Selections from Drug & Therapeutics Letter*

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DOES NEPAL NEED "VIAGRA" ?

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Sildenafil citrate (Viagra) works in erectile dysfunction by improving blood flow to the penis leading to erection. For pharmacological details of the drug, see page 3.

The drug is targeted for 50- to 70-year old population, in whom the prevalence of erection disorders can be over 50%. Before the availability of this orally effective remedy, many empirical and cumbersome measures like vacuum therapy, injection into the corpus cavernosum, and other cocktail of sex hormones, vitamins and stimulants were used. Viagra in this respect is likely to be more acceptable than those injections and mechanical devices.

Viagra was licensed in USA on 27 March 1998. In this country the prescription for the drug peaked to around 260,000 a week in April 1998.

The drug is being globalised very rapidly. Viagra has became a very common word, even beyond the manufacturer's expectation, due to overt media enthusiasm. In many instances it was not the manufacturer or the doctors who created this extraordinary popularity but the men who craved for its use or those who traded it.

The major concerns associated with its availability are: (i) its potentially serious adverse effects, especially on self-medication; (ii) its potential for misuse by the healthy population as an agent to "pep up" sex lives; and (iii) worries regarding the increase in health care cost and unwillingness of insurers to cover for its therapy for more than any other usual concerns like safety and efficacy. Because
of this, the regulatory authorities are taking

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additional measures like issuance of guidelines or stipulation of conditions qualifying its use (funding, prescription control, detailed label information in layman language, clinical monitoring, etc).

What should we do in Nepal?

There is no doubt that Viagra has become the fastest selling drug ever, at least in USA. Media hype, the drug's association with sex and the real need of people, all may have contributed to it. It can be availed through order on the Internet or on street more than any OTC drug, even though it is licensed everywhere as a prescription drug.

So far, it seems that we are away from the Viagra issue. But we may not be so distant away. Before we face it, how about putting a sound mechanism in place so that we do not fail to comply with a minimum prerequisite.

The existing registration process in Nepal requires for a new drug either to appear in one of the recognised pharmacopoeias or to be approved by the Drug Advisory Committee before it can be marketed in the country. The former criteria would not usually be applicable if the drug in question is required soon after its first appearance in the global market (because it usually takes a few years for a drug to appear in pharmacopoeias). A new drug, therefore, has a chance to become available in Nepali market only if the Drug Advisory Committee decides in favour of it. It is thus extremely important that such decisions are based on all the available evidences and relevant information.

The priorities of the East and the West have varied widely in the past in many fronts, including the pharmaceutical needs. The aging patterns and the needs of the population over 50 years of age are also different.

Many questions may arise. Do we have an expressed need for Viagra already or are we creating a market for it? Are there any estimates in Nepal of the population seeking therapy for established erectile dysfunction as a medical condition? How are we going to establish eligibility criteria for prescribing Viagra if at all there is need of this product in our population? How can we be sure that we are not introducing Viagra more for recreational motive than for therapeutic purposes? Could not there be a possibility of disharmony in otherwise stable conjugal lives if a careless approach is taken with regard to its availibility and prescribing?

Even if Viagra is made available for the benefit of a limited subset of population, are we in a position to create equity of access with public expenses? Are we in a position to spend about Rs.700 for an orgasm? If the drug is subject to prescription control, are we in a position to say clearly which level of prescribers are eligible to attend impotence cases and how and where the drug should be available? What will we do if its fate becomes like that of other pescription-only- medicines, including antibiotics? When we have a problem of compliance of regulatory measures against indiscriminate prescribing and sale-distribution of so many prescriptive drugs, how can we think that the situation will be different in Viagra case, unless additional or special restrictions on availability are imposed? In the light of free movement of goods across the border and subsequent black-marketing, it is doubtful that a product that is risky, has high

misuse potential, costly and a probable candidate for counterfeiting will be sold, distributed, prescribed and used rationally.

The other dimension that also needs equal attention, if not more, is the possibility of degradation of social norms and values following Viagra misuse as a recreational agent. What mechanisms do we have for surveillance of post-marketing aspects like socio-economic consequences and abuse as an aphrodisiac? How are we going to handle possible medical emergencies (such as priapism and angina induced by sexual act, which are known adverse effects of Viagra)?

All these questions and issues need to be attended carefully before we think of registering Viagra.

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PHARMACOLOGY OF SILDENAFIL ("VIAGRA")

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Erectile dysfunction can be defined as the inability of a man to achieve and maintain an erection to an extent he thinks is satisfactory for sexual intercourse. The causes can be organic (such as diabetes mellitus, cardiovascular diseases, neuro-logical dysfunction, androgen deficiency, penile abnormalities) or psychological (such as depression, anxieties about sexual performance, stress). The dysfunction may also have a mixed aetiology. Certain drugs, alcohol, or smoking can also cause or precipitate pre-existing problems.

Nitric oxide released from nerves supplying the local vessels in response to sexual stimulation increases the intracellular cyclic guanosine monophosphate (cGMP) level. The latter acts on vascular smooth muscle of arterioles in the corpora cavernosa of penis, causing vasodilatation. The vasodilatation leads to erection. Cyclic GMP-

specific isoenzyme phosphodiesterase type 5 (PDE5) terminates the action of cGMP by converting it to inactive non-cyclic GMP . The drug sildenafil selectively inhibits PDE5, which results in prolonged cGMP activity with consequent enhancement of erectile response to sexual stimulation. Sildenafil does not cause an erection without sexual stimulation.

The efficacy of sildenafil is well-documented. Analyses of studies conducted so far show that sildenafil is effective in organic, vascular, neurological, psychogenic, and diabetic erectile dysfunctions. There is little study on men without erectile dysfunction.

Safety of sildenafil was determined from more than 28 trials, involving over 2500 patients. The most common adverse effects were headache, flushing, dyspepsia, nasal congestion, flu-like syndrome and ocular side effects (green/blue tingling of vision, increased sensitivity to light, and blurred vision). The effects were generally mild, transient and dose-related. Nine patients died during the trials; one was on placebo and eight on sildenafil. The eight deaths on sildenafil were all of cardiovascular origin. Though the investigators attributed none of the deaths to sildenafil, this point needs attention. Additionally, the fact that 69 deaths (21 from unspecified or unknown cause, two from stroke, and 46 from other cardiovascular events) had been reported until November 1998 in the United States since its launch calls for much attention regarding its safety.

Hypotension is the most important adverse effect of sildenafil. Its administration to healthy subjects also receiving organic nitrates leads to severe acute hypotension. This can also occur in patients taking nitrates or amyl nitrites ("poppers") to enhance sexual performance.

Some cases of priapism have been reported with sildenafil. So caution should be taken in men with conditions predisposing to priapism (sickle cell anaemia, leukaemia, and multiple myeloma). Furthermore, as the drug is yet new, unperfected hideous adverse effects may manifest in the future.

Sildenafil is *contraindicated* in men with severe hepatic impairment, hypotension, cardiovascular problems, and degenerative retinal disorders. *Caution* should be taken in men with penile deformity, bleeding disorders or active peptic ulcers.

Sildenafil is orally active. Tablets containing 25 mg, 50 mg or 100 mg sildenafil are available. The drug has already been marketed in the USA, Europe (including the UK), and some other parts of the world.

Based on literature, the following initial *dosing recommendation* has been made: if the patient is otherwise healthy, starting dose should be 50 mg one hour before the intended sexual activity. Older patients and patients with hepatic or renal impairment should start with 25 mg.

About four doses per month may be appropriate. Not more than six doses per month is recommended. More than one dose should not be taken in one day.

Sildenafil should be prescribed only when there is an explicit need. Moreover, its use should not discourage a thorough investigation of the erection disorder. The drug is not an

alternative to identifying and managing any coexisting primary diseases.

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ESSENTIAL DRUGS IN NEPAL

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Concept of Essential Drugs

Health institutions need to manage the resources allocated for Pharmaceuticals in such a manner that more drugs be available in less cost. The drugs should also be available to the general public in affordable price. A large number of newly invented drugs as well as multi-ingredient proprietary products are available in the market in excessively high price. To make drugs within the reach of common people, WHO brought forward the concept of essential drugs. The first model list of essential drugs was published in 1977.[1] The list is updated every two years. Till now 141 countries have prepared their essential drug lists.[2] In Nepal the National List of Essential Drugs (EDL) was first published in 1986 and its first and second revisions were published in 1992 and 1997, respectively.[3]

WHO defines essential drugs as "those that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms". The choice of drugs depends upon many factors such as the pattern of prevalent diseases, treatment facilities, training and experience of available personnel, cost/benefit ratio, etc. Drugs with sound and adequate data on efficacy and safety as well as evidence of performance in general use in a variety of medical settings are selected. Where two or more drugs appear to be approximately similar in efficacy, the selection depends upon comparison of other aspects such as safety, quality, price and availability. Dosage forms and strength are also important to avoid unlimited preparations in the market. The drug should be available in a formulation that assures its quality, bio-availability and stability within its shelf-life. Most essential drugs should be formulated as single compound. Fixed-ratio combination products are acceptable only when the combination has a proven advantage over single compounds

administered separately in terms of therapeutic effect, safety or compliance.

Implementation of EDL Concept in Nepal

The first National List of Essential Drugs of Nepal (EDL), published in 1986, contained 245 drugs.[3] The list did not include formulations and dosage forms. Later editions of 1992 and 1997 included formulations and dosage forms as well. The second revision includes 262 drugs, of which 233 are main drugs and 29 complimentary drugs.[4] The drugs in the main list are those agents that satisfy the health care needs of the majority of population whereas the complimentary drugs are for treating rare disorders or when drugs in the main list cannot be made available or become ineffective or inappropriate for a given individual.[5]

Shorter lists have been worked out for various levels of health facilities. The EDL of 1997 includes 177 drugs for the district level, 88 for the health post level, 50 for the sub-health post level and 18 for the primary treatment level.[4]

The EDL serves as the guideline for procurement of drugs for health facilities of various levels. Some studies have been carried out to study the situation of implementation of essential drugs concept in Nepal. These studies show that the essential drugs are prescribed more in public health facilities than in private practice. Drugs prescribed from within the EDL in private practice in Kathmandu Municipality was found to be 32.4%[6], whereas this figure in health posts and sub-health posts of Terai districts was 85%.[7] Drugs from EDL in zonal hospitals was found to be 42%.[8] The list of drugs needed for basic health programme in 1988 contained 60 drugs out of which 48 were from EDL.[9] However, the drugs supplied to health posts and sub-health posts at present are entirely from EDL. Studies in Siraha and Dhading districts showed that about 80% of drugs prescribed at district hospital, health post and sub-health post were from EDL.[10]

These findings reveal a few interesting facts. The drug supply to public health facilities is from EDL and the prescriptions from such health facilities mainly contain drugs from the EDL. However, if the health facilities do not have their pharmacy or if drugs are not available at the health facilities, the tendency is to prescribe drugs not included in the EDL.

The selection of essential drugs is done considering many factors such as safety, efficacy, affordability, relevance to prevailing diseases, risk/benefit ratio, capability of health workers at different levels of health care, etc. In Nepal the Essential Drugs List has been reviewed and updated periodically. The Department of Drug Administration (DDA) takes the initiative for such revisions. Members of working groups comprising of medical experts and pharmacists are nominated to undertake the initial work on specific therapeutic categories. The draft prepared is reviewed by the Drug Advisory Committee, chaired by the Health Secretary. Then it is forwarded to the Drug Consultative Council chaired by the Minister of Health, prior to government approval.

Benefit of EDL Concept for health care system

At present the concept of EDL is implemented at lower levels of health facilities

and some health facilities operated by NGOs and INGOs. Since most of the hospitals do not have well-developed pharmacies and the prescriptions are sent to private pharmacies outside the hospitals, implementation of EDL concept is not so easy. However, the concept would benefit more people if it could be implemented at all health facilities.

There are many benefits of implementing EDL concept, some of which are as follows:

- Selection of drugs for prescribing from a relatively short list, so that rational prescribing becomes easier.
- Mostly single ingredient products, so therapeutic benefit is predictable and chances of drug interactions are less.
- Clear, unbiased drug information easily available.
- Affordable price.
- Easy inventory management due to limited number of formulations.
- Implementation of Standard Treatment Schedule possible.
- Quality assurance of the products easier.
- Less cost involved in drug procurement and inventory management.
- Easy to evaluate the drug requirement of health facilities.

Central, referral or specialised hospitals normally have Drugs and Therapeutics Committees to select the drugs. Some of them have developed their own hospital formularies. One example is that of TU Teaching Hospital.[11] Specialised tertiary care hospitals may need to have drug lists that are larger than the national list of essential drugs. However, even within such hospitals the highest priority should be given to essential drugs wherever possible. To facilitate the development of hospital formulary and to provide information on commonly used drugs, the Department of Drug Administration has published Nepalese National Formulary[12], which is available free of cost on request to health institutions and medical practitioners registered with NMC.

Implementation of essential drugs concept is essential for providing medicines to the needy at reasonable and affordable price. All the key players should join hands for the promotion of this concept.

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NATIONAL LIST OF ESSENTIAL DRUGS, NEPAL

Acetazolamide
Acetic Acid
Acetylsalicylic acid
Acriflavine
Actinomycin
Albendazole
Albumin, human
Allopurinol
Alprazolam
Aluminium diacetate
Aluminium hydroxide
Amidotrizoate
Aminophylline
Amitriptyline
Amoxycillin
Amphotericin
Anti-D immunoglobulin (human)
Antirabies hyperimmune serum
Ascorbic acid
Antihaemorrhoidal drugs
Atenolol
Atropine
Azathioprine
Barium Sulfate
BCG vaccine (dried)
Beclomethasone
Benzathine benzylpenicillin
Benzoic acid + Salicylic acid
Benzyl benzoate
Benzylpenicillin
Betamethasone
Bismuth Iodoform Paraffin
Bleomycin
Bupivacaine
Busulphan
Calamine lotion
Calcium chloride
Calcium gluconate
Calcium folinate
Carbamazepine
Carbidopa (see Levodopa with)
Carbimazole
Cefotaxime
Cetrimide
Charcoal, activated
Chlorambucil
Chloramphenicol
Chlordiazepoxide
Chlorhexidine
Chloroquine
Chlorpheniramine
Chlorpromazine
Ciprofloxacin
Cisplatin
Clofazimine
Clomifene
Clove oil
Cloxacillin
Coal tar
Colchicine
Compound solution of Sodium lactate
Compressed Air
Cortisone
Cotrimoxazole (see sulfamethoxazole with)
Cresol soap solution
Cromoglicic acid
Cyclophosphamide
D-tubocurarine
Dapsone
Desmopressin
Dexamethasone
Dextran 40
Dextran 70
Diazepam
Diclofenac Sodium
Diethylcarbamazine
Digoxin
Diloxanide
Diphtheria antitoxin
Diphtheria- tetanus Vaccine
Diphtheria-pertussis-tetanus vaccine
Disopyramide
Disulfiram
Dopamine
Doxorubicin
Doxycycline
Enalapril

Ephedrine
Epinephrine
Ergocalciferol
Ergometrine
Ergotamine
Erythromycin
Ethambutol
Ether, anaesthetic
Ethinylestradiol
(see norethisterone with)
Ethyl alcohol
Ferrous salt + Folic acid
Ferrous salt
Fludrocortisone
Fluorescein
Fluorouracil
Fluphenazine
Folic acid
Formaldehyde
Frusemide
Gama benzene hexachloride (see Lindane)
Gentamicin
Gentian violet (see Methylrosanium chloride)
Glibenclamide
Glucose (see oral rehydration salt)
Glucose injectable
Glucose with Sodium chloride
Glycerine, see Sodium bicarbonate with
Glyceryl trinitrate
Griseofulvin
Halothane
Heparin sodium
Hepatitis B vaccine
Homatropine
Hydralazine
Hydrochlorothiazide
Hydrocortisone
Hydroxycobalamin
Hyoscine butylbromide
Ibuprofen
Ichthammol (10%) + Glycerine 5%
Insulin - injection (soluble)
Insulin intermediate acting
Insulin protamine zinc (long acting)
Intraperitoneal dialysis solution
Iodine
Iopanoic acid
Iron Dextran
Isoflurane
Isoniazid *(see Thicatezole with)*
Isoprenaline
Isosorbide dinitrate
Isoxsuprine
Japanese Encephalitis Vaccine
Ketamine
Ketoconazole
Lactulose
Leucovorin (see Calcium folinate)
Levodopa + Carbidopa
Levothyroxine
Lignocaine
Lindane
Liquid paraffin
Lithium carbonate
Lomustine
Lugol's iodine
Magnesium sulfate
Magnesium trisilicate
Mannitol
Measles vaccine (live attenuated)
Mebendazole
Medroxyprogesterone acetate
Mefloquine
Melphalan
Meningococcal vaccine
Mercaptopurine
Mercurochrome
Metformin
Methotrexate
Methylated spirit
Methyldopa
Methylrosanilinium chloride (gentian violet)
Metoclopramide
Metrizamide
Metronidazole
Miconazole
Mitomycin
Morphine
Naloxone
neostigmine
Niclosamide
Nicotinamide
Nifedipine
Nitrofurantoin
Nitrofurazone
Nitrous oxide
Norethisterone *(see Ethinylestradiol with)*
Nystatin
Omeprazole
Oral rehydration salts
Oxygen
Oxymetazoline
Oxytocin
Pancuronium bromide
Paracetamol
Paraldehyde
Penicillamine
Pentamidine
Pentazocine
Pethidine
Pheniramine
Phenobarbital
Phenol

Phenytoin
Phytomenadione
Pilocarpine
Piperazine
Poliomyelitis vaccine (Live attenuated)
Polygeline
Polyvenum antisnake serum
Potassium chloride
Potassium Permagnate
Povidone Iodine
Pralidoxime
Prednisolone
Primaquine
Procainamide
Procaine benzylpenicillin
Procarbazine
Promethazine
Protamine Sulfate
Protamine zinc insulin (see Insulin)
Pyrazinamide
Pyridoxine
Pyrimethamine (see Sulfadoxine with)
Quinidine
Quinine
Rabies vaccine
Ranitidine
Retinol
Riboflavin
Rifampicin
Salbutamol
Salicylic acid *(see Benzoic acid with)*
Selenium Sulfide
Senna
Silver nitrate
Silver sulfadiazine
Sodium Bicarbonate (1%) + Glycerine (5%)
Sodium bicarbonate
Sodium chloride
Sodium Chromoglycate
Sodium iodide
Sodium lactate (see Compound solution)
Sodium Nitroprusside
Sodium stibogluconate
Spironolactone
Stilboestrol
Streptomycin
Sulfacetamide
Sulfadoxine + Pyrimethamine
Sulfamethoxazole + Trimethoprim
Sulphasalzine
Suxamethonium chloride
Tamoxifen
Testosterone
Tetanus antitoxin
Tetanus immunoglobulin (human)
Tetanus toxoid
Tetracaine
Tetracycline
Thiacetazone + Isoniazid
Thiamine
Thiopental
Thioridazine
Timolol
Triamterene
Trihexyphenidyl
Trimethoprim (see Sulfamethoxazole with)
Trisodium citrate dihydrate (see Oral rehydration salt)
Tuberculin, purified protein derivative (PPD)
Valproic Acid
Verapamil
Vincristine
Warfarin
Water for injection
Yellow fever vaccine
Zinc oxide
Zinc sulphate

SOURCE

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