Implementation of Principles of Pharmaco-economics & Pharmacovigilance to Achieve Optimal Financial & Therapeutic Benefits through WHO- Essential Medicine Policy

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Received: 9/11/2018; Revised: 10/15/2018; Accepted: 10/17/2018
Available online: 24th October 2018

Abstract: It is evident and revealed by the experience of State of Maharashtra during 2007-2011, that the Effective Application of principles of pharmaco-economics & pharmacovigilance in Medication Management, not only gives assurance about the all-time availability and quality of essential medicines but also saves substantial amount of government exchequer, by procuring the Assured Quality Generic Medicines at most economic rates.

These policies were based on following principles of Pharmaco-economic:

2. Pooling of need of medicines of all state run hospitals at state level to obtain lowest rates through economies of scale.
3. Selection of “Quality Assured Generic Medicines-through Pre-Qualification conditions.
4. Selection of multiple suppliers per medicine to improve all time availability of essential medicines.
5. Reducing expenditure and workload of procurement, storage and inventory of medicines.
6. Curtailing wastage of funds on procurement of non-essential medicines.

Pharmacovigilance-The policy of limited number of essential medicines had been further helped in improving the health care services in the state of Maharashtra, by:

1. Promoting Ethical & Rational use of medicines at physicians, nurses & pharmacists level through publication of “State Hospital Formulary”.
2. Protecting the health of patients from use of harmful effects of non-essential medicines & irrational Fixed Dose Combinations (FDCs).
3. Improving patient compliance to the therapy by patients through establishment of “Patient Counseling Centers” at Out Patient Departments in the hospitals and by optimal utilization of pharmacy services.

The overall boost in the Image of public healthcare services—The availability of quality assured generic medicines, had gained the confidence of physicians, and had reduced the expenditure on hospital stay of the patients because of fast recovery. And all these benefits together had boosted overall image of the hospital in the society.

Keywords: Pharmacovigilance, Pharmaco-economic, Physicians, Healthcare services

Introduction

Many people worldwide do not have adequate and regular access to even a limited basket of basic, low-cost essential medicines. The high burden of out-of-pocket payments for medicines and health products frequently increase inequities in many countries, leading to catastrophic payments and impoverishment of individuals and families.

Poor selection of medicines and health products, inadequate domestic or government financing and ineffective policy interventions and processes to manage expenditure and out of pocket expenditure (for medicines and some vaccines) contribute to a lack of access to medicines and health products and unaffordable prices [1]. WHO in its Development of the roadmap on access to medicines and vaccines 2019-2023 has emphasized that- It is difficult to achieve efficiency in the hospital pharmaceutical system if there are too many medicines. All aspects of drug management, including procurement, storage, distribution and use, are easier if fewer essential medicines must be dealt with (WHO Bulletin) [2].
Review of Prevailing Situation of Indian Pharmaceutical Market

Pharmaceutical market and in turn availability and affordability of medicines in any country has been typically effected by many factors like total numbers of manufacturing units available, strong regulatory mechanisms in place, observance of global & domestic standards of manufacturing and, various government policies to regulate the industry. To start with, it was therefore very essential and necessary to take a stock of current scenario of pharmaceutical manufacturing & marketing in India before deciding on policies for the procurement of generic medicines in public health care services.

After its independence, Indian government took a conscious decision to become self-sufficient on availability of medicines and took many policy decisions to promote local industry. Various tax concessions were offered by the government for this purpose. This resulted in emerging of around 10,000-11,000 strong pharmaceutical manufacturing units in India during first four to five decades. However, over a period, uncontrolled growth and unregulated market had led to introduction of lakhs of medicines in the market. Availability of all medicines was improved successfully. However accessibility & affordability of essential medicines was denied to common & poor population. Drugs Price Control Act, is in place to make the essential medicines affordable. However, Pharmaceutical industry stopped manufacturing essential drugs to escape price net, resulting in shortages of essential & lifesaving medicines during epidemics. At the same time, industry started pushing many non-essential and “Me Too” medicines and Fixed Dose Combinations (FDCs) by creating a new market for these medicines. With the effect that today’s medicine market is a therapeutic jungle. Most of these medicines are non-essential and are sold at Maximum Retail Price (MRP), which is highest possible price.

Paradoxically, there is a disconnect between Indian Health Policy and Indian Drug Policy as the former is designed by Ministry of Health and later is designed by Ministry of Chemicals & Fertilizers. As a result, today we have probably highest number of industries engaged in pharmaceutical manufacturing & marketing highest number of non-essential medicines in the world.

Various Global & Domestic Standards of Quality of Generic Medicines available in India

Generic drugs can reduce the healthcare expenditure significantly since their prices are substantially lower than branded drugs [3]. However, physicians are apprehensive regarding the quality of generic drugs [4,5]. Although the generic medicines are bio-equivalents of their innovator branded counterparts, these are widely believed as inferior in their therapeutic efficacy and quality to branded products [6-10]. Quality criteria are purity (absence of impurities), potency, and uniformity of dosage form, bioavailability and stability. All these aspects of quality may be affected by the manufacturing process, packaging, storage and other factors called as Good Manufacturing Practices (GMP). Globally to ensure assurance of quality of generics moving in international market, the minimum manufacturing standards called “WHO. Good Manufacturing Practices (WHO-GMP)” certification is needed. This certification is mandatory for the Indian manufacturer to export generics from India, to developing countries, Moreover, to export to developed countries like, EU, US, Japan, Australia and New Zealand etc., still higher standards called as cGMP (Current GMP i.e. most updated version of GMP standards) are needed for Indian manufacturer. However, for domestic market the Indian manufacturer has to follow Domestic G.M.P. certification, which is an updated version of prevailing global WHO-GMP and cGMP standards. Thus, the Indian manufacturer had to follow three different standards of manufacturing for particular generic medicine, namely:

1) cGMP for export to developed countries, 2) WHO-GMP standards for export to developing countries where each batch of medicines is tested for its bio-availability and 3. Un-updated Domestic GMP standards for domestic market.

Secondly, in Generic market, for a particular generic substitution, three generic equivalents are available:

1) Chemically Equivalent Generics (CEG); 2) Bio-Equivalent Generics (BEG); and 3) Therapeutic Equivalent Generics (TEG).

However, what is needed clinically is therapeutically equivalent or at least bioequivalent generic. Merely having chemical equivalence will provide a generic with “assumed quality” but not necessarily “assured quality generic”. In U.S, which is the largest generic market, there is a website called “Orange Book”, where generics having all three equivalents CEG, BEG and TEG are displayed on this website, since 1980s, so that a clinician or pharmacist can substitute the particular generic medicine as per the clinical needs. However, due to lack of availability of this data on the website of Indian drugs regulator’s websites, it becomes responsibility of hospital procurement department to provide these choices to clinicians as per their needs.
Thirdly, in India generics are manufactured under three different licenses: 1) OWN license, where the license holder is manufacturer and marketer too. 2) LOAN license, where the license holder is not actual manufacturer but gets the generics and even branded medicines manufactured on Loan License basis from other manufacturer. He only markets the medicine but not manufacturers it; and 3) THIRD PARTY license holder where license holder gets the generics & even branded medicines manufactured from a third party as outsourcing manufacturing. Thus in case of loan & third party manufacturing the license holder is merely a marketing agency & not actually manufacturing the medicines he sells.

Under such licensing system, the quality liability of the medicines is 100% with owner of the license only if it is Own License. In case of rest two loan and third party licenses, the quality liability is not shouldered by the license holder owner but by the loan or third party licensee. Most big pharmaceutical companies get their most branded and generic products manufactured on either loan license or on third party licenses from small & medium scale firms, at very low rates and add huge profit on it and sell their brands, as most trusted expensive branded products. However, because of this facility of outsourcing the manufacturing is a big flaw & blunder of the Indian drug regulatory system. Because, for any type of quality lapses during manufacturing of medicines, these big firms can easily escape the legal nets and push this Quality–Burden on third party and loan licensee as they themselves do not manufacture medicines but get it manufactured on outsource basis.

**Challenges faced by all State Government Public Health Care Services in India**

The challenges faced in the medication management by public healthcare services in India, are mainly because of unidentified and hence unattended and unresolved root causes in the procurement system and are common, typically faced by all states in India, with more or less by same extent. The four major root causes are as follows:

1. Haphazard Selection of Medicines resulting in irrational use of medicines at the cost of essential medicines.
2. Lack of application of Pharmaco-economics & Pharmaco-vigilance tools resulting in procurement of quality assumed and not quality assured medicines.
3. Lack of Standard Operating Procedures (SOPs) of medication management at all levels resulting in Total lack of Accountability, Monitoring & Evaluation of all procedures of procurement processes.

**Haphazard selection of medicines - WHO’s Essential medicines concept–A tool to achieve optimal Pharmacoeconomics in the procurement of medicines**

Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available in health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at prices that are sustainable and affordable. WHO introduced the concept of essential medicines in 1977 and since then the list has been revised every 2 years. The concept of essential medicines has been worldwide accepted as a powerful tool for the attainment of the highest possible level of health [11,12].

**Lack of application of tools of Pharmacoeconomics & Pharmaco-vigilance tools**

The application of various economic tools like Health Technology Assessment, Inventory Control, Safety –Efficacy comparison, Cost–Benefit analysis etc. have been used effectively for proper selection of medicines and to optimize the fund utilization. The quality of medicines is of paramount importance in achieving desired effect. Besides it helps in improving overall trust in the public health care services. Various Pharmaco-vigilance tools can be used to assure the quality of medicines procured. Irrational use of medicines by the physicians, and pharmacists, improper use of medicines by the nursing staff and misuse, self-medication non-compliance to the therapy are found to be very common and various pharmaco-vigilance tools can be employed to monitor and encourage rational and proper use of medicines at all levels its use.

**The lack of well-defined Standard Operating Procedures (SOPs) in public health care services provides scope for corruption and unaccountability at all levels of medication management**

I planned the present case study the State of Maharashtra, where I was working as an Assistant Director-(State Head for Medicine Procurement) during 2007 to 2011. However, it needs to mention here that the positive results which had gained through
this study were possible due to the encouragement and support of Mr. Bhushan Gagrani, and Mr. Millind Mhaisakar, both Secretary Medical Education & Drugs and late Dr. Vasudev Tayade, then Director, Medical Education & Research.

**State of Maharashtra**

The state of Maharashtra having population about 11.5 crore is providing public health care services through its state run hospitals working under three directorates, namely, Public Health, Medical Education & Employees State Insurance Scheme (ESIS). The directorate of public health services provides primary and secondary health services through its district and maternity hospitals and public health centers, located throughout the state. The directorate of medical education provides medical education and tertiary health services through its 14 medical, 3 Ayurvedic and 3 dental colleges. The directorate of ESIS caters the need of health services of employees covered under state insurance through its hospitals.

**Observations & Data Analysis**

**Challenges faced by Maharashtra State Health Services during 2002-2007**

The challenges faced in the medication management were same as mentioned above in introduction and were mainly because of unidentified and hence unattended and unresolved root causes in the procurement system.

**Reforms in the Medication management during 2007 to 2011**

Under this situation, immediate focus was to plug all these gaps effectively and put the system in order. To achieve this, the first fundamental task was to design, adopt and implement strategies and policies based on Concept of Essential Medicines advocated by WHO and various pharmaco-economic and pharmaco-vigilance tools in the medication management.

Pharmaco-economics is a branch of health economics which particularly focuses upon the costs and benefits of drug therapy [13]. Knowledge of pharmaco-economics is therefore vital for doctors to promote rational prescribing. Drugs account for a significant proportion of the total healthcare cost. The writing of a prescription is the most common therapeutic intervention in medicine [14]. Consumption decisions in healthcare are taken by the doctor and not by the consumer (the patient) [15].

**Market Dominated Medicine Needs, Lead to Creation of Therapeutic Jungle of too many Medicines and Demands for Non-essential Medicines**

The financial constraints and lack of proper medication policies leads to shortages of medicines in public health centers, where patients are most of the times forced to purchase medicines from alternative sources at very high cost from open market. This has detrimental effect, as the hard earned money is wasted on purchase of non-essential medicines at the cost of essential medicines by the poor patients. Under this situation of market dominated medicine needs, it became necessary and important specially in case of public health care services, to develop and to adopt procurement policies based on Essential Medicines List Concept, to improve availability of essential medicine at lowest expending minimum budget. With these objectives in focus, during 2003, the Directorate of Medical Education, under Ministry of Medical Education & Health took a conscious decision to adopt and implement selection of medicines based on Essential Medicine Policy so it would be possible to provide all the poor patients visiting state run hospitals, all essential medicine free of charge and at the same time at minimum budget requirement.

Consequently, following action plan was designed by the Ministry of Health & Medical Education have these policies in to action:

1. Reinforcement of functions of State level committees engaged in finalization of tenders.
4. Pharmaco-vigilance in place so as to have rational use of medicines at all levels.

**Reinforcement of Functions of State Level Committees**

There were following three state level committees constituted by the state for finalization contracts of medicines supply.

1. Committee for selection of Medicine & Surgical Supplies called as Drugs Approval Committee.
2. Committee for approval of contracts of medicine & surgical supplies, called as Tender Approval Committee.
3. Appeal Committee for Grievance Redressal regarding tendering procedure.

However, because of lack of proper S.O.Ps, & time bound work by the staff of tendering department called “State level Rate Contract Cell-Drug Purchase Cell”, these committees were underperforming and their role was underutilized. Hence, reinforcement of functions of these committees was of topmost priority.
Revised Functions of State Level Committee for Selection of Medicines

Selection of “Only Essential Medicines” based on prevailing WHO essential medicine list

As mentioned above, the prevalent selection of medicines was haphazard without any proper clinical justification. The committee was therefore advised to select the medicines based on the guidelines of WHO. This simple exercise by the committee reduced total number of medicines to nearly half from prevailing total number of medicines 2000.

Pharmaco-economic based selection of genetic medicine—Generic substitution

Generic substitution is the dispensing of a product that is generically/chemically equivalent to the prescribed product, with the same active ingredients in the same dosage form, and identical in strength, concentration and route of administration. Since there are many generic products available on the market, (branded generics, and generics with chemical name) often at much lower prices than branded products, the committee was given a task to select the essential medicines as generic names and not brand names. This Generic substitution also helped in reducing total number of medicines.

Deletion of irrational & unsafe fixed dose combinations (FDC) of medicines

The study of prevalent list of medicines by the committee revealed that there was rampant use of various unethical combinations of medicines and around 200 such irrational Fixed Dose Combinations (FDCs) were being used in state run hospitals. Most of these FDCs were simple combinations of vitamins with minerals, combinations for treating cough & cold, combinations of antibiotics, antibiotics with lactobacillus, various combinations of analgesics, proton pump inhibitors, the committee sent this list FDCs to all concerned Heads of Clinical Departments and asked for evidence based justification for the inclusion of these FDCs within specific period. However, no request for inclusion of these FDCs was received from clinicians during this time limit. Hence, it was decided by the committee to delete them from the State list. All the clinicians supported this decision of committee.

List of essential medicines came into existence

Thus, with great efforts and continuous deliberations with clinicians by the members of Drugs Approval Committee the first.

Revised Functions of Tender Approval Committee

Model quality assurance system—Procurement of only quality assured essential medicines quality evaluation of generic substitution

Though the list of essential generic medicine was prepared by the Drug Approval Committee, poor quality of generic medicines available in the market was a great concern. The poor quality of medicines not only undermines health care but also is a main hurdle in low cost generic substitution. Poor quality may result in lack of therapeutic effect, and even may cause adverse or toxic reactions; these in turn may result in harm to patients (through prolonged or drug-induced illness), as well as waste of limited resources and loss of faith.

In market dominated procurement, prescribers and procurement departments cannot distinguish between good-quality and poor-quality generic products and therefore some prescribers believe that all the generic products are cheap hence, to be of poor quality. On the other hand, some clinicians believe that branded generics are of high quality hence are costly. They are hardly aware that many stakeholders are involved in quality assurance of medicines namely—drug licensing authorities, regulatory bodies, enforcement authorities and inspectorates, drug procurement offices, pharmacies and prescribers. Quality of medicines is thus needed to be ensured through adherence to total quality assurance by all stakeholders. Typically, there are two extremes of qualities of generics available in the pharmaceutical market:

- Firstly, the small & medium scale firms that offer the cheapest prices and to do so by buying impure ingredients and cutting corners in formulation.
- Secondly, the big firms get their medicines manufactured by outsourcing the manufacturing to small firms to grab the advantage of lowest cost and add and earn 1000 times profit by simply marketing it by using/ giving brand names.
- Good procurement therefore dictates that the cheapest as well costliest tenders are not accepted if they are of dubious quality, even though it is difficult not to be swayed by price and illusion of quality of brand names.

Economy of scale and rate contracts of medicines

By pooling needs of all medicines of all state run hospitals (under three different directorates) at state level, the economy of scale was obtained by “obtaining lowest possible rate” in state level rate contract for medicines & surgical devices. These rate contracts were valid for two years. All the state run hospitals were allowed to purchase medicines at these fixed rates as per their need throughout the period of two
years. This system of Rate Contract has two main advantages, firstly “rate being fixed” for two years, rates are not subjected to market fluctuations which usually at higher side, and secondly the hospital is at liberty to procure the medicines only when and only if needed. This avoids the loss due to expiry of medicines if procured under Quantity Contract, where buyer has to buy the medicines as per tendered “fixed quantity”, even if it is not needed.

Introduction of pioneering prequalification criterion for the selection of only quality conscious pharmaceutical manufacturer

The State Level Tender Approval committee studied in detail all above discussed market dynamics, specifically, having various global standards of GMPs, various types of licenses and possible three generic equivalents available in the Indian pharmaceutical market, and came out with a policy of Prequalification Criteria for participation in the tenders called for medicines. This policy thus insured the tender process to get a Quality Assurance of generic medicine by selecting only quality conscious manufacturer from the pool of quality Assumed manufacturers. As per this policy, the following prequalification conditions were made mandatory for participation in the e-tenders called for medicines by State of Maharashtra.

Only those manufacturers who qualify following prequalification conditions were allowed to participate in e-tendering process called for medicines in the State of Maharashtra:

1. Those who manufacture the generic medicine on Own licensing and not on Loan or Third Party License.

2. The manufacturers holding WHO-GMP certification and not having merely, “Domestic G.M.P. license/certification”.

3. Those manufacturers having Annual Minimum Turnover above Rs. 25 crores during preceding three years.

This policy of prequalification, advocated by the TAC (Tender Approval Committee) really helped in screening/ filtering out three types of frivolous and unfaithful manufacturers: 1) Small firms who quote “unreasonably and unjustifiable lowest rates”, 2) Manufacturers having “domestic GMP” license, which do not guarantee bio-equivalence of generics and 3) Big firms who “outsource” manufacturing of branded generics at lowest cost and quote “unreasonably highest rates to earn unreasonably high profits under the pretext of having high quality of brand medicines”.

This policy advocated by TAC, indeed worked very effectively and by this screening process only 350-400 quality conscious manufactures (out of around total 11,000 Indian manufacturers) became qualified to supply the medicines in the tender called by the state. This Policy is worth emulating in all public health care services to get “Quality Assured Generics”.

It is evident from the comparative rates obtained in the tender which are shown in above Table 1, looking at the lowest rates obtained in tenders, substantial amount of government exchequer had been saved throughout by the state run hospitals on the purchases made under this contract during 2007–2010. This had helped in providing all essential medicines “free of charge to patients below poverty line” and medical devices under Jeewandaji Yojana, (an

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Insurance Scheme) provided to poor patients as very less funds were needed due to very low rates obtained in tenders. Previously, this was not possible effectively for all patients because of the limited available funds.

**To improve availability of essential medicines through selection of multiple suppliers per item for all medicines**

The second problem which was faced in most of the public health care procurement procedure was that- Few firms after getting contract used to stop the supplies. This mainly because of two reasons, firstly financially they failed to sustain the burden of bulk supplies to be made throughout the state and secondly, they were also unable to withstand the long outstanding payments from the hospitals. To tackle this problem of non-supply by the approved firms on tender a totally new policy approach was advocated by Tender Approval Committee. Under this policy, multiple suppliers were selected for each medicine so that at a particular time if one supplier fails to execute the purchase order the standby supplier can supply. For this, the bidder at rank of L2 and L3 were called and asked to match the rates offered by bidder at L1 level and at the lowest rate and then the quantity of supply was divided as 50% quantity to L1, 30% quantity to L2 and 20% to the L3 level bidder. With this arrangement, each medicine had three suppliers at the same lowest rate, the latter two L2 and L3 suppliers were used as “back up suppliers” in event of non-supply by the contractor at L1 level.

**Application of Various Tools for Effective Implementation of Pharmaco-vigilance**

**Publication of the state hospital formulary called as Rate Contract Book-2007**

The formulary process is the cornerstone of good pharmaceutical management and rational drug use. It consists of preparing, using and updating a formulary list of essential medicines list with generic names and providing information on drugs with, Standard Treatment Guidelines (STGs) and Standard Operating procedures (SOP) for Medication Management. Based on these WHO guidelines first State Hospital Formulary called as Rate Contract Book was published by the Maharashtra State during 2007. This reference book provided to all state run hospitals giving information on what medicines were available, at what cost, and how they should be stored be used effectively. This helped to ensure that physicians were provided with the best possible cost effective medicines [16].

**Quality use of medicines by physicians, pharmacists, patients and community at large**

It is now well documented fact that- Medicines worth crores of rupees are procured but the patients do not use the medicines properly. This is mainly because of failure of education of patients on proper use of medicines by the hospital staff, mainly doctors and pharmacists. This has resulted not only immergence of antibiotic resistance but, also in failure of many national programs like national anti-Tuberculosis program, as patients failed to take the medicines as per schedule. This ultimately, has ended up in starting DOTs (Directly Observed Treatments) program. It was therefore necessary to understand that providing medicines is only half work done.

It was therefore one of the important and equally important task of State of Maharashtra to design Standard Monitoring Methods to improve on proper and quality use of medicines by patients and to improve the compliance to the therapy. To achieve this, to start with, all state run hospitals were advocated and instructed to establish “Patient Counseling Centers”, at the OPD of all hospitals. It was thought that this would not only improve compliance to the therapy by the patients and public at large but would also help in proper and optimal utilization of pharmacy services which otherwise were professionally underutilized by engaging them only in distribution of medicines.

**Summary & Conclusion-Human Health Implementation of the Results**

It is observed from this study that following pharmaco-economic and pharmaco-vigilance benefits had been obtained by the Maharashtra state during 2007-2011. Which had overall impact on improving the services of public health care in the State Of Maharashtra.

• As evident and revealed from the experience of State of Maharashtra, the Quality Procurement Policies can be designed and can be implemented successfully and effectively. However, these policies need to be based on four basic principles:
  1) Selection of only essential medicines with generic names based on WHO Essential List of Medicines.
  2) Pooling of need of medicines of all state run hospital at state level to obtain lowest rates through economy of scale.
  3) Selection of Quality Assured Generic Medicines and 4) Selection of multiple suppliers per medicine to improve all time availability of essential medicines throughout all state runs hospitals.

• This policy of essential medicines had further improved the health care services in the state by:
  1) Promoting rational use of medicines, 2) Protecting

DOI: http://dx.doi.org/10.14303/ijbio.2019.8.1.2

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the health of patients from harmful effects of unethical FDCs 3) Reducing financial burden and workload of procurement, storage and inventory of medicines and 4) Curtailing wastage of funds on procurement of non-essential medicines.

• The Effective Application of principles of pharmaco-economics, pharmaco-vigilance and Quality Procurement Management Principles as evident from the experience of Maharashtra State, not only gives assurance about the quality of essential medicines but also saves substantial amount of government exchequer, by procuring the Assured Quality Medicines at most economic rates.

• Since its effective implementation, it had improved all time availability of essential medicines throughout state, which further had improved confidence of physicians, had reduced hospital stay of the patients because of fast recovery due to use of quality generics. And all these benefits together had helped in improving the image of the public health care services in the society.

To put it succinctly, these policies are pioneering. Looking into the success these policies, it is really pertinent to implement in all public health care systems in India to achieve optimal benefits.

References: