [Section 56(4)]: Every company shall deliver the certificates of securities allotted, transferred or transmitted, within a period of 1 month from the date of receipt of the instrument of transfer or the intimation of transmission, in case of transfer or transmission of shares. This restriction as to time will not apply if transfer or transmission is prohibited by any provision of law or any order of Court, Tribunal or other authority.

Transfer of securities by legal representative [Section 56(5)]: The transfer of any security or other interest of a deceased person in a company made by his legal representative shall be valid as if he had been the holder at the time of the execution of the instrument of transfer.

Question: Every employee of the company shall be eligible to participate in Employees Stock Option Scheme (ESOS). Comment. CS (Executive) - Dec 2012

Ans.: Following persons can participate in ESOS or ESOS:

- Permanent employee of the company who has been working in India or outside India.
- A director whether a whole-time director or not but excluding an independent director.
- An employee of subsidiary company or of an associate company

Following persons cannot participate in ESOS or ESOS:

- An employee who is a promoter or a person belonging to the promoter group.
- A director who either himself or through his relative or through any body corporate, directly or indirectly, holds more than 10% equity shares of the company.

Thus, it is correct to say that the option to participate in ESOP/ ESOS is not open for all employees of the company.





BRAINY BITS...



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X a proprietorship firm is registered under PF ESIC having 42 employees and 50% of their employees are below ₹15,000/-. The proprietor learned that the Government of India has recently announced covid relief package and the entire 24% percentage of PF burden will be borne by the Government. Whether X proprietary firm can claim these benefits?

Please send your answers to, newsletter.icsimysore@gmail.com along with your name, qualification, and designation. Name of the person with most appropriate answer with reasoning, shall be published in the next edition of eMagazine



Opinion to Last Month's Brainy Bits

Answer Received by our Reader



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Facts of the case

- M/s XYZ is a CBSE School in the state of Telangana
- M/s PQR., (hereinafter referred as (“Registered Person”), registered in the state of Telangana, providing catering services to M/s XYZ
- M/s PQR charges GST on their services rendered to M/s XYZ and issues Tax Invoice
- M/s XYZ contends that the services provided by M/s PQR are exempt from GST

Legal Provisions & Notifications

- Section 7 of the Central Goods and Service Tax Act, 2017 - Supply
- Section 2(47) of the Central Goods and Service Tax Act, 2017 - Exempted Supply
- Notification No. 12/2017- Central Tax (Rate) Dated 28th June 2017
 - Entry No.66 of Notification No.12/27- Central Tax (Rate) Dated 28th June, 2017 reads as under

Sl. No.	Chapter, Section, Heading, Group or Service Code (Tariff)	Description of Services	Rate (percent.)	Condition
66	Heading 9992	<p>Services provided -</p> <ul style="list-style-type: none"> a. by an educational institution to its students, faculty and staff; b. to an educational institution, by way of,- <ul style="list-style-type: none"> i. transportation of students, faculty and staff; ii. catering, including any mid-day meals scheme sponsored by the Central Government, State Government or Union territory; iii. security or cleaning or house-keeping services performed in such educational institution; iv. services relating to admission to, or conduct of examination by, such institution; upto higher secondary: <p>Provided that nothing contained in entry (b) shall apply to an educational institution other than an institution providing services by way of pre-school education and education up to higher secondary school or equivalent.</p>	NIL	NIL

Education Institution as defined in **Notification No. 12/2017- Central Tax (Rate) Dated 28th June, 2017,**

“educational institution” means an institution providing services by way of,-

- i. pre-school education and education up to higher secondary school or equivalent;
- ii. education as a part of a curriculum for obtaining a qualification recognised by any law for the time being in force;
- iii. education as a part of an approved vocational education course

- Notification No. 14/2018- Central Tax (Rate) Dated 26th July, 2018, an amendment to Notification No. 12/2017- Central Tax (Rate), provides that "For removal of doubts, it is clarified that the Central and State Educational Boards shall be treated as Educational Institution for the limited purpose of providing services by way of conduct of examination to the students."

Conclusion:

Pursuant to above notification,

1. M/s. XYZ, being a CBSE school falls under the definition of Educational institution
2. The catering services provided to M/s XYZ by M/s PQR falls under Entry 66 (b) (2) attracting Nil rate of tax.

Pursuant to Section 2(47) of the Central Goods and Service Tax Act, 2017, Exempted supply includes Nil rated supply. Hence, the catering services provided to M/s XYZ are exempt from GST.

Further, the Authority of Advance Ruling, Karnataka vide Advance Ruling No. KAR ADRG 36/2020 dated 21.05.2020 reiterated the above view in its ruling as stated below:

"The supply of services made by the applicant in the form of supply of food and drinks to the educational institutions is covered under Entry No. 66 of Notification No. 12/2017 - Central Tax (Rate) dated 28.06.2017 and entry No. 66 of Notification (12/2017) No. FD 48CSL 2017 dated 29.06.2017 and are hence exempted from CGST and SGST."



Companies Act, 2013

Updates on Amended Rules

MCA has amended Companies (prospectus and allotment of securities) Rules, 2014 which shall be known as Companies (prospectus and allotment of securities) Amendment Rules, 2020,

In the principle rules, following proviso shall be inserted after third proviso of sub-rule (1) of rule 14;

"provided also that in case of offer or invitation of any securities to qualified institutional buyers, it shall be sufficient if the company passes a previous special resolution only once in a year for all the allotments to such buyers during the year."

The company need not pass the resolution every time, it can pass a single special resolution for all the invitations or offers made to QIB in a year.

Companies (prospectus and allotment of securities) Amendment Rules, 2020



Delhi Diaries



Vikram Hegde, Advocate

Advocate on Record
Supreme court of India
Co- Founder, VH Law Chambers
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Babulal Vardharji Gurjar v. Veer Gurjar Aluminium Industries - Either Astrologers or time machines

It is a well-established principle in law that an amendment or legislation that pertains to a procedural aspect is usually retrospective in nature, and an amendment or statute that creates substantive rights and liabilities of the parties is prospective in nature unless otherwise specified. However, when a law is held to be retrospective in nature, can a party be penalized for not having taken the procedural steps as required by a later amendment? That perhaps is a question that arises out of the judgment in Babulal Vardharji Gurjar v. Veer Gurjar Aluminium Industries.

In the October 2018 edition of this column, we noted the amendment to the IBC by which limitation act was made applicable to proceedings under the IBC and also examined the decision in B.K. Educational Services Pvt. Ltd. v. Paras Gupta and Associates wherein it was held that the amendment would be retrospectively applicable. While it was acknowledged at the time that this would affect pending litigations as well, let us see its effect on one such pending case.

In the case of Babulal Vardharji Gurjar the corporate debtor, had been declared an NPA by various banks and other financial creditors as far back as 2011 and various recovery proceedings were being pursued under SARFAESI and other legislations.

Then, on 21.03.2018, JM Financial, an Asset Reconstruction Company, being a Financial Creditor of the Corporate Debtor moved an application under Section 7 of the Code before the Adjudicating Authority, seeking initiation of CIRP of the Corporate Debtor. It is relevant to note that amendment to include Section 238A of the IBC, applying the Limitation Act to IBC came about only on 06.06.2018. The Adjudicating Authority vide order dated 09.08.2018 initiated CIRP. Thereafter on 11.10.2018, the Supreme Court in B.K. Educational Services Pvt. Ltd. v. Paras Gupta and Associates applied the same retrospectively.

Thereafter, after one round of appeals all the way to the Supreme Court, the case of the insolvency of Veer Gurjar Aluminium Industries was remanded to the NCLAT for a decision on the question of limitation alone. Now, the financial creditor sought to take the defence of acknowledgement as a way to fob off the bar of limitation. The repeated acknowledgement of the debt in the balance sheets was considered as an acknowledgment for the purpose of extension of limitation. Readers will recollect that we have examined this controversy at the NCLAT in the previous edition of this column. However, what arises here is a different aspect.

The main controversy in this case, is whether in view of the later application of the limitation act, in view of the pleadings of the application made by the Financial Creditor to the NCLAT. The Court in Babulal Gurjar held that Section 18 was not applicable in this case because the application under Section 7 did not mention a subsequent acknowledgement of the debt by the Corporate Debtor despite noting the date of default as being 2011.

On a plain reading, it may make sense that to invoke the plea of acknowledgement under Section 18 of the Limitation Act, it has to be pleaded in the application. However, place yourself in the shoes of the Financial Creditor who made an application on 21.03.2018. On that date the amendment to the IBC making limitation applicable had not been enacted. The Financial Creditor could not have anticipated the application of limitation act and hence could not have pleaded acknowledgment as per the amendment.

Retrospective application of the limitation act is understandable. If however, the court expects the parties to have made pleadings as if the limitation act was applicable on the said date, it may be said in a lighter vein that either the court expects the parties to time travel and make their applications so as to suit later law, or to consult an astrologer before filing applications!



"One important key to success is self-confidence. An important key to self-confidence is preparation."

--Arthur Ashe



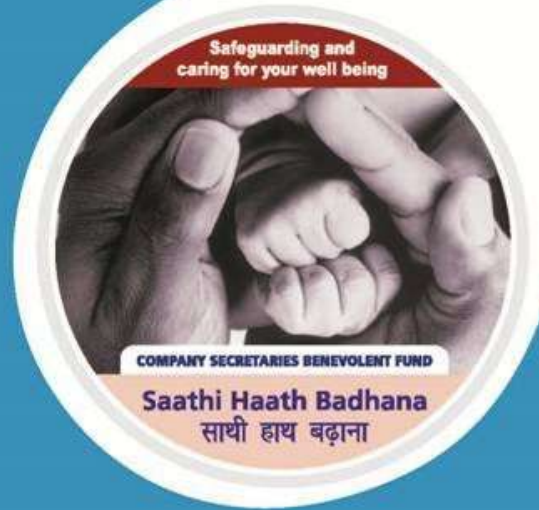
THE INSTITUTE OF Company Secretaries of India

भारतीय कम्पनी सचिव संस्थान

IN PURSUIT OF PROFESSIONAL EXCELLENCE
Statutory body under an Act of Parliament
(Under the jurisdiction of Ministry of Corporate Affairs)

CSBF

COMPANY SECRETARIES BENEVOLENT FUND



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The Company Secretaries Benevolent Fund (CSBF) is a Society registered under the Societies Registration Act, 1860 and is recognized under Section 12A of the Income Tax Act, 1961.

The CSBF was established in the year 1976 by the ICSI, for creating a security umbrella for the Company Secretaries and/or their dependent family members in distress.

The amount of ₹ 7,50,000 (in the case of death of a member under the age of 60 years) has been increased to ₹ 10,00,000

The subscription amount is being increased from ₹ 10,000 to ₹ 12,500 soon

Is it the right time to enrol in CSBF?

CSBF is the protection you and your family need to survive the many ups and downs in life, be it a serious illness or a road accident which derails your plans for the future.

Is it a requirement?

Yes, as your dependents need the protection. Your dependents be it your parents, your spouse, or your children will have to bear the brunt of paying off your home/education personal loans and even for managing day-to-day expenses without your contribution.

If you do not want to leave behind such a situation in your absence, enrol in CSBF today.

Advantages of enrolling into CSBF

1

To ensure that your immediate family has some financial support in the event of your unfortunate demise

2

To finance your children's education and other needs

3

To ensure that you have extra resource during serious illness or accident

4

Subscription/Contribution to CSBF qualifies for deduction under Section 80G of the Income Tax Act, 1961

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