

CDSCO/DCGI : Theatre of the absurd

The law exists for easy administration & regulation but not for creating a personal fiefdom to hold the citizens to a ransom & extort a pound of flesh. It goes without saying that the law has to be transparent & specific so that the same can be complied with. It is a basic tenet that the law must be strictly construed, according to natural construction of words - Words must say what they mean, nothing should be presumed or implied, they must say so - True test must always be the language used. However, the problem is that when the law is implemented with an eye for rent seeking then there is no way that there is any room for transparency or clarity.

The Central Drugs Standard Control Organization (CDSCO)/Drugs Controller General of India (DCGI) is the law administering authority for the Drugs & Cosmetics industry. However, just see how absurd is the position in respect of even the basic minimum. The CDSCO/DCGI has not even given a list of the drugs, which are under their administration. This is not the only cause of serious concern but no one in the industry has guts to demand the list though the drug manufacturing empires are running into billions of Dollars in this country & all the multinationals are part of the industry. My analysis & experience says that nobody dares the CDSCO/DCGI because then there is looming threat of closure of the manufacturing facilities & raids therefore keeping your mouth shut is one of the Golden Rules for operating a Drug manufacturing unit in this country.

The then Chief Commissioner of Customs, JNCH port way back in 2011 asked for a list both from the Regional & the Delhi headquarters so that the Customs officials are in a position to know that which Shipping Bills & Bill of Entries are to be sent to the ADC for the issue of NOC. In spite of this, the CDSCO/DCGI has failed to compile & publish such a list. Therefore the Customs authorities all over India are required to comply with the provisions of the Drugs & Cosmetics Act, 1940 without even know which item is a drug. The irony is that really the Customs authorities comply with the Act of Parliament without knowing the controlled substances. The Customs authorities are not the only ones committing this crime but the DGFT authorities are a part of the whole game. They also comply with the Act of Parliament, without knowing the names of substances falling under it. It sounds very simple that when everybody is so happy the way the things are administered then where is the cause for concern & writing this article? Please not be alarmed to note that this way of functioning can never give good governance because the central piece about what is to be governed i.e. list of drugs in itself is missing & this can only propagate & thrive rent seeking & nothing else.

The arrogance of the DCGI officials is par excellence. They will issue single line conclusive verdicts though they are obligated to issue reasoned speaking orders in terms of the Apex court ruling. However, who will demand a reasoned speaking order when no one dares to even get the list of drugs. Therefore the word of the ADC is the Gospel truth. The ADC ruling stands & the beneficiary is doomed & then the way out is you take care of me & I take care of you approach & from the high podium they will climb down to oblige you in very cunning & deceptive ways. The citizens are left with no solutions. The details will follow in subsequent parts of this article.

The CDSCO/DCGI ape the west but then why they fail to implement the good things. You go to the website of the US, FDA & you can get the list of the drugs there. This transparency leaves no room for any scope for interpretation in the hands of the administering authorities & at the same time ensures that nobody escapes the law. You send a mail to the US, FDA sitting anywhere in the world & you get a reply but then you send e mail to the CDSCO/DCGI leave aside reply there will be no acknowledgement received. Even the PMO acknowledges e mails sent but then the corrupt will never like to leave a tell tale sign behind.

Please note that it will be clear to any person with little common sense that the list of substances which are drugs need to be made available by the administering authority for transparent & effective implementation of the law. Then why the CDSCO/DCGI is not willing to come out with such a list?

Please note that this article is dealing with the very basics therefore the issues may appear to be raised in an oversimplified manner. The real life is not so simple. A particular chemical may have several uses. For e.g. Boric Acid is used as an industrial chemical, bulk drug & a pesticide. Then what are the regulating authorities required to be doing about controlling it & which is the relevant industry. Now, if this Boric Acid is coming as an industrial chemical for the Chlor Alkali industry then why the CDSCO/CIB should have any reason to object to it. The authorities cannot forget at any point of time that they have to facilitate what is legitimate & not exercise control in an abusive manner to strangle the legitimate user therefore why the declaration of the importer should not settle the issue because the declaration is the only way forward & thereafter the regulating authority keeps a tab on usage. However, the regulating authorities would never indulge into that because it then brings responsibility & accountability. It is not essential to even account for imports conducted in the past for future NOC s. At this point of time, we are only talking about the import of chemical substances as such i.e. bulk drugs but even in case of pharmaceutical formulations there can be conflict in terms of classification of the product. There are umpteen cases where conflict will be visible such as whether item is a food or drug. Different countries can treat items in a different manner. Similarly there can be a conflict that whether an item is a drug or cosmetic. Therefore, any way you look at it, it is essential for the authority to declare the list of drugs under control. The drugs industry is highly regulated with most scientific back up therefore there should not be any problem with the authorities to be transparent & specific. The doctor cannot treat a patient without knowing what the ailment is then how can the CDSCO/DCGI control the import of drugs without declaring the list of drugs. Some will argue that for this reason the doctor gives 5 pills comprising broad spectrum antibiotic, antipyretic, ant-analgesic, vitamins & one to treat the current trend of patients but then CDSCO/DCGI cannot shoot blindly & consider any chemical to be a drug under their control. One good example is Citric Acid, which is always present in the human body at any point of time. Indian Drugs industry thrives on exports & very significant for the total Indian exports then why the CDSCO/DCGI bent upon strangulating it. The USFDA 483 issuances are failures of the Indian authorities & not of the industry alone because the regulator has no interest in development & up-gradation of the industry by comprehending the paradigm shift of the definition of quality product but being happy with rent seeking.

Why go far, please see the other laws of this country such as the Insecticides Act, 1968 or the NDPS Act 1985, they specify the substances controlled under the act so that administration is clean & transparent. The case of the Drugs & Cosmetics Act, 1940 is no different then why is the CDSCO/DCGI defying the wisdom.

There are various substances which are controlled all over the world for various reasons. The movement of Wildlife & Flora is controlled or the UN controls the movement of dual use chemicals, the US controls the movement of SCOMET (Special Chemicals, Organisms, Materials, Equipment and Technologies items) & in all these cases also, precise details of what is controlled is given. Not for any other reason because that is the basic & the central requirement.

Therefore any way you look at it whether in terms of the national Laws or International laws or just by way of common sense even, the CDSCO/DCGI is obligated to declare the list of the controlled substances but then they are the children of higher gods who can never be subjected to any accountability or scrutiny. It cannot be the case of the CDSCO/DCGI that all others are stupid to publish the list of the controlled substances. Therefore, the whims & fancy of the CDSCO is the hallmark of the implementation of the law & nobody dare to challenge because if you do then reportedly the raid & manufacturing facility closure is coming. However, I fail to understand that as on date any successful bulk drug manufacturer will be subject to constant scrutiny by way of inspecting authorities then why there is lurking fear of reprimand still keeping the industry quiet?

What is really there to worry about?

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