BDNF

BANGLADESH NATIONAL FORMULARY 2015

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Published by
Directorate General of Drug Administration
In Association with
Bangladesh Medical Association
Bangladesh Pharmaceutical Society

Bangladesh National Formulary
(BDNF)
2015

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Bangladesh Medical Association
Bangladesh Pharmaceutical Society

BDNF 2015

An official publication about drugs and related items officially used in Bangladesh for rapid reference and includes all the available information for prescribing and dispensing.

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CONTENTS

Preface		i-iii
Committees		iv-v
Contributors		vi-vii
User's Guide		viii
Guidance on Prescribing		ix-xv

Notes on drugs and preparations

1.	Infections	1-99
2.	Gastro-Intestinal System	100-132
3.	Cardiovascular System	133-202
4.	Respiratory System	203-227
5.	Endocrine System	228-266
6.	Obstetrics, Gynaecology and Genito Urinary-Tract Disorders	267-293
7.	Central Nervous System	294-341
8.	Anaesthesia	342-363
9.	Musculoskeletal and Joint Diseases	364-391
10.	Eye	392-421
11.	Ear, Nose and Throat	422-436
12.	Skin	437-477
13.	Immunological Products and Vaccines	478-502
14.	Malignant Diseases and Immunosuppression	503-538
15.	Anaemias and Other Blood Disorders	539-553
16.	Nutrition	554-576
17.	Contrast Media	577-583

Appendices And Indices

Appendix-1	Treatment Guidelines	584-608
Appendix-1a	Treatment Guidelines for Acute Watery Diarrhoea	584
Appendix-1b	Treatment Guidelines for Tuberculosis	589
Appendix-1c	Treatment Guidelines for Leprosy	592
Appendix-1d	Treatment Guidelines for Dengue Infection	594
Appendix-1e	Treatment Guidelines for Acute Respiratory Tract Infection	598
Appendix-1f	Treatment Guidelines for Drug Addicts	598
Appendix-1g	Treatment Guidelines for Burn Injury	602
Appendix-1h	Treatment Guidelines for Malaria	605

Appendix-1i	Treatment Guideline for Kala-azar	606
Appendix-2	Drug Interactions	609-677
Appendix-3	Liver Diseases	678-684
Appendix-4	Renal Impairment	685-693
Appendix-5	Pregnancy	694-733
Appendix-6	Breast-Feeding	734-739
Appendix-7	Poisoning	740-748
Appendix-8	Immunization Schedule	749-756
Appendix-9	Essential Drug List	757-763
Appendix-10	List of Controlled Drugs	764
Appendix-11	Adverse Drug Reactions Monitoring (ADRM) and Pharmacovigillance	765-774
Appendix-12	Clinical Pathology and Other Biomedical Table	775-788
Appendix-13	Pharmaceutical Abbreviations	789-792
Appendix-14	Medicinal Gases	793-798
Appendix-15	Nuclear Medicine and Radiopharmaceuticals	799-807
Appendix-16	Parenteral Doses (for Adults and Children) of Drugs for Medical Emergencies	808-811
Dental Practitioners' Formulary		812-839
Index of Pharmaceutical Manufacturers in Bangladesh		840-847
Abbreviations & Symbols Used in the Formulary		848-849
General Index		850-920
Reporting Form of Suspected Adverse Drug Reactions		

Preface

The Bangladesh National Formulary (BDNF)-2015 (Fourth Edition) is a comprehensive list of the drugs available in the local market that support the health care providers to offer the most effective drug therapy with limited resources. It helps us to offer the safest, most effective and least costly health care ensuring the rational use of medications.

Directorate General of Drug Administration as National Regulatory Authority (NRA) has been striving to upgrade the status of pharmaceutical sector. This new, advanced and revised edition of BDNF is intended to provide sound and updated information about the use of drugs with their properties such as presentation, dosage and administration, side effects, cautions, indications, contraindications, proprietary preparations etc. to physicians, pharmacists and other healthcare professionals. We are responsibly aware-up that such a comprehensive information is very important and inevitable for public health care and that helps physician to know the efficacy, price, risks and other information about a drug before prescribing. This advanced edition also included a list of new and high tech products like hormones, vaccines; anticancer drugs etc. with their properties and of course a general index.

Now-a-days our pharmaceutical industries are increasing their market place with high quality products not only in Bangladesh but also in the outer world very rapidly and progressively. At present a total of 275 allopathic medicine manufacturing companies have been producing and marketing around 13026 types of Generic Products and 24,404 kinds of Brands which worth more than 12000 Crore taka per year in the country. Presently there are many pharmaceuticals companies of Bangladesh are capable of manufacturing drugs according to the stringent quality requirements of the advanced countries like the USA, EU, Australia, Canada etc.

Pharmacy sector in Bangladesh is undergoing a change according to the escalating cost, advances in technology, fierce competition and vast generic opportunity and gradually becoming an important contributor to the health of global population. . We acknowledge the outstanding contribution of all the members of Editorial Board to prepare the fourth edition with regards to addressing new problems and modification of some chapters.

Due to some unavoidable circumstances we were not able to review and upgrade the publication timely but finally we have succeeded to bring out this latest edition which is upgraded and more informative than ever before.

PREFACE

I express my sincere thanks and appreciations to Bangladesh Medical Association (BMA) & Bangladesh Pharmaceutical Society (BPS) for their participating approach and full involvement in publishing the fourth edition. We are indeed grateful to the Honorable Minister, The Honorable State Minister, the Honorable Secretary, Ministry of health & Family Welfare, Government of the People's Republic of Bangladesh, for their patronage which has added a new dimension to our endeavor to publish this edition.

With sincere thanks and deep appreciation we would like to record here that the United States Agency for International Development (USAID)'s Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, implemented by Management Sciences for Health (MSH) has funded the printing of the fourth edition of BDNF.

We are also grateful to the conveners and members of various committees, contributing authors for their contribution, active support and help, without which this document of national importance would not be possible to publish.

Despite our sincere efforts if there are any unintentional mistakes and lapses might have remained we shall try to rectify them in future editions of publication. Our valuable users are welcomed with their constructive criticism, useful information and suggestions for improving the quality and contents of this document. In future we will try to publish this document on regular basis.

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User's Guide

While compiling the Bangladesh National Formulary (BDNF), the Editorial Board has tried to follow the style in which the British National Formulary (BNF) has been arranged. This is because of the fact that the target users of the BDNF, i.e., the physicians, pharmacists, dentists and other interested groups of Bangladesh, are already used to making use of the BNF.

All the drugs (both locally manufactured and imported), which are registered with the Directorate of Drug Administration up to 30th May,2014 and are in current use in Bangladesh, are included in the BDNF. Each of them is described individually. They are first grouped into Chapters according to their pharmacological or physiological or other medical category. This edition of the BDNF has such 17 Chapters. Each Chapter is again sub-divided into Sections using numerical proceeds according to more distinct co-relations between the items included in each Section. Each of these Sections begins with a brief description of the subject matter, i.e., the drug or its group, which is expected to be useful for the target users. Description of the drug is followed by brief notes on its indications, side-effects, cautions, contra-indications, warnings, drug interactions, doses, names of the proprietary preparations containing the said drug, names of the manufacturers, the available dosage forms of the drug and their strengths.

The opening Chapter of the BDNF includes a Guideline on Prescriptions, which highlights various aspects of prescription writing, prescribing for children and the elderly and prescribing in terminal illness. It also includes notes on the concept of essential drugs and control of narcotics.

This issue of the BDNF also includes Chapters on Abbreviations used in the Formulary, Dental Practitioners Formulary, Index of Manufacturers, Adverse Drug Reactions Monitoring, a General Index and 16 Appendices.

For readers convenience the body of the text and index is composed in double columns with no colours in the main captions, but the sub-heads and sub-sub-heads in the body are printed in colours. Rulers are used above all sub-heads, thickness of which are varied using black colour depending on the importance of the heads. Separate superscript symbols are used to denote essential drugs (ED), controlled drugs (CD), and imported drugs (I). Names of the microorganisms are printed in Italics. Names of the generic drugs are printed in bold letters. Proprietary names are kept in bold regular but the Company names are in Italics.

Indications, Cautions, Contra-indications, Side-effects, Interactions and Doses are printed in regular and bold types. Generic items are printed in capital and bold letter.

It should be noted here that the price of the individual drug, which is sold and used in Bangladesh is also mentioned in this issue.

Guidance on Prescribing

GENERAL GUIDANCE

Appropriate prescribing implies the choice of medicines based on efficacy, safety, suitability and cost relative to other drugs or treatments that may be available. Medicines should be prescribed only when they are necessary. Taking time to explain to patient (and relatives) the treatment options, as well as the rationale and potential risks ofchosen treatment regimen encourages the patient to take the medicines as prescribed. Successful therapy comprises much more than choosing an appropriate drug; it requires knowledge, judgment, skill, wisdom, responsibility, and above all, patient and doctor compliance.

COMPLIANCE

Patient compliance means adherence to a prescribedtreatment schedule. Patient non-compliance is a major factor in therapeutic failure.

Reasons for patient non-compliance include: (a) poor patient-doctor relationship with resultant failure to follow the instructions; (b) lack of adequate information about the medications; (c) frequency and complexity of drug regimen; (d) forgetfulness; and (e) fear or anxiety about drug reactions.

Discussing the rationale and possible adverse effects of treatment to the patient or relatives improves compliance. Simplifying the regimen may also help. The patient should know the nature of the disease and reasons for drug therapy including expected benefits; how and when to take the medicine(s) with special instructions, if any; how long a drug needs to be taken; what to do if a dose is missed; how to recognize possible adverse effects; and when to report back to the doctor.

Doctor compliance is no less important and relates to his/her professional obligations and responsibilities. A doctor should have full knowledge about the drugs he/she prescribes, and be very careful and accurate in prescribing and telling the patients what they need to know.

DRUG INFORMATION: ROLE OFBDNF

Most physicians recognize that they need unbiased drug information to choose from the various medicines available in the market, which are often seductively promoted to them by pharmaceutical companies.
Bangladesh National Formulary (BDNF) aims to provide prescribers,pharmacists, and other healthcare professionals with up-to- date information about use of medicines.
It provides key information necessary for the selection, prescribing, dispensing and administration of medicines, registered and approved by the Directorate General of Drug Administration, Bangladesh.
Information on medicines provided in BDNF has been drawn from manufacturers product literature,verifiedby professional experts with standard medical and pharmaceutical literature like BNF, BP, USP, Martindale, and national guidelines. Generic and International Non-proprietary Names (INN) where applicable have been provided. Proprietary or brand names are as registered by the Drug Administration. The doses mentioned areintended for general guidance only. The BDNF advocates

caution that 'prescription-only drugs' and 'controlled drugs' need to be prescribed only by a qualified and registered physician or dental surgeon.

ESSENTIAL DRUG CONCEPT: IMPORTANCE IN PRESCRIBING

The essential drugs (EDs) concept was first promoted in 1977 by World Health Organization (WHO);encouraged each of the member countriesthe need to compile and regularly update a list of a minimal number of appropriate (effective, safe, suitable and least costly) drugs that will satisfy the healthcare needs of its majority population. The Govt. should then ensure that the listed essential drugsbe available at all times, in adequate amounts, in appropriate dosage forms and in affordable prices; and doctors be encouraged to prescribe from the list of essential drugs. In 1977 WHO compiled its first model list of essential drugs, updated regularlysince then, the most recent list contains about 300 items.

The National Drug Policy (NDP) of 1982 was thefirst determined effort to implement WHO concept of essential drugs in Bangladesh. The NDP selected 150 essential drugs of which 45 were identified as Primary Health Care Essential Drugs (PHC-ED); a supplementary list of another 100 essential drugs was selected for tertiary and specialized care (*see Appendix-9*). Essential drugs have been marked by symbol $^{(ED)}$ in BDNF.The essential drug list following NDP of 1982 have been revised and updated in 2008 which contain 209 items.

Prescribing fromthe list of essential drugs is considered to be relatively effective and safe and of acceptable quality and most cost-effective. .

PRESCRIPTION WRITING

Prescription shouldbe legible and dated containing the name, age and address of the patient, and should be signed in ink by the prescriber.
The age of the patient should always be mentioned in cases of 'prescription-only drugs' for children under 12 years.
A prescription ordering 'controlled drugs' must in addition specify the prescriber's address, the formulation and strength of the preparation, and the total quality of the preparation to be supplied (or the number of dose units) in both words and figures. A prescription ordering a 'controlled drug' should clearly mention that it can be dispensed only once and it's refilling is not permitted.

DRUG NAMES IN PRESCRIPTION

Names of drugs or medicinal products should be written clearly and not abbreviated. Drugs prescribed may be either in non-proprietary (generic) or in proprietary (brand) names.

There are growing awareness for using generic names in prescribing for obvious advantages—uniformity, convenience, economy, and better comprehension. Prescribing in non-proprietary (generic) names is also less taxing on the memory of the prescriber.

However, whenit is considered important to ensure consistency of a product in respect of its quality or bioavailability, and when it is thought that the control over the quality relative to other manufactured products may not be as rigorous as one would expect, a doctor may opt to prescribe by proprietary names.

In the prescription, unit dose strength should be clearly stated

- Avoid unnecessary use of decimal point; e.g. 5 mg and not 5.0 mg.
- Quantities in grams should be written as 1 g or 1.2 g etc.
- Quantities less than 1 gram should always be written in milligrams; e.g. 500 mg and not 0.5 g.
- Quantities less than 1 mg should be written in micrograms; e.g. 100 micrograms and not as 0.1 mg
- Micrograms or nanograms should not generally be abbreviated, because it may create confusion with milligrams.
- ml (for milliliter) should only be written and not cc (for cubic centimeter).
- When decimals are unavoidable for quantities less than one, a zero should be written before the decimal; e.g. 0.5 g and not .5 g.

The quantity to be supplied may be specified in numbers or volume; it may also be stated by indicating the number of days of treatment required.
The directions for use should preferably be in a language that is understood by the patient and should be without any abbreviations.

PRESCRIBING FOR THE ELDERLY

Prescribing for elderly patients especially very old requires special consideration.They are usually more vulnerable to adverse effects.Factors responsible include multiple therapy (poly pharmacy) and alteration of pharmacokinetic or dynamic parameters.
Elderly patients often receive multiple drugs for their multiple diseases or symptoms, which greatly increasethe risk of adverse effects and/or drug interactions. Elderly patients' medicines should be reviewed regularly and those that are not of benefit should be stopped. Prophylactic medicines are inappropriate if they complicate treatment or produce side-effects Non-pharmacological means are more appropriate for symptoms like headache, sleeplessness, light-headedness particularly when associated with social stress.
In the very old, manifestations of normal ageing may be mistaken for diseases, leading to inappropriate prescribing. Age related muscle weakness, difficulty in maintaining balance etc. are often confused with neurological diseases. Nervous system of the elderly patients is more sensitive to many commonly used drugs like opioids, benzodiazepines, anti-psychotics, anti-Parkinsondrugs which when used need caution and regular monitoring.
Pharmacokinetic changes in the elderly can greatly reduce renal clearance and markedly increase tissue concentration, resulting in slow excretion of drugs particularly of nephrotoxic drugs. Acute illness can lead to rapid reduction in renal clearance especially if accompanied by dehydration. Bleeding associated with aspirin and other NSAIDs are more likely to have serious outcomes in elderly patients with renal impairment or cardiac diseases.
Hepatic metabolism of lipid soluble drugs particularly with narrow therapeutic window is reduced in elderly patients because of reduction in liver volume.
Very old patients may have difficulty in swallowing tablets or capsules and in case of drugs like NSAIDs if left in the mouth may lead to ulceration Elderly patients should therefore be advised to take tablets/capsules with enough fluid, and in upright position. Liquid formulation if available may be preferable
Simple treatment regimen is always better for the elderly patients. Once or twice daily preparation is preferable. Full instructions must be written on the prescription. It is also

important to check the patient's compliance by counting the remaining tablets or capsules. Stopping a drug at the right time is as important as starting it.

PRESCRIBING FOR CHILDREN

Responses to drugs in neonates(first 1m),infants(up to1yr)and children(upto12yrs) are not the same as in adults. The risk of adverse effects are more due to relative deficiency of drug metabolizing enzymes, differing sensitivity of target organs, inefficient renal filtration, and inadequate detoxifying systems. Special care should be taken while prescribing for children and neonates.
Liquid preparations are particularly suitable for infants. Sugar-free liquid preparations are preferable for long term treatment to avoid risk of dental caries. Many children are able to swallow tablets or capsules and may prefer a solid dosage form. Whenever possible, painful intramuscular injections should be avoided. Strength of the tablet or capsule should be clearly mentioned in the prescription.
Inclusion of age of the child or infant in the prescription is a legal requirement while ordering 'prescription-only drugs' for them; in fact it is advisable to mention the age while prescribing any drug for children or infants

PRESCRIIBING IN PALLIATIVE CARE

Palliative care is the 'total care' needed for a terminally ill patient whose disease is not responsive to any curative treatment. Aim of the 'total care' is to provide the best quality of life for the patient and family. Control of pain and other symptoms, management of complications, maintenance of nutrition, and psychological support of the patient and familyare the main stay of the palliative care
For a total care plan, it is important to make careful assessment of symptoms and the needs of the patient preferably by multidisciplinary team. Many patients wish to remain and managed at home with their families, butshould be admitted in specialized palliative care hospital if the family cannot cope.
While prescribing drugs, the number should be as few as possible. Oral administration is the route of choice unless the symptoms are severe enough, in which case drugs may be administered parentally.

Control of Common symptoms:

Pain: Non-opioids(paracetamol,NSAIDs)opioids(codeine,morphine)analgesics; and adjuvant(antidepressants, antiepileptics) are used alone or in combination according to type of pain and response.In mild cases, **paracetamol** may be enough. Moderate pain may be treated by aspirin or other NSAIDs. In some cases, **codeine** may be added for better relief. NSAIDs' induced gastric upset may be relieved by PPIs(ranitidine150 mg twice daily). If these measures fail, **morphine** (orally or parentally) is the most useful analgesic. The dose should be adjusted carefully with assessment of the pain.Laxatives should be prescribed to prevent morphine-induced constipation. Bowel colic may be relieved by **loperamide** or **hyoscinehydrobromide.**Pain due to muscle spasm usually responds to**Diazepam.** Pain due to nerve compression may be reduced by **dexamethasone**.Patients with neuropathic pain may benefit from a trial of a tricyclic antidepressant. An antiepileptic (gabapentine or pregabaline) may be added or substituted if pain persists.

Nausea and vomiting: may be due to disease itself, its treatment or concurrent medical or surgical conditions. The cause should be identified before prescribing any anti-emetic. **Metoclopramide,**anti-emetic with pro-kinetic action is the drug of choice. Anti-emetic therapy should be reviewed every 24hrs and if necessary, a substitute anti-emetic (haloperidol, cyclizine,levomepromazine) may be prescribed.

Hiccup: An antacid with an anti-flatulent may be prescribed. If this does not work well**, metoclopramide**orally or i.m can be added.Alternately chl**orpromazine** may be tried.

Dyspnea: Breathlessness at rest may be relieved by carefully titrated doses of **morphine**, starting at 5mg every 4 hours. **Diazepam** 5-10 mg daily may be helpful. If there is bronchospasm or partial obstruction, **dexamethasone** 4-8 mg daily may be tried.

Anorexia: Anorexia may be due to a tumor or its complication, treatment by radiotherapy or chemotherapy, oral ulceration, depression or anxiety. The approach to treatment is by removing the cause if possible, alteration of diet and the use of appetite stimulants. **Prednisolone** 10-30 mg daily or **dexamethasone** 2-4 mg daily may improve appetite.

Dysphagia: Dysphagia may be due to a tumor itself, treatment, neurological damage or concurrent illness or a combination of these factors. If patient cannot swallow a solid diet, a liquid diet is advised. If liquid diet also cannot be taken, endo-esophageal tube may be needed. **Dexamethasone** 8 mg daily may help. Dry mouth associated with candidiasis can be treated with oral preparation of **Nystatin** or **miconazole.**.

Convulsions: Convulsions are common in patients with cerebral tumor or uraemia. **Phenytoin** or **carbamazepine** may be prescribed as prophylaxis. If oral medication is not possible**, Diazepam**given as suppository (10-20 mg every 4-8 hours) or Phenobarbitone injection (50-200 mg twice daily) is continued as prophylaxis.

PRESCRIBING CONTROLLED DRUGS

Narcotic and psychotropic drugs, which are under dual control of Directorate of Drug Administration and Department of Narcotics Control (under The Narcotics Control Act, 1990;Act no. XX of 1990) and are permissible for use as medicinal products in Bangladesh, are included as monographs in the BDNF. Such drugs are distinguished throughout in the BDNF by the symbol [CD], meaning “Controlled Drugs”. A list of controlled drugs is shown in *Appendix-10*.

Prescription requirements in respect of controlled drugs are as follows:

1. A registered medical practitioner or a dentist as per clause (m) and (e) of section 2 of the Bangladesh Medical and Dental Council Act, 1980 (XVI of 1980) only shall prescribe any of the controlled drugs.
2. Prescription for controlled drugs must be written, signed and dated in prescriber’s own handwriting; and specifies prescriber’s full address.
3. The prescription must state patient’s name and address, the total quantity prescribed and the number of dose units in both words and figures.
4. It should be stated that the prescription is not refillable, and shall not be dispensed more than once.

5. If a patient under care of a physicianbecomes an addict requiring treatment, shall be referred to a narcotics addiction treatment/rehabilitation centre, and as per section 17(2) of the Narcotics Control Act, 1990 shall inform the Director General, Department of Narcotics Control,President's Secretariat, 1 SegunBagicha,, GPO Box No. 3169,Dhaka-1000.

STORAGE AND DISPENSING OF CONTROLLED DRUGS

1. Controlled Drugs, especially A-Class and B-Class narcotics and psychotropic drugs (*see Appendix-10*), should be stored in pharmacies and in hospitals or health centers or clinics in a secured place under lock and key.
2. The name and address of the seller/dispenser and the date on which the prescription is dispensed must be recorded on the prescription by the pharmacist/dispenser.
3. The prescription for a controlled drug shall not be dispensed more than once (*see Section 13(3) of Narcotics Control Act, 1990*).
4. It is recommended that pharmacies maintain a separate register for dispensing of all A-Class and B-Class narcotics and psychotropic drugs (*see Appendix-10*), wherein the name and address of both the prescriber and the patient, and name and quantity of the drug dispensed along with the date of dispensing are recorded.
5. A pharmacist is not allowed to dispense a controlled drug unless all the required information is given on the prescription.

ADVERSE REACTIONS TO DRUGS

Any drug may produce unwanted or unexpected adverse reactions. Rapid detection, management and reporting of adverse drug reaction is of utmost importance. Some reactions like nausea, vomiting, headache, allergic rashes, convulsionsetc may appear soon enough after the administration of a drug. Some other reactions like malignancy, agranulocytosis, retinopathy, retroperitoneal fibrosis, etc. may appear months or years after the exposure. Any suspicion of such an association should be carefully investigated and reported.
When an infant is born with some congenital abnormality or there is an abortion of a malformed fetus, doctors should consider whether this might be an adverse reaction to a drug taken by the mother during pregnancy. Doctors should be particularly careful and alert about adverse reactions to drugs in the elderly and in infants.

To prevent adverse drug reactions—

1. Do not prescribe a drug unless there is a good indication. If the patient is an infant or an elderly or a pregnant woman, do not use a drug unless the need for it is imperative.
2. Specially be careful in prescribing drugs for a person with previous history of allergy or any adverse drug reactions.
3. Find out whether the patient is already taking some other medicines and avoid possible drug interactions (*see Appendix-2*) while prescribing.
4. Age and hepatic or renal disease may alter metabolism and excretion of drugs, so that much smaller doses may be needed to avoid adverse side effects.

5. Prescribe as few drugs as possible. Simplify the drug regimen and provide clear instructions so that the patient (especially the elderly) has no difficulty in understanding.
6. Whenever possible, use a familiar or established drug which is already included in an official pharmacopoeia. Be especially careful in prescribing 'new drugs'.
7. If serious adverse reactions are known to be associated with a drug, warn the patient while prescribing it.

Reporting Adverse Drug Reactions:

Doctors working in public hospitals or health complexes or in private hospitals/clinics or engaged in private practice have a special responsibility of reporting suspected adverse reactions to any therapeutic agents including blood products,vaccines,contrast medias, herbal products; and all cases of adverse reactions that were fatal, life-threatening, disabling or which needed hospitalization.

Detection management and reporting of adverse drug reactions, especially those in respect of 'new drugs', is of vital importance.

There is an Adverse Drug Reactions Monitoring (ADRM) cell in the office of the Directorate General of Drug Administration, which works in collaboration with WHO. Details about the ADRM cell and a Blue Card for reporting adverse drug reactions to this cell are included at the end of the BDNF.