Pharmacoeconomics and its Application in Public Health Sector
Public health sector worldwide is facing financial constraints and restrictions due to the economic crisis. Health policy decision making and demonstration of value for money for the new, expensive drugs has become an absolute necessity. In the current health care environment, all pharmaceutical products must provide the most beneficial outcomes at the lowest cost to patients, health care systems, and society at large. Pharmacoeconomics emerged as a reliable practice to manage this responsibility.

Pharmacoeconomics is the form of economic evaluation applied to pharmaceuticals in which the costs, consequences and benefits of alternative drug therapies are compared. Pharmacoeconomic evaluations provide a basis for resource allocation and utilization. A pharmacoeconomic evaluation may also be incorporated into clinical trials as an economic assessment where the new drug/procedure is compared with an older drug or existing intervention.

The production costs of drugs include research, marketing, distribution, storage etc. This money comes back to the manufacturer from the consumer - the patient. Only ten among ten thousand new chemical entities in discovery move into preclinical development phase and further, only five enter clinical development phase. Finally, only one entity might be approved. The large amount of money spent on pursuing the molecules which are not approved will be recovered by manufacturers from the consumers of the approved drugs. In this scenario, pharmacoeconomics plays an important role to identify, measure, and compare the costs and consequences of pharmaceutical products and services and in describing the economic relationship involving drug research, drug production, distribution, storage, pricing and use by the people. It ultimately influences all the sectors involved in pharmaceuticals.

Pharmacoeconomics is a sub-discipline of health economics. The economic evaluation is classified mainly into three forms, cost-effectiveness analysis (CEA), cost-utility analysis (CUA) and cost-benefit analysis (CBA) based on the way the consequences of a treatment are measured. In cost-effectiveness analysis, most obvious effect is measured. Depending on the therapeutic area being studied, the choice of units for cost-effectiveness analysis might differ. For instance, years of life gained such as treatments for chronic renal failure might be the most appropriate effectiveness measure in life saving therapy. Criteria such as “asthma-free days” or “symptom-free days” could be the unit of choice in a field such as asthma.

In cost-utility analysis (CUA), another form of economic evaluation, costs (inputs) and benefits (consequences) of interventions are evaluated relative to one another through the use of patient’s quality of life, ability to absorb cost, or preference for one treatment over another. Then the superiority of one treatment over another can be expressed in terms of the quality adjusted life years (QALYs) gained or the number of years lived in full health by the beneficiaries. Finally, in a cost-benefit analysis (CBA), the various consequences may be valued and costs and benefits relative to one another are expressed, in monetary terms. Since all costs and consequences are expressed in the same unit (that is, money) CBA can be considered as the broadest form of economic evaluation. In CBA, we assess the justification of costs of an intervention in terms of total benefits accrued. However, in CEA and CUA, justification of value for money involves the judgment of benefits to the society (a life year or QALY, for instance) with the intervention.

Nowadays, public health service providers in many countries request new information on the economic aspects of a new product. The first jurisdiction which adopted pharmacoeconomics as a part of decision making process was Australia. Canada, New Zealand, Norway, Finland, Sweden and Scotland (in the UK) also utilize pharmacoeconomic data for decision making procedures related to new drugs. Though nations such as England, Germany, Hungary, the Netherlands, and Portugal also use pharmacoeconomics studies, they use it only for selected new drugs. Drug makers and decision makers in few jurisdictions such as USA, Denmark, France, and Italy use pharmacoeconomic data on voluntary basis. For instance, if managed care groups in USA request economic data, these can be supplied by manufacturers according to a format devised by the Academy of Managed Care Pharmacy.
Public health service providers generally request pharmacoeconomic information in a country-specific value dossier. The value dossiers are generally similar but there might be slight differences. The authorities publish guidelines on submission of data in value dossiers. The information contained in value dossiers usually includes the clinical added value of the intervention in the approved indication in comparison to the standard of care, the patients and patient groups who probably benefit from the new treatment and the extent to what these patients might benefit. The yearly costs of the proposed interventions are illustrated based on the assumptions on the added value. Decisions on reimbursement and pricing will be finally based on these dossiers.

In order to facilitate the widespread application of pharmacoeconomics, the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) was established with members from 90 countries, the majority of which come from the US and Europe. Till date, the drugs for which pharmacoeconomic analysis is widely applied are the anti-TNFs in rheumatoid arthritis and other indications.

In a world which is driven by value for money considerations and in the health sector where the emphasis is on containing healthcare costs worldwide, demand is likely to increase for pharmacoeconomic analysis which provides evidence that drugs provide good value for the money spent on them. Thus, value for money considerations should be one of the main factors driving the drug development process and the successful manufacturers will be those who focus on developing products that are cost effective in a wide range of indications and patients. Indeed, data on the economic value of a drug will have to be generated in addition to clinical efficacy and safety data in order to support the process of pricing. The objectives of clinical trials should therefore include economic issues. In conclusion, pharmacoeconomics is a science whose need is undeniable and that will improve with application.