Cost analysis study of different brands of commonly used drugs for bronchial asthma available in india -A pharmacoeconomics study

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Abstract

Introduction: To evaluate the price variation of various brands of antiasthmatic drugs available in single and in combination.

Materials and Methods: An observational study was carriedoutusing 'CIMS' &'IDR' (July-Oct 2016), where in the difference in the maximum and minimum price of a particular drug beingmanufactured by differentpharmaceutical companies, in the same strength, number and dosage formwas compared and the percentage variation in price was calculated. Data is analysed using descriptive statistical formula.

Results: In single drug therapy, among bronchodilator, β2 sympathomimetic: salbutamol (4mg) andsalbutamol (20µg) shows maximum and minimum price variation of 333.5% and1.47%. Among Leukotriene antagonists, montelukast (5mg tab) shows maximum of 185% and minimum of 0.539% as chewable tablet. Mast cell stabilizer ketotifen (1mg) shows maximum of 195.23% and minimum 142.307% as syrup. Among systemic corticosteroids methylprednisolone showed maximum and minimum of 701.01% and 4.16% 4mg and 2mg dosages. Inhalational steroids budesonide (0.5mg/ml) shows maximum of 486.5% and fluticasone propionate (50µg) shows minimum of 0.41%. In combination therapy salbutamol with theophylline shows a maximum of 900% and terbutaline, ambroxol hydrochloride with guaiphenesin shows minimum of 0.71% while Inhalational steroids maximum of 80.06% with fluticasone(100µg), formoterol fumarate(6µg) combination and minimum of 0.37% with budesonide(40µg) and formoterol fumarate(6µg).

Conclusion: The percentage price variation of different brands of the same drug and dosage manufactured in India for treatment of bronchial asthma is substantially wide. The pricing should be considered in view of better compliance. The clinicians should be aware of these price variations to reduce the economic burden of drug therapy.

Keywords: Cost analysis, Antiasthmatic drugs, Brands, Cost evaluation, Price variation.

Introduction

Pharmacoeconomics refers to the scientific discipline that compares the value of one pharmaceutical drug or drug therapy to another.(1) Pharmacoeconomics identifies measures and compares the costs and consequences of pharmaceutical products and services. High cost of medicines has economic implications for the patients and patient compliance may be significantly dependent on the cost of medicines prescribed. In addition to the confusing brand names of various medicines in the Indian market, price variation poses a dilemma for practicing doctors. In case of many medicines there is a wide difference in the prices between different brands, which could be twofold to more than 100-fold.(2) It is not always easy for the practitioner to decide which brand to prescribe by merely considering the medicine price.The objective of Pharmacoeconomics study is to influence policy formulation and effective decision making, rational prescribing behaviour and effective utilization of resources, to make a person or a group of people change their behaviour and persuade them that a new course of action is more efficient.(3)

In terms of production, the India pharma industry ranks 3rd on a global scale, whereas in terms of turnover worth, it ranks 14th. Medication prices are among the lowest prices in the world. However, the overall expenses associated with medications continue to soar in the country.(4) Although India is a producer of abundance of quality drug at low cost, only one third of its population has access to essential medicines.

Bronchial asthma is a common respiratory disorder with prevalence ranging from 1-18% in different populations. It is an important public health problem in India with significant morbidity. The prevalence of asthma in India is about 2% with a burden of about 17 million asthmatic patients.(5)The global prevalence of asthma, using a definition of clinical asthma or treated asthma, is estimated to be about 4.5%.(6)Between 100 and 150 million people around the globe roughly the equivalent of the population of the Russian Federation suffer from asthma and this number is rising. Worldwide, deaths from this condition have reached over 180,000 annually.(7) Over the past decade, most of the controlled studies show that asthma prevalence in children has increased annually 5-6% and doubled in the last 20 years. It is estimated that the world-wide prevalence of asthma has increased almost 50% during the past 10 to 15 years. Moreover it is predicted by 2025, 100 million be added to the population of the world's asthma patients.(6)Asthma is responsible for significant morbidity worldwide. It is the 25th leading

cause of disability adjusted life years (DALYs) lost per year accounting for an estimated 15 million DALYs lost.[8]

Thus, asthma imposes a tremendous burden on the healthcare system and society of India due to loss of productivity, especially due to the fact that young individuals in the most efficient phase of their life, are affected.[5] Due to the uncontrollable nature of asthma disease and its increasing in prevalence and severity, costs imposed on society and patient will be higher by the day. Therefore, better control of the disease significantly reduces the costs.[9]

Indian Pharmaceutical Industry has many branded formulation and generic brands of the same drug with large difference in selling price. The cost has affected the consumers, prescribers and health care providers. But very few studies are available in our scenarios which compare the cost of drugs of different brands. Therefore we decided to carry out the study which compares the cost of various anti-asthmatics of different brands (mostly branded- generics) compared with the same molecule by calculating percentage variation of cost.

Thus the current study aims evaluating the price variation of various brands of anti-asthmatic drugs available in single and in combination to ensure better patient compliance for these drugs.

Aim & Objectives

To compare the cost of various anti-asthmatics of different brands (mostly branded- generics) compared with the same molecule by calculating percentage variation of cost.

Objectives

This Pharmacoeconomics study is designed with the main objectives of,

1. To evaluate the cost of anti-asthmatic drugs of different generic classes and different brand names of one compound.
2. To evaluate the difference in cost of differentbrands of the same active drug by calculating percentage variation of cost.

Materials and Methods

CIMS (current index of medical stores) & IDR(Indian drug review) [2016 issues]http://www.cimsasia.com, were reviewed for the prices of drugs used in the management ofdiabetes mellitus.

1. The retail cost of a particular drug beingmanufactured by different companies, in thesame strength, number and dosage form wascompared.
2. The difference in the maximum and minimumprice of the same drug manufactured by different pharmaceutical company's wascalculated.
3. The percentage variation in price wascalculated.
4. The drugs being manufactured by only onecompany or being manufactured by differentcompanies however, in different strengthswere also included.

The percentage variation in price was calculatedusing the following formula

Findings of our observational study were expressed asabsolute numbers as well as percentage.

- Price of most expensive brand– Price of least expensive brand X 100
- Price of least expensive brand

Results

The prices of a total of 106 drugs (38 single and 68 combination preparations), available in 491 differentformulations were analyzed. These 491 formulations aremanufactured by different pharmaceutical companies. In single drug therapy the maximum cost variation is 788.88% shown by Theophylline (300mg) and minimum variation is 0.27% shown by inhalational steroid Fluticasone propionate (250µg).

In combination therapy maximum cost variation is 900% shown by Salbutamol (2mg) and Theophylline (100mg) combination while minimum variation of 0.37% shown by formeterol fumarate (6µg) and Budesonide (40 µg) 1puff×150md formulation.

Single drug therapy

In Single drug therapy, Table 1 shows, β2 sympathomimetic in which Salbutamol (4mg) and Salbutamol (20µg) shows maximum and minimum price variation of 333.5% and 1.47%.

Table 2 shows methylxanthines group in which Theophylline (300mg) and Theophylline (80mg/15ml) as 200ml syrup showed maximum and minimum variation of 788.88% and 29.50% respectively. In Table 3 showing anticholinergic group of drugs under bronchodilators showed maximum of 38.62% by Tiotropium bromide (18 µg) and minimum cost variation of 2.31% shown by Tiotropium bromide (9µg).Table 4 showing Leukotriene antagonists depicts montelukast (5mg tab) shows maximum of 185% and minimum of 0.539% as chewable tablet.

Table 1: Price variation in Beta2 sympathomimetic group of drugs

Drug	Formulations	Doses	Manufacturing companies	minimum price(INR)	maximum price(INR)	%Price variation
Salbutamol	17	200µgx8's	1	5		-100
		200µgx30's	2	16.26	16.5	1.476015
		2mgx10's	8	1.05	3.86	267.619
		4mgx10's	12	1.58	6.85	333.5443
		8mgx10's	4	7.09	9.21	29.90127
		2mgx30's	1	15.26		
		100µgx1puffx200md	9	73.26	137.57	87.78324
		100µgx1puffx400md	1	90.87		
		100µgx1puffx120md	1	102.5		
		100mgx1's	1	78.6		
		50µgx10's	1	17		
		2.5mg/3ml/3ml	1	4.1		
		10mg/ml	1	12.95		
		2mg/5ml/100ml	4	14.1	16.69	18.36879
		2.5mg/2.5ml/100ml	2	3.35	3.35	0
		5mg/ml-15ml	3	15.2	16.13	6.118421
Xinofoate		50µgx1's	1	440		-100
Levosalbutamol	5	100µgx30's	1	14.25		-100
		50µgx1puffx200md	1	82.9		-100
		0.31µg/2.5ml/2.5ml	1	14.09		-100
		0.6µg/2.5ml/2.5ml	2	5	16.22	224.4
		01.5µg/2.5ml/2.5ml	2	6	16.33	172.1667
Salmeterol	3	25µgx1puffx120md	1	93.94		-100
		25µgx1puffx200md	3	91.06	99	8.719526
		50µgx30's	2	40	62.5	56.25
Bambuterol	4	10mgx10's	6	20.4	49.5	142.6471
		20mgx10's	6	40.08	69.8	74.1517
		1mg/ml/60 ml	3	24.25	29	19.58763
		2mg/ml/60 ml	1	28		-100
Ephedrine	2	30mg/ml/ml	1	17.8		-100
		25mg/0.5ml/0.5ml	1	35		-100
Formeterol	2	12µgx1puffx120md	2	110.25	142	28.79819

Table 2: Methylxanthines

Drug	Formulations	Doses	Manufacturing companies	minimum price(INR)	maximum price(INR)	%Price variation
Theophylline	12	600mgx10's	5	41.85	60	
		300mgx10's	3	6.75	60	788.8889
		400mgx10's	13	6.95	55.8	702.8777
		250mgx10's	1	12.75		-100
		200mgx10's	8	9	35	288.8889
		125mgx10's	1	9.05		-100
		100mgx10's	1	4.89		-100
		300mgx15's	1	15.88		-100
		200mgx15's	1	13.41		-100
		200mgx20's	1	6.22		-100
		80mg/15ml/200ml	2	21.62	28	29.50971
		50mg/5ml/100ml	1	10.17		-100
Piperazine theophyllinethylethanoate	2	250mgx10's	1	28.5		-100
		125mg/5ml/100ml	1	28.76		-100
Theophylline anhydrous	2	400mgx10's	1	103.5		-100
		600mgx10's	1	111.45		-100
Aminophylline	4	100mgx1000's	1	125		-100
		250mg/2ml/10ml	1	6.32		-100
		25mg/ml/10ml	2	130	350	169.2308
		250mg/10ml/10ml	1	22		-100
Aminophylline anhydrous	1	25mg/ml/10ml	1	13.9		-100
Aminohylline hydrate	2	225mgx10's	1	44.8		-100
		350mgx10's	1	58.8		-100
Doxophylline	7	400mgx10's	44	29.5	94.8	221.3559
		800mgx10's	10	78	139	78.20513
		200mgx10's	1	25		-100
		400mgx15's	1	89.25		-100

		100mg/5ml/100ml	12	37.85	85	124.5707
		100mg/5ml/60ml	7	11.71	84	617.3356
		100mg/5ml/10ml	3	9.7	30	209.2784

Table 3: Anticholinergic

Drug	Formulations	Doses	Manufacturing companies	minimum price(INR)	maximum price(INR)	%Price variation
Ipratropium bromide	5	250µgx1puffx150md	3	29.5	38.2	29.49153
		42µgx1puffx150md	1	121		-100
		20µgx1puffx200md	2	125.81	158.9	26.30157
		500µg/2ml/2ml	1	12.1		-100
		40µgx30's	1	47		-100
Tiotropium bromide	5	18µgx30's	2	130.3	133.31	2.310054
		9µgx1puffx180md	2	303	407.36	34.44224
		9µgx1puffx120md	3	290	402	38.62069
		18µgx1puffx100md	1	305		-100
		18µgx15's	1	145.05		-100
Tiotropium bromidemonohydrate	1	18µgx15's	1	139		-100

Table 4: Leukotriene antagonists

Drug	Formulations	Doses	Manufacturing companies	minimum price(INR)	Maximum price(INR)	%price variation
Montelukast	9	50mgx10's	9	35	100	185.71429
		10mgx10's	13	59	150	154.23729
		4mgx10's(chewable tab)	3	33	64	93.939394
		5mgx10's	2	74.1	74.5	0.5398111
		10mgx10's	1	83.2		-100
		4mgx10's(dispersible tab)	1	39.4		-100
		5mgx10's(film coated)	1	73		-100
		10mgx10's	1	131.85		-100
		4mgx10's(granules)	1	5.85		-100
Montelukast sodium	11	4mgx10's	5	76	91.55	20.460526
		5mgx10's	7	70	100.85	44.071429
		10mgx10's	8	90	178.56	98.4
		4mgx10's(chewable tab)	3	54	91.4	69.259259
		5mgx10's	3	78.4	100.3	27.933673
		10mgx10's	**1**	**182.8**		**-100**
		4mgx10's(dispersible tab)	1	62.5		-100
		5mgx10's	2	70	70	0
		4mgx10's	2	63.4	110.65	74.526814
		5mgx10's	2	74.1	138.52	86.936572
		10mgx10's	3	96	192.4	100.41667
Zafirlukast	1	10mgx10's	1	40.72		-100

Table 5: Mast cell stabilizers

Drug	Formulations	Doses	Manufacturing companies	Minimum price(INR)	Maximum price(INR)	%price variation
ketotifen	2	1mgx10's	14	10.5	31	195.2381
		1mg/ml/5ml	6	26	63	142.30769
Sodium chromoglycate	7	5mgx1puffx112md	1	147.5		-100
		2mgx1puffx112md	1	120.78		-100
		2.8mgx1puffx112md	1	100		-100
		1mgx1puffx400md	1	147.5		-100
		10mg/ml/2ml	**1**	**7.5**		**-100**
		20mg/ml/10ml	1	45.29		-100
		20mgx30's	1	60.75		-100

Table 6: Inhalational Steroids

Drug	Formulations	Doses	Manufacturing companies	minimum price	max price	%price variation
Beclomethasone	6	50µgx1puffx7.5ml	2	100.25	141.5	41.147132
		50µgx1puffx200md	1	171		
		100µgx1puffx200md	3	150	268.2	78.8
		250µgx1puffx200md	1	297.97		

		10µgx20's	1	25		
		200µgx20's	1	35		
Beclomethasone propionate	7	50µgx1puffx200md	1	141.5		
		100µgx1puffx200md	1	189.931		
		200µgx1puffx200md	1	231.66		
		250µgx1puffx200md	1	242.5		
		100µgx30's	1	44		
		200µgx30's	1	62		
		400µgx30's	1	78		
Budesonide	12	200µgx1puffx120md	1	378		
		200µgx1puffx200md	7	272	335	23.161765
		200µgx1puffx100md	1	215.1		
		400µgx1puffx100md	1	342.21		
		100µgx1puffx200md	7	186.5	264	41.55496
		100µgx1puffx400md	1	400.22		
		64µgx1puffx200md	2	231.7	269.1	16.141562
		100µgx1puffx150md	1	162		
		50µgx1puffx200md	2	178.86	270.1	51.011965
		0.25mg/ml/2ml	2	12	13.5	12.5
		0.5mg/ml/2ml	4	16.24	95.25	486.51478
		1mg/ml/2ml	3	21	117.5	459.52381
Ciclesonide	9	50µgx1puffx100md	1	210		
		50µgx1puffx120md	2	221.59	246.25	11.128661
		80µgx1puffx14ml	1	310		
		160µgx1puffx14ml	1	350		
		500µgx10's	1	125		
		200µgx30's	1	180.83		
		400µgx30's	1	195		
		80µgx1puffx120md	1	278.2		
		160µgx1puffx120md	1	350		
Flunisolide benzalkonium chloride	1	0.035w/v 10ml	1	146.25		
Fluticasone Furoate	2	0.05w/w/120md aerosol	3	240	389.9	62.458333
		27.5µgx1puffx120md	5	240	264	10
Fluticasone propionate	15	50µgx15ml	1	191		
		25µgx1puffx120md	1	130		
		50µgx1puffx120md	4	160	228.86	43.0375
		125µgx1puffx120md	2	240	257.34	7.225
		100µgx1puffx120md	1	189.97		
		50µgx1puffx100md	2	150	171	14
		0.5mg/2ml/2ml	1	34.5		
		2mg/2ml/2ml	1	55		
		50mg/10ml/2ml	1	166.2		
		50µgx30's	2	60	60.25	0.4166667
		100µgx30's	2	90	100	11.111111
		250µgx30's	2	180	180.5	0.2777778
		50µgx20's	1	40		
		100µgx20's	1	60		
		250µgx20's	1	120		

Mast cell stabilizer ketotifen (1mg) showed maximum 195.23% and minimum 142.307% as 1mg/5ml syrup formulation is shown in table 5.Table 6 Inhalational steroids Budesonide (0.5mg/ml) shows

Maximum of 486.5% and Fluticasone propionate (250µg) shows minimum of 0.27%. Fig. 1& 2 shows variations in cost among single drug therapy.

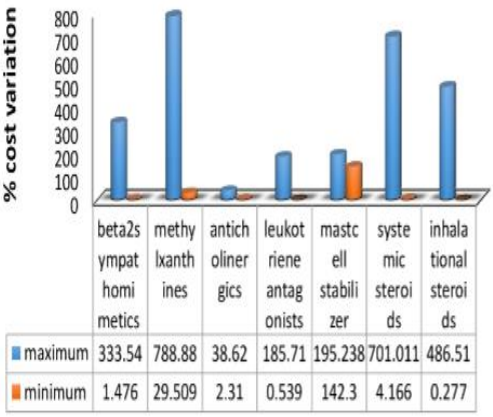

Fig1: Single drug therapy

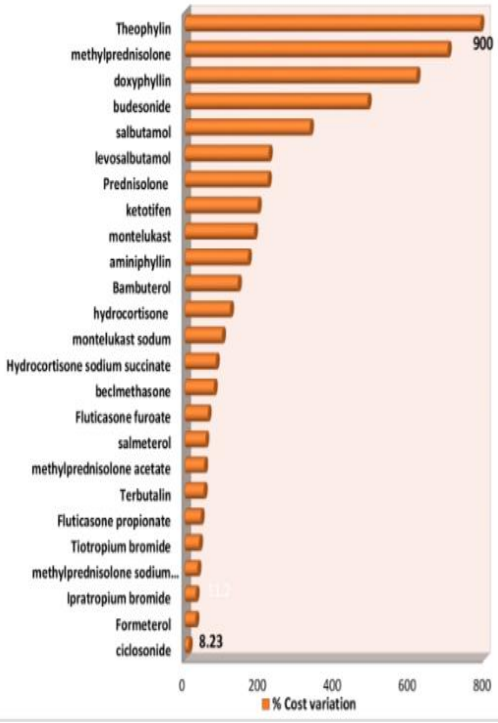

Fig. 2: Single Drug Therapy

Combination Therapy

In combination therapy Salbutamol with Theophylline shows a maximum of 900% and terbutaline, ambroxol hydrochloride with guaiphenesin shows minimum of 0.71% among bronchodilators while Inhalational steroids maximum of 80.06% with Fluticasone(100µg), formeterol fumarate(6µg) combination and minimum of 0.37% with Budesonide(40µg) and formeterol fumarate(6µg) combination. Fig. 3 shows variation in cost among combination therapy. Fig. 4 depicts the relationship between manufacturing companies and percentage cost variations among drugs used in bronchial asthma.

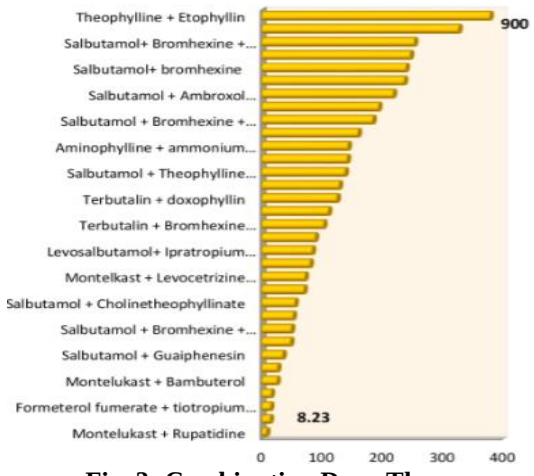

Fig. 3: Combination Drug Therapy

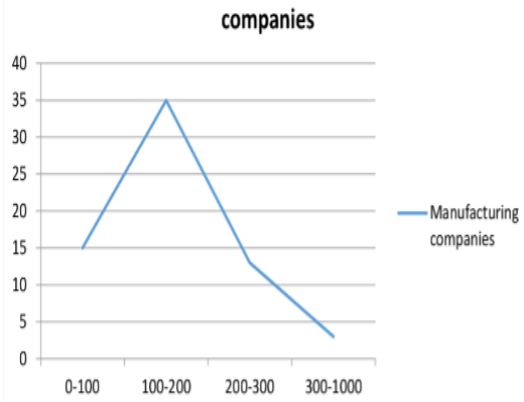

Fig. 4: % cost variation among manufacturing

Discussion

Bronchial Asthma as the most common chronic disease in childhood reduces the quality of life of children and their families. And require a long term usage of medications sometimes throughout life. So the expenditure for the medication of lifelong therapy becomes a burden for patient and accounts to poor compliance.

In Europe, the estimated direct costs of asthma treatment are about 17.7 billion Euros every year while the indirect cost due to loss of productivity is about 9.8 billion Euros annually.[10] Similarly in United States, the total additional cost of asthma to society was 56 billion dollars, with loss of productivity due to morbidity accounting for 3.8 billion dollars and productivity losses due to mortality amounting to 2.1 billion dollars.[11]

In India, the estimated cost of asthma treatment per year for the year 2015 has been calculated at about 139.45 billion Indian rupees (approximately 2.3 billion US dollars). Interestingly, it has been deduced that this cost is likely to come down to about 48.5 billion Indian rupees if all asthmatics receive treatment according to evidence-based guidelines. It is noteworthy that this estimate does not include the indirect costs of asthma.[12]

The current study conducted to evaluate the cost analysis for drugs in bronchial asthma showed a wide variation in the pricing of same drug in same dosage by different pharmaceutical companies a major reason for this price variation is the pricingpolicy for medicines. The prices of all medicines not under price control, they have been left to the market forces. The maximum allowable most manufacturing expense (MAPE) permitted for medicines under price control is 100 per cent and ceiling prices have been fixed for these.[13] For the other medicines, there is no restriction on the MAPE, resulting in large and variable prices. The variation in prices of the same medicine but sold under different brands is large. So the study was designed to analyzeprice variation of a chronic and debilitating disease. The drug prices available in CIMS & IDR manual of an updated version were compared. Antiasthmatic drugs were selected as it is one of the most expensive and the treatment requires continuous prescription drug use. Our findings reveal that the prices of most of the Antiasthmatic brands have percentage price variation above 100-200% which is not an acceptable situation for patients. Out of 106 drugs studied, most of which are commonly prescribed, percentage price variation is very wide leading to economic burden on the patient. The reasons for this price variation could be as follows.[12]

1. Government regulations and pricing policies like DCGO and National Drug Pricing Controletc
2. The existing market structure of the pharmaceutical industry
3. Industry costs – manufacturing cost, labor cost, marketing cost etc...

Patients have to pay more unnecessarily if costly brands are prescribed. The costly brand of same generic drug is scientifically proved to be in no way superior to its economically cheaper counterpart. It has been observed that the physicians have suboptimal awareness of drug cost.[14]Thus, educational intervention methods and strict compliance to WHO drug policies could play a role in generic prescribingthe situation can be improved if drug cost is given greater emphasis during medical training program of doctors. A mention of the drug cost is also required in medical literature and drug advertisement. Either cheapest brand or drugs from generic stores should be prescribed as far as possible to reduce the cost of treatment for the patient. Hence, to avoid this, drug should be prescribed in generic to reduce the cost of treatment as well as to enhance the patients' compliance.[15]The situationcan be improved by incorporating an analysis of prescription costs in the medical curriculum andby providing updated and complete informationregarding bioequivalence, quality and cost of thepharmaceutical preparation to the doctors.Wherever possible a cheaper brand should beprescribed because the superiority of anyparticular brand over the others has never beenproved scientifically.

Conclusion

Government should have a policy whereby the prices of branded-generic drugs can be made realistic and affordable to common man. We need to have legislation to that effect. Currently, very few medicines are under drug prices control order. Hence it is desired that the Government should bring all lifesaving and essential medicines under price control. At the same time Physicians should consider the cost while prescribing antiasthmatic drugs based on the patients socioeconomic status. Studies have shown that providing a manual of comparative drug prices annotated with prescribing advice to physicians reduce their patients drug expense

References

1. Fox Rushby J and Cairns J. "Economic Evaluation", Open University Press, 2005.
2. Lofolm PW, Katzug BG. (2004). Rational prescribing and prescription writing. In: Katzug BG, editor. Basic and clinical pharmacology. 9th ed. Mc GrawHill:New York. Pp.1091-100.
3. World Health Organization's Task force on Health Economics and Health Sector Reform report (WHO-TF/HE/HSR/75), 1996, 1-56.
4. Draft national pharmaceuticals pricing policy, 2011(NPPP, 2011) [Last accessed on 2012 Feb 20]. Available from: http://pharmaceuticals.gov.in/mshT2810/FTY2.pdf.
5. Guidelines for diagnosis and management of bronchial asthma: Joint ICS/NCCP (I) recommendations Lung India. 2015 Apr; 32(Suppl 1): S3–S42.doi: 10.4103/0970-2113.154517PMCID: PMC4405919.
6. The Global Asthma Report. International Union against Tuberculosis and Lung Disease, Paris, 2011. [Last accessed on 2014 Mar 5]. Available from:http://www.globalasthmanetwork.org/publications/Global_Asthma_Report_2011.pdf.
7. World Health Organization. Global surveillance, prevention and control of chronic respiratory diseases: A comprehensive approach. 2007. [Last Accessed: 2012 Nov]. Available from:http://www.who.Int/evidence/bod.
8. Murray CJ, Lopez AD. Measuring the global burden of disease. N Engl J Med.2013;369:448–57.[PubMed: 23902484].
9. Laforest L, Ernst P, Pietri G, Yin D, Pacheco Y, Bellon G, et al. Asthma-related costs relative to severity and control in general practice. Pediatr Asthma Allergy Immunol.2005;18:36–45.
10. The European Lung White Book. The first comprehensive survey on respiratory health in Europe, 2003. [Last accessed on 2014 March 05]. Available from:http://www.erswhitebook.org/chapters/the-economic-burden-of-lung-disease/.
11. Barnett SB, Nurmagambetov TA. Costs of asthma in the United States: 2002-2007. J Allergy Clin Immunol.2011;127:145–52. [PubMed:21211649].
12. Murthy KJR, Sastry JG. Economic burden of asthma. Back-ground papers; Burden of disease in India. [Last accessed on 2014 Mar 5]. Available from:http://www.who.int/macrohealth/action/NCMH_Burden%20of%20disease_%2829%20Sep%202005%29.pdf
13. Sarkar PK, A rational drug policy, Indian j med ethics, 12, 2004, 30-3.

14. Lowy, D.R. Low, L. and Warner, R.S. A survey of physician awareness of drug costs. Am J Edu1972,47:349-355.
15. Steven Reichert, Todd Simon, Ethan A. Halm. Physicians' Attitudes about Prescribing and Knowledge of the Costs of Common Medications. Arch Intern Med.2000,160:2799-2803.
16. Government of India, Drug policy,1986. Available from: http://nppaindia.nic.in/dp1986mod.htm.