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Chairman, Task Force
& Commissioner, FDCA
Gujarat.

No. FDCA/Task force/

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Date:- 5/03/2012

To
Mr. Sudhirkumar
Under Secretary to Government of India.
Nirman Bhavan,
New Delhi.

SUB: Final report of Task Force regarding the issues of networking for Software for Drugs Manufacturing Tracking System..
REF: Your letter No.02/Misc/2010-DC/DFQC, Dated.10/03/2011.

Respected Sir,

With reference to above subject I am please to submit the detail report of Task Force, constituted by Government of India, Ministry of Health & Family Welfare Department vide order Dated:-10/3/2011. Regarding the Networking and suggesting the requirement of software for Drugs Manufacturing Tracking system.

Thanking You,

Yours Faithfully,

(Dr. H. G. Koshia)
Chairman,Task force
&
Commissioner
Food & Drugs Control Administration

Encl:-Final Report of the Task Force.

Report of the Task Force

Submitted by

Dr. H.G. Koshia

(Chairman & Commissioner FDCA Gujarat)

Submitted to

Ministry of Health & Family Welfare

Government of India.

Dated:05/03/2012

PREFACE

i. There has been a concern in the country regarding movement of Spurious, Substandard and Misbranded drugs. This has been deliberated in various fora and due to the nature of the illegal operation the true magnitude of the problem is not easy to assess.

ii. Medicines which are not of standard quality and are not manufacture by genuine manufacturer can not only harm the public but also the reputation of the regulatory authorities. The drug control department's license manufacture and sale of medicines in the country however, it is mostly the unlicensed manufacturers who indulge in the illegal activity of manufacturing spurious drugs.

iii. This matter has been discussed regularly in such meetings like the Drug Consultative Committee by various Drug Controllers and the stress was laid for more vigorous control by the Inspectors at the ground level. This is an effective way to control movement of unwanted drugs however, due to lack of adequate manpower in most of the drug controller authorities, the action at the ground level cannot be always as desired.

iv. The matter of counterfeit medicines is not only confined to the country but has affected India's exports to their counties also. It was reported earlier that Chinese medicines where labeled as "Made in India" and sold to African countries. This has the image of the Indian manufacturers who was exporting drugs to other countries.

v. The Ministry of Health has decided that all medicines procured by the Medical Store Organisation will be bar coded for proper distribution.

Formation of Task Force

1. The matter of networking of drugs distribution was initiated by a court order of the Allahabad High Court in the case State v/s Bhramaji, in which the Hon'ble High Court in the hearing on 20th October, 2010 (A 1) had directed that the proposal for networking of all transactions of medicines from the manufacturer to the dealer may be discussed in the next DCC meeting and NIC be also invited to participate in the meeting. The court hereafter was appraised of the actions taken by the Government in this matter.

2. The Court in a order dated 28.01.2011 (enclosed as annexure-A) directed that the Government of India and the Drug Controller (India) and other authorities will setup a necessary task force and the task force of the drug controller will come up with an actionable programme preferably as to how the bar coding system and unique bar coding system are to be putting in place.

3. Thereafter a Task force was constituted by the Government of India by its order No. 02/Misc/2010-DC/DFQC dated 10.03.2011 (enclosed as annexure-B) comprising of the following members under the Chairmanship of Mr. H.G. Koshia, Commissioner, Food&Drug Control Administration (FDCA), Gujarat.

i. Dr. B. Jagashetty, Drugs Controller, Karnataka.

ii. Mr. M.Mitra, Dy. Drugs Controller (I) Central Drugs Slandered Control Organization(CDSCO).

iii. Mr. VishwajitRinge, Sr.Technical Director, NIC.

iv. A Representative of the Department of Consumer Affairs.

v. Mr. Dev Kant (ILS), Deputy Legal Adviser, Department of LegalAffairs, Ministry of Law.

vi. Ms. Mridul Jain, Director, Department of Commerce.

vii. Mr. Sudhir Kumar, Under Secretary (Drugs Quality Control), Ministry of Health and Family Welfare.

viii. Mr. Rishi Kant, Legal Consultant, CDSCO.

ix. Dr. S. Eswara. Reddy, ADC (I), CDSCO.

TheTerms of Reference of the Task Force

a. To examine the feasibility of networking and tracking the Drugs Distribution System in the country from the manufacturer to the retail.

b. To indicate the requirements for the Software for drugs tracking system to be developed by NIC.

c. To examine different IT tools and methodologies and select the most suitable for implementation in the country.

d. To suggest if bar-coding and Unique Identification Number can in any way help in the networking of the drugs distribution with respect to manufacturing, import and export,

e. To examine and suggest the requirements for different stake holders like manufacturers , distributors and retailers,

f. To recommend amendments in the Drugs and Cosmetics rules with respect to drug distribution system and tracing and tracking technology.

g. The task force can, if required, interact with IT experts and professionals and also invite opinions in the field of networking from various stakeholders like Industry, consumer associations etc.

h. Any other issue with permission of the chair.

Working of Task Force

1. The task force met 5 times as follows:-

   i. 20th April, 2011 at FDA Bhawan, CDSCO (HQ), New Delhi.

   ii. 19th and 20th May, 2011 at the O/o Commissioner, FDCA, Gujarat.

   iii. 14th and 15thJuly, 2011 at the O/o Drugs Controller, Karnataka.

   iv. 26th August, 2011 at O/o Commissioner, FDCA, Gujarat.

   v. 23rd Feb 2012 at FDA Bhawan, CDSCO (HQ), New Delhi.

   [Enclosed as annexure C1, C2, C3, C4 & C5]

2. During the above meeting the task force members met a cross section of stakeholders which included manufacturers, sellers, hardware suppliers and Software developers.

3. Representative of the National Informatics Centre played a key role in understanding the various methodology of track and trace system.

4. A Report of the working group on the Scientific and Technological measures to counterfeit Spurious and Sub- Standard drugs and Diagnostic Centers prepared for the office of the Principal Scientific Advisor to the Government of India was also discussed in the task force meeting by the members. (enclosed as annexure-D)

5. The issues of the mandate of the Ministry of Commerce for bar coding of Drugs meant for exports was examined by the task force and compared with the mandate for all India implementation of the barcode and bar code system for all manufacturer for all products in the country. (Enclosed as Annexure-E).

Methodologies Discussed

Most of the task force members were not very conversant with the detailed technical procedures to be adopted in track and trace of drugs from manufacturers to sellers. In this the National Informatics Centre helped in explaining the most likely procedure that can be followed. Examples such as online tracking in the Public Distribution System for supply of essential items to consumer were also discussed.

The enormity of the whole procedure can be seen in the light of the number of manufacturers and their products moving in the market. There are about 8000 manufacturers in the country manufacturing scores of products in their license. These are distributed and sold through distributers, wholesalers and retailers in the country.In reality, thousands of different products and formulations moving in the market. This is further compounded by the fact that the primary packages of products are in strip, blister, ampoules and vials and also various other primary packages.

The primary packages are packed in secondary packages, which in turn are packed in tertiary packages (shippers).

It may be seen from the above that the task force members had to come to a conclusion and decide for a solution which can be applied on different type of

packages, through a range of products and can be identified at any point in a distribution chain. The system should be easily available and cost effective.

The task force had also to consider a solution by which a common man in the street gets a preliminary data of a medicine that he consumes.This has also been asked for by the Allahabad high court dated 28.01.2011.

To meet the above objectives the task force met and discussed in details all relevant issues concerning track and trace with the manufacturers' associations, some individual manufacturers,associations of sellers of medicines, manufacturers of hardware like printers etc and software solution providers. The details that was obtained by the task force is described in the following pages alongwith a possible road map for implement this.

STAKEHOLDERS

The task force met and heard a various stakeholders who are linked to the procedure for track and trace of the drugs in the country. The following stakeholders were met during the meetings (List of presentations made by different organizations is placed at annexure-E).

MANUFACTURERS:-

1. Indian Drug Manufacturer Associations (IDMA).
2. Confederation of Indian Pharmaceutical Industry (CIPI).
3. Federation of PharmaEnterpreneurs (FOPE)
4. All India Organisations of Chemist and Druggist (AIOCD).
5. M/s. Medreich Limited Bangalore.
6. M/s. Phillips Medical.

HARDWARE MANUFACTURER AND SUPPLIERS:-

1. M/s. Markem
2. M/s. Domino Printech.
3. M/s. Control Print.

SOFTWARE MANUFACTURER AND SOLUTION PROVIDERS:-

1. M/s. Arable
2. M/s. Holostik India Ltd.
3. M/s. Pharma Secure.
4. M/s. Pharmaleaf/Accenture.
5. M/s. Bilcare Research.
6. M/s. Synergia Foundation Ltd.
7. M/s. Kezzeler AS, Norway.

OTHER STAKEHOLDERS:-

Dr. AppajiRao, Executive Director, Pharmexcil was invited in the second meeting at Ahmadabad to give his views as exported drugs are to be bar coded as per the instruction of Ministry of Commerce from 1st October, 2011.

CONSUMER ORGANIZATION:-

1. Dr. H. Sudarshan, Honorary Secretary, Karuna Trust, Bangalore.
2. Shri. AshimSanyal, Chief Operating Officer, Consumer VOICE, New Delhi.
3. Dr. S. N. Chaturvedi, Vice President, Consumer Forum, New Delhi.
4. Dr. Jayashree Gupta, President, Consumer India, New Delhi.

Possible Technologies Available

TRACK AND TRACE

1. The technologies afford and described by the stakeholders are basically 2D Bar-coding which can be read by a bar-coder. One point that emerged from the software providers presentation was that theoretically and technically track and trace of drugs from manufacturer to retail level may be possible. Various solutions were provided for track and trace and authentication of the products moving in the market. The basic solution mentioned by all the software providers was based on a central portal having links to all the manufacturers' data base. Whenever tracking is done from any point in the distribution chain, the query will be send to the central portal from where it will be directed to the manufacturers' data base. This will help in keeping a track of the movement of drugs.

2. As per the presentation given by software manufacturers a barcode on a label will have the details of a product including its batch Number anddate of manufacturing. During labelling of products by themanufacturers this unique bar code will be affixed on the label. A set of unique numbers will be generated by a computer for each bar code for a batch. Therefore a batch will have as many unique bar codes as labels fixed on the final packaging. This will also mean that a set of bar code will be provided for secondary and tertiary packages of the products of the same batch.

3. The data relating to a batch's details including the bar code used will be uploaded in the manufacturer's portal which will be used as a central data base for the firm's products.

Feasibility of Networking and Tracking the Drugs Distribution System in the Country from the manufacturer to the retailer.

The task force members examined the issues of the feasibility of networking and tracking the drug distribution system in the country by way of using modern computerized methods. It may be mentioned here that tracking and networking of the drugs is already in place under the provisions of the Drug and Cosmetics Rules. The present regulations make it mandatory for selling a medicine with a bill by any manufacturer or a dealer. Therefore, medicines can be track by linking all purchases to the seller of the drugs and ultimately the track can be traced to the manufacturer. Due to thousands of manufacturers and sellers of drugs selling innumerable number of products in the market, the manual system of tracking by bills is cumbersome and extremely time consuming.

It is with this background the task force members agreed that a computerized and a web based track and trace system is the need of the day to effectively and instantly track movement of the drugs. This procedure can also have added advantage of gathering additional information of distribution of particular drugs and their pattern across the country. By this system, it is assumed that counterfeit and spurious drugs from the market can be weeded out.

The members also felt that since this is a new system of recording the distribution of drugs from the existing system, the stakeholders may be initially reluctant to adopt it since not only do they have to break away from the existing method of working but also invest in the hardware, software and training of his personnel.

The members felt that a beginning has to be made in this direction and gradually all the stakeholders have to be convinced, educated and gradually made to follow the system. It was also deliberated and decided that labelling provision under Rule 96 of Drugs and Cosmetics Rules have to be suitably amended to include track and trace. This is essential as the stakeholders will not follow the Government directive of track and trace if it is not mandated in law.

Keeping in view the above, the task force went about examine the whole issue.

The requirements for the Software for drugs tracking system to be developed by NIC and to examine different IT tools and methodologies and select the most suitable for implementation in the country.

The requirements for the software cannot be obtained of the shelf therefore the matter required extensive deliberation and discussion amongst the members and also the users that is, manufacturer and sellers of drugs apart from the above discussions has to be carried out with the vendors who can provide a software solution for track and trace. As there can be no single generic solution for this, various system and software were examined by the task force members. Being a system which is not widely used amongst the Pharmaceuticals industries, it was noticed that, cost was usually estimated by the stakeholders and solution providers and varied greatly.

Simple SMS based verifications system was being used by certain big companies but where stand alone systems belonging to individual companies. For implementation of SMS based verifications system, a uniform standardised solution is required. Therefore various options had to be examined by the task force members.

As far as track and trace is concerned the solution appear to be more complex. Different models where examined by the task force members to see the merits and cost effectiveness of each model.

The task force members examined 3 hardware providers and 7 solution providers and examined their presentationsthere was not much difference to chose from hardware providers as hardware essentially consisted of bar code readers, Computers and printers. The stakeholders at the lower end of the supply chain can use their existing computers and internet connection to be part of the system in case of track and trace.

In case of SMS based authentication of drugs, other than manufacturers, no body requiredhardware for authentication. A normal mobile phone, which is widely available to a large section of population, can be used for authentication.

Views of the Manufacturers

The task force members met manufacturer's organizations like Confederation of Indian Pharmaceutical Industry (CIPI), Federation of Pharma Entrepreneurs (FOPE), Indian Drugs Manufacturers Associations (IDMA), Organisation of Pharmaceutical Producers in India (OPPI),most of the pharmaceuticals manufacturing organizations expressed their view against the track and trace system.

All the manufacturer's associations who gave presentations invariably disagreed for any kind of track and trace for drugs and where extremely pessimistic of the whole scheme, though they principally agreed that the intention of the Allahabad High Court is noble. The reasons cited for disagreement are high cost of implementation, lack of power at many places in the country, requirement of training and also the fact that the industry had already spent a lot of money on implementation of the Schedule M, with more investment required for implementation of Schedule L-1.

The representatives of Confederation of Indian Pharmaceutical Industry and Indian Drugs Manufacturers Association (IDMA) have also made a presentation and stated that product unique identification system and track and trace system would effect on its survival as these systems involves huge investment, manpower, training etc. and also informed that it may not practically possible to implement such systems.

Various reasons were stated that against the track and trace system, some of which are as follows:

1. High investment required to implement which can be at least 40-50 lakhs per unit.
2. SMS based system may not serve the purpose as even counterfeit drugs authentic numbers can move in the market.
3. There is hardly any space on the primary labels after printing of the statuary requirements under Drugs and Cosmetics Rules.
4. The members are not aware of the proposed system of UID and 2D bar coding and the source from which these can be obtained.
5. Revision of price may be allowed for price control drugs by the NPPA.

The above objections are that rules will be changed for labels and therefore the manufacturers usual methods are labelling and marketing will be disturbed. This is usually the case whenever a rule is changed. However it may be mentioned that manufacturers did agreed that slow implementation may be agreed by them.

It is of the task force members that in spite of the objections of the manufacturers, UID and track and trace should be implemented so that in spite of the investments by the manufacturers, ultimately all drugs moving in the market

Views of All India Organization of Chemist and Druggist (AIOCD)

AIOCD is an organization of chemist and druggist is a majority of sellers of drugs in the country. AIOCD has also impeded themselves as a party in the Allahabad High Court PIL, Brahamaji VS Union of India. It was stated by the representatives of AIOCD that a company has been formed by them known as AIOCD AWACS which has already embarked on Electronic Data Exchange (EDE) initiative in Oct 08.

It was stated by them that about 5797 (27%) of the distributors have been enrolled in the phase 1 of the initiative. This is the linkage between the manufacturer and the distributors. A total of 17 companies representing 37% of market share are engaged in the 1st phase. It was learnt during the interaction that the companies are large Indian companies and they have been linked to some of their distributors.

The phase 2 of the program which willlink the distributors and sellers will be in the 2nd phase. It is claimed by AIOCD that company's nationwide EDE will be implemented in 5 years time. It is also mentioned that the cost to implement the EDE will be less than 0.1%.

AIOCD is using GS1 bar codes in its programme. It was mentioned that more than 700 pharmaceutical companies are registered with GS1 India for bar codes, however unfortunately, 99% use them only for export batches.

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The cost mentioned by AIOCD is on annual turnover basis. Therefore no fixed expenditure on implementation can be computed. A tentative action step has been submitted by AIOCD (enclosed as annexure- G).

MANUFACTURERS ASSOCIATIONS

1.Confederationof IndianPharmaceutical Industry (CIPI)

2. Indian Drugs Manufacturers Associations (IDMA).

3. Federation of Pharmaceuticals Entrepreneurs

The representatives of Confederation of Indian Pharmaceutical Industry and Indian Drugs Manufacturers Association (IDMA) had made presentations and stated that product unique identification system and track and trace system would effect on its survival as these systems involves huge investment, manpower, training etc. and also informed that it may not practically possible to implement such systems.

These associations were against any kind of change with respect to track and trace and UID. It was traced that the huge investments may force closure of their some of the members. It was also stated that in case Government provides subside of set the cost of implementation to the manufacturer they may try to implement the same. It was suggested that there should be revision of prices for price controlled drugs so that the manufacturers do not bear the burden of additional expenditure.

The manufacturers associations stated that a particular technology has to be decided before as this keeps on changing. It was mentioned by FOPE that one needs to invest minimum Rs. 1.5 Crores (assuming that there are minimum 4 packaging lines on an average in a manufacturing set up in small and medium scale units. They also mentioned that the cost Vs benefits ratio has to be ascertained before a decision is taken.

It is therefore assumed that no manufacturers associations will implement the track and trace/UID System voluntarily but some sort of change in the

labelling norms in Rule 96 has to be made so that there is legal provision in the rules for implementation.

Mention may be made of a representation made by SME Pharma Industries Confederation (India), New Delhi to Prime Minister of India in which it has stated that bar coding will not solve the problem of fake /spurious drugs. It is argued that the counterfeiting of medicines is usually done for costly medicines only. Therefore bar coding of cheaper medicines have no justifications.

It may be mentioned here that though CIPI has disagreed for bar coding, they have written a letter, dated 15.11.2010, to all their members requesting all the federating members to impress upon their manufacturing units who have not so far adopted bar coding, may do so at the earliest possible.

M/s. Medreich Limited Bangalore

M/s. Medreich Bangalore which has a pharmaceuticals formulation unit in Bangalore wanted to give a presentation on track and trace that they are in the process of developing for their products.The firm gave a detailed presentation on the procedure, cost and modalities of track and trace system that can be adopted. The presentation also highlighted that the estimated cost of 7 packing lines would cost approximately Rs. 3, 51, 40, 000. As the figures quoted was extremely high and deferred from earlier presentation made by other stakeholders, it was assumed that the presentation actually took an ideal situation with the best of the equipments and software to arrive at the above figures.However the procedure described by the firm in detail was similar with the procedures by others.

M/s. Philips Health Care

M/s. Philips health CareLtd, gave a presentation on bar coding on medical devices. It was impressed upon by the firm that apart from GS1, HIBCC Numbering formats for UID may be adopted. It was stated that most of the medical device manufacturers and some pharmaceutical companies use the HIBCC system for track and trace purposes. In this context it was mentioned that if the Government mandates compulsory usage of GS1 barcoding, it would mean that the existing players using for barcoding would have to change over to GS1 System needing large investments. The presenter requested that the change over from HIBCC to GS1 should be gradual and not immediate as a common bar code reader can read both the types of bar code systems and the HIBCC system will not interfere with the GS1 system.

It was mentioned that Global Harmonisation Task Force (GHTF) which regulates the medical Devices across most nations recognized both HIBCC and GS1 System of bar coding.USFDA and EuropeanUnion Guidelines are recommending unique identification on class three devices only before being implemented on other classes. Similarly it was mentioned that Asian Harmonisation Working Party (AHWP) is also planning the develop guidelines for UDI. A common bar code reader can read both system of bar coding.

HIBCC is comparable to GS1 in terms of technology but has the advantage of having no cost associated with obtaining the numbering system. This is greatly advantageous to manufacture for keeping costs down and would be

especially significant to small and mid size companies, especially many domestic Indian manufacturers.

It may be mentioned that HIBCC has been accepted by the ISO 22742: Linear Bar Code and Two-Dimensional Symbols for Product Packaging.ISO is non-Governmental, worldwide federation of national standards institutes. Since its creation in 1947, ISO has published over, 13,700 International Standards. The Standards are involved in a variety of programs, including agriculture, mechanical engineering, medical devices, information technology developments, and many others.

HIBCC is an Industry-sponsored, non-profit standards development organization (SDO), established in 1984 by major national healthcare associations to develop and maintain information technology standards for healthcare applications. HIBCC extends its mission globally via IHIBCC, an International network of HIBCC offices. HIBCC and the HIBC standards are accredited by the American National Standards Institute (ANSI) and the European Committee for Standardization (CEN).

HARDWARE MANUFACTURERS

Some Hardware manufacturers were also asked to give their presentations regarding the requirements for hardware for printing and controlling of the process of bar coding and printing of UIDs. Three firms gave their presentations and they are M/s. Markem, M/s. Control Print and M/s. Domino. Presentations of the firms showcased various kinds of printers which can be used online by manufacturers for printing of Bar codes on labels. Most of the printers are custom made high end printers which can print label rolls online. It was further noticed that the hardware manufacturers are also offered online camera scanning systems to check for misprints and missing labels.

The various types of technology can be used for printing of bar codes on labels either directly on a label or on the containers itself. Some of the technologies that can be used are as follows: - 1.inkjet 2. Laser etch 3. Thermal transfer 4.YAG Laser 5.Inkjet (on demand) 6. Direct part marking. A comparative chart and its application on various packaging materials is shown below:-

Substrate / Technology	Paper	Corrugated	Glass	Plastic	Metal
Inkjet	Yes	Yes	Yes	Yes	Yes
Laser Etch	For specific colours or specific finishing	For specific colours or specific finishing	under certain conditions	If contrast can be achieved or specific finishing	Painted or oxidised
Thermal transfer (on-demand)	Useful for adhesive labels	No	No	Plastic films	No
[illegible]	Coloured background or specific finishing	Coloured background or specific finishing	No	Yes	Yes
Inkjet (on-demand)	Yes	Yes	No	No	No
Direct Part Marking	Film transfer	Film transfer	No	Yes	Yes

The types of printer and other hardware like camera that may be required by Individual companies will depend on the volume and nature of products to be printed and can be decided by individual manufacturers.

It was also explained by hardware manufacturers that some time in case of low volume of work existing laser printers being used by companies for printing of labels can also be used for printing.

SOFTWARE MANUFACTURER AND SOLUTION PROVIDERS

There are lot of software manufacturers and solution providers in the market who can provide track and trace technology and also solution for authentication of products. A list of such solution providers is mentioned above. These solution providers gave their presentations of the type of solution they can provide for track and trace and also individual authentication of products.

The basic procedure that was common to most of the solution providers for track and trace was by generating a bar code which is to be printed on labels or packages. This data is to be stored in the manufacturer's portal. Each time the product is invoiced or transferred to a subsequent whole-seller or retailer, the data would be updated in the manufacturer's portal. This updation would be by way of bar code readers at each distribution step connected to the internal. The stored data at the portal is to be kept after the date of expiry of product.

One hurdle of this system is thata enormous amount of data will be generated taking into consideration that there are more than 8000 manufacturers in the country manufacturing thousands of different types of products. For this it was suggested by the software providers that a central portal managed either by the Government or an agency can be set up. Portals space can be hired by the manufacturers to store the data. The Government or any interested manufacturers can access this data to find out the track of a sold drug.

Authentication

Authentication of drugs, which can include individual primary packaging, Secondary packaging and Tertiary packaging can be carried out by way of verification of the product through its Unique Identification Number (UID). The general procedure that the software providers explained is basically the same.

It consists of providing an UID numbers to each primary package which is linked to the manufacturer's portal which contains the data of the product. Whenever anyone wishes to authenticate a product, the UID number printed on the label can be either sent through SMS or read by a reader and sent to a predefined number through a mobile phone or to the portal by the reader. The data regarding the product will be returned back to the mobile phone or the bar code reader giving details of the products. This will the useful for any person in any part of the country to get a product authenticated immediately.

There is however a drawback in the system. In case the UIDs are copy in more than one package, the results of authentication would be the same. It was explained that in case of multiple authentication an alert would be noticed by the manufacturer and an investigation can be initiated in the local area from where the authentication requests had come.

Consumer Organization

Dr. H. Sudarshan, Honorary Secretary, Karuna Trust, Bangalore was invited to get a public stakeholder prospective on the issue of public participation in authentication of drugs. Dr. Sudarshan was extremely enthusiastic and supportive of the whole scheme and stated that slight encourage in the price of a drug would not matter much if the product that he gets is authenticated and is genuine.

Dr. Sudarshan also had a good suggestion by which an individual product can be tracked to a patient. He suggested that if UID (ADHAR) issue to a person is also integrated in the system and the prescription mentions the patients ADHAR number, a product can be tracked back from a patient to a manufacturer. With this system, if a patient's drug is counterfeit and is not having therapeutic activity, the ultimate manufacturer of the drug can be located.

The other consumer organization representatives were also unanimous in their view the project of Track and Trace should be implemented as it will help the common man to get good quality and authentic medicine. The Consumer Association also assured that they would carry out consumer education on this issue at an appropriate stage.

Conclusion

The task force after detailed deliberation on the issue of track and trace and UID authentication was of the considered view that in a country like India where multiple products are manufactured by a large number of companies, this would be a boon if applied. Initially there would be problems of application due to various reason including financial and technical issues, but a beginning should be made so that ultimately the benefits of the system is available to all.

Out of the various methodologies of track and trace examined, anyone of them can be adopted as the basic procedure is the same. It may be mentioned here that M/s. Kessler's Digital Mass Encryption Technology is found to be slightly more secure as the data is encrypted and no data base is involved for storage. However the generation of encrypted data will be done from M/s. Kessler's headquarter in Sweden.

The UID authentication system for individual packages and products can be done by the above procedure of Kezzler also but a better method is explained by M/s. Bilcare Research, Pune.

M/s. Bilcare has developed a unique patented non-clonable ID which cannot be copied. If copied and authenticated the results would show it is a fake. The non-clonable ID is temper proof at consist of a unique finger print for each product. This ID alongwith an alphanumeric 16 digit number is supposed to be extremely secure. Another uniqueness of the product is that the non-clonable IDs can be purchased as bulk by small manufacturers and stickered on to the product

labels and there will be no need for an online printing and labelling machine. The only cost is that of a unique reader to read the unique non- clonable ID.

Going through the meetings with various stake holders, the Task Force finally concluded that track and trace, to be effective, the following two systems should be implemented simultaneously;

1. Unique Identification Number for each primary pack for identification of a drug by a consumer.
2. 2-D Bar Coding with all details of a product incorporated in it for easy retrieval of data from any point in the supply chain.

LegalImplications:-

Anything printed on the label which is not mentioned in the Rule 96 of Drugs and Cosmetics Rules and which will be used by the regulators in its day to day functioning has to be mandated by law. Therefore Rule 96 should be suitably amended to include UID and bar coding as mandatory requirements to be implemented by the manufacturers.

No manufacturer may come forward to voluntarily accept UID and barcoding until there is a legal backing for the same. A small committee can be formed by the Government to suggest suitable amendments in the Drugs and Cosmetics Rules to include the above provisions. Initially though the manufacturers may be asked to volunteer to try out the system, eventually however legal mandate would be required for proper implementation.

Cost of the project

Cost of the project cannot be ascertained at this stage as there is a number of variable relating to software,hardware, other consumables, volume of business etc. Wide variations have been noticed in the pricing of hardware software etc. to be used in project. Exact pricing structure can be arrived at after a decision is taken at the final technology solution which will be implemented for the purpose. For this purpose once the task force gives its report, the NIC which is the sole technology service provider for the Govt.may be directed to prepare a detailed project report (DPR). Following submission of the DPR a cost estimate for implementation of the project can be arrived at. The cost of the project would also include cost of conducting training and awareness of the consumer and the industry.

TRAINING AND AWARENESS:

A project of this magnitude will require extensive consumer awareness and training for the stake holders. For this purpose once the DPR is finalized and a decision is taken on particular methodology, a structured training and awareness plan has to be created. The training will be multi-centric in nature and shall be held in various part of the country. The training can be imparted by the regulators, NIC and consumer forums for the general public.

Implementation of the project

The task force members extensively deliberated on the mechanism and the time frame for implementation of the scheme. A tentative roadmap that can be followed is as follows:

1. The first requirement is for the NIC to prepare a feasibility study based on the above report. The basic details of the requirements that the NIC will work upon is mentioned above and the NIC will provide as early as possible.
2. The NIC will guide on the requirement of hardware for successful implementation of the scheme.
3. It was estimated that about 2 lakhs SMS per day will have to be verified by the system initially. This will be after extensive propagation of the scheme through various means like print, electronic media etc.
4. It was decided to implement UID and track & trace for drugs in 3 phases which is as follows:

A. Authentication by SMS through UID (either alphanumeric or non-clonable) :

a) Phase I :

i. The members decided to proceed on this system by doing a pilot project initially which may be for a period of 1 year. Following the pilot project the feasibility of

the scheme will be examined and necessary changes made.

ii. Approximately 200 products would be identified during the pilot project from fast moving category of drugs in the market by the CDSCO in consultation with major states. The drugs can be selected by doing a market survey and also obtaining necessary market research data.

iii. The products may include drugs of both large and SME's.

iv. The feasibility of extending the scheme to imported drugs also can be examined during this Phase and can be applied in selected products.

b) Phase II:

i. Phase II would be a period of approximately 2 years.

ii. Phase II would commence after successful completion of the Phase I and the data obtained from the Phase I is examined and necessary changes made in the scheme.

iii. Approximately 2000 companies would be included in the Phase II

iv. In this Phase all the products of the selected companies will be included.

v. About 50% of the selected firms will carry out bar coding also for their primary packages in this Phase.

vi. A further evaluation of the scheme would be done after completion of the Phase II and if necessary changes made.

vii. Evaluation of the success of bar coding in the primary packages would be examined in detail and suitable amendments made in case of very small primary packages.

c) Phase III:

i. In the Phase III all manufacturers in the country will be included.

ii. Every 6 months the progress of implementation of the scheme in the country would be examined and minor changes made if and when required.

B. Track & Trace through Bar Code etc.: This scheme will start 6 months after the commencement of the Phase II of UID scheme.

a) Phase I :

i. It was decided to carry out a pilot project initially which may be for a period of 2 years as this Phase may require a heavy initial investment by the companies. After

completion of the pilot project the feasibility of the scheme will be examined and necessary changes made.

ii. Approximately 100 products manufactured by various companies would be identified during the pilot project from fast moving category of drugs in the market by the CDSCO in consultation with major states. The drugs can be selected by doing a market survey and also obtaining necessary market research data.

iii. The products may include drugs of both large firms and SME's.

iv. The feasibility extending the scheme to imported drugs also can be examined during this Phase and can be applied in selected products.

b) Phase II:

i. Phase II would be a period of approximately 2 years.

ii. Phase II would commence after successful completion of the Phase I and the data obtained from the Phase I is examined and necessary changes made in the scheme.

iii. Approximately 500 companies would be included in the Phase II

iv. In this Phase all the products of the selected companies will be included.

v. A further evaluation of the scheme would be done after completion of the Phase II and if necessary changes made.

c) Phase III:

i. In the Phase III all manufacturers in the country will be included.

ii. Every 6 months the progress of implementation of the scheme in the country would be examined and minor changes made if and when required.

5. The Government will consider amending the Drug & Cosmetic Rules during the operation of the Schemes and a draft Notification may be issued. After the Phase III of the UID and Phase I of the Track & Trace schemes, feedback received on the draft will be examined and considered changes made in the draft, if necessary.