

ESSENTIAL MEDICINES and COUNTERFEIT MEDICINES

Facilitator:

Dr. NAVPREET

Assistant Prof., Deptt. of Community Medicine

GMCH Chandigarh

Specific Learning Objectives

- At the end of session, the learner shall be able to know about:
 - Essential Medicines
 - Model List of Essential Medicines
 - Counterfeit Medicines.

ESSENTIAL MEDICINES

- Satisfy the priority health care needs of the population.
- Essential medicines are intended to be available within the context of functioning health systems at all times
 - adequate amounts,
 - appropriate dosage forms,
 - assured quality, and
 - at a price the individual and the community can afford.

Criteria for Selection of Essential Medicines

- Essential medicines are selected with due regard to
 - disease prevalence,
 - evidence on efficacy and safety, and
 - comparative cost-effectiveness
- As costs of medicines change over time, the price of a medicine is not a reason to exclude it from the WHO Model List if it meets the other stated selection criteria.
- Cost-effectiveness comparisons are made between alternative medicines within the same therapeutic group.

Millennium Development Goal: 8

- The availability of medicines in developing countries is undermined by several factors:
 - poor medicine supply and distribution systems; insufficient health facilities and staff; and low investment in health and the high cost of medicines.
- The Essential Medicines List can help countries rationalize the purchasing and distribution of medicines, thereby reducing costs to the health system.

Essential Medicines Lists

- The Model List is a guide for the development of national and institutional essential medicine lists.
- It was not designed as a global standard.
- However, for the past 30 years the Model List has led to a global acceptance of the concept of essential medicines as a powerful means to promote health equity.

- Applications for inclusion, changes or deletions to the Model List are submitted to the secretary of the Expert Committee for the Selection and Use of Essential Medicines.
- The Expert Committee:
 - responsible for reviewing the evidence provided in an application and deciding whether to include or delete a medicine.
 - identifies knowledge gaps and makes recommendations for future research that may be needed about medicines for the treatment of priority health problems.

- A medicine will be considered for deletion from the WHO Model List if:
 - its public health relevance has been questioned and/or
 - there are concerns
 - about its safety and efficacy and
 - comparative cost-effectiveness compared to other medicines for the same condition.

The evolution of medicine and the WHO Model list of essential medicines

- In 1897, aspirin was introduced as the first synthetic pharmaceutical.
- In the 100 years since, the world has seen the introduction of the first modern antibiotic (1941), the first commercially formulated antimalarial (1943), and the first antitubercular (1944).
- The 1950s saw the first clinical use of oral contraceptives, of drugs for diabetes and of drugs for mental illness. The development of drugs for other infectious diseases, for cardiovascular diseases and for a wide range of other conditions quickly followed.

Current list

- When WHO published the first Model List of Essential Drugs in 1977, it identified 208 individual medicines which together could provide safe, effective treatment for the majority of communicable and non-communicable diseases.
- The 18th is the current Model List of Essential Medicines, prepared by the WHO Expert Committee in April 2013.

How is the Model List used?

- The WHO Model List of Essential Medicines is an evidence-based resource that can be used by countries as a guide to develop their own national essential medicines list.
- Since the first WHO Model List of Essential Medicines was developed in 1977, many countries have developed their own national list.

- National lists of essential medicines can be used as the basis for:
 - procurement and supply of medicines in the public and private sector,
 - schemes that reimburse medicine costs, medicine donations and
 - to guide local medicine production.
- National lists of essential medicines usually relate closely to national guidelines for clinical health care practice which are used for the training and supervision of health workers.

- Essential medicines are one of the most cost-effective elements in modern health care and their potential health impact is remarkable.
- Million will be due to acute respiratory infections, diarrhoeal diseases, tuberculosis, and malaria -- all conditions for which safe, inexpensive, essential drugs can be life-saving.
- Simple iron-folate preparations can reduce maternal and child mortality from anaemia of pregnancy;
- Treatment of sexually transmitted diseases reduces transmission of the AIDS virus; and
- Treatment of hypertension reduces heart attacks and strokes.

A global concept

- The concept of essential medicines is forward-looking.
- It incorporates:
 - the need to regularly update medicines selections to reflect new therapeutic options and changing therapeutic needs;
 - the need to ensure drug quality; and
 - the need for continued development of better medicines, medicines for emerging diseases, and medicines to meet changing resistance patterns.

Access, quality and rational Use of Medicines and Essential medicines

- The economic impact of pharmaceuticals is substantial -- especially in developing countries.
- Spending on pharmaceuticals represents:
 - Less than one-fifth of total public and private health spending in most developed countries
 - 15 to 30% of health spending in transitional economies and 25 to 66% in developing countries.

- In most low income countries pharmaceuticals are the largest public expenditure on health after personnel costs and the largest household health expenditure.
- And the expense of serious family illness, including drugs, is a major cause of household impoverishment.
- Despite the potential health impact of essential drugs and despite substantial spending on drugs, lack of access to essential drugs, irrational use of drugs, and poor drug quality remain serious global public health problems

- Lists of Essential Medicines guide:
 - the procurement and supply of medicines in the public sector,
 - schemes that reimburse medicine costs, medicine donations, and
 - local medicine production.

Key Facts about Essential medicines

- Satisfy the priority health care needs of a population.
- Selected with regard to disease prevalence, safety, efficacy, and comparative cost-effectiveness.
- Over 350 medicines to treat priority conditions (WHO Model List).
- Listed by their International Non-proprietary Name (INN) or generic name, without specifying a manufacturer.
- Updated every two years, using a transparent evidence-based process.
- The WHO Model List can be used by countries as a guide for the development of their own national essential medicines list.

- Identifying a limited number of essential medicines may lead to a better supply, more rational use, and lower costs.
- The selection of medicines has a considerable impact on the quality of care and the cost of treatment (cost-effective).
- Careful selection of medicines, linked with clinical treatment guidelines and monitoring and evaluation of prescribing can contribute to better health care.

Access to essential medicines as part of the right to health

- Access to essential medicines as part of the right to the highest attainable standard of health ("the right to health") is well-founded in international law.

**Spurious/Falsely-labelled/
Falsified/Counterfeit (SFFC)
Medicines**

SFFC medicines

- SFFC medicines may include products:
 - with the correct ingredients or with the wrong ingredients,
 - without active ingredients, with insufficient or too much active ingredient, or
 - with fake packaging.
- Both branded and generic products are subject to counterfeiting.
- All kinds of medicines have been counterfeited, from medicines for the treatment of life-threatening conditions to inexpensive generic versions of painkillers and antihistamines.

SFFC medicines

- Deliberately and fraudulently mislabelled with respect to identity and/or source.
- Can result in treatment failure or even death.
- Public confidence in health systems may be eroded.

Extent of the problem

- Defining the extent of counterfeiting is difficult for a number of reasons.
- The variety of information sources makes compiling statistics a difficult task.
- Sources of information:
 - Reports from:
 - National medicines regulatory authorities, enforcement agencies, pharmaceutical companies and nongovernmental organizations.
 - Ad hoc studies on specific geographical areas or therapeutic groups.

- The different methods used to produce reports and studies also make compiling and comparing statistics difficult.
- Studies can only give snapshots of the immediate situation.
- Counterfeiters are extremely flexible in the methods they use to mimic products and prevent their detection.
 - They can change these methods from day to day, so when the results of a study are released, they may already be outdated.
- Finally, information about a case under legal investigation is sometimes only made public after the investigation has been concluded.

- Counterfeiting is greatest in regions where regulatory and enforcement systems for medicines are weakest.
 - In many African countries, and in parts of Asia, Latin America, and countries in transition, a much higher percentage of the medicines on sale may be SFFC.
- In most industrialized countries with effective regulatory systems and market control, incidence of SFFC medicines is extremely low – less than 1% of market value according to the estimates of the countries concerned.
 - i.e. Australia, Canada, Japan, New Zealand, the United States of America, and most of the European Union,
- Variation can also be significant within countries
 - e.g. between urban and rural areas, and between cities.

SFFC medicine	Country, Year	Report
1. Avastin (for cancer treatment)	USA, 2012	Affected 19 medical practices in the USA. The drug lacked active ingredient ¹
2. Viagra and Cialis (for erectile dysfunction)	UK, 2012	Smuggled into the UK. Contained undeclared active ingredients with possible serious health risks to the consumer ²
3.Truvada and Viread (for HIV/AIDS)	UK, 2011	Seized before reaching patients. Diverted authentic product in falsified packaging ³
4. Zidolam-N (for HIV/AIDS)	Kenya, 2011	Nearly 3 000 patients affected by falsified batch of their antiretroviral therapy ⁴
5. Alli (weight-loss medicines)	USA, 2010	Smuggled into the USA. Contained undeclared active ingredients with possible serious health risks to the consumer ⁵
6. Anti-diabetic traditional medicine (used to lower blood sugar)	China, 2009	Contained six times the normal dose of glibenclamide. Two people died, nine people were hospitalized ⁶
7. Metakelfin (antimalarial)	Tanzania, 2009	Discovered in 40 pharmacies. The drug lacked sufficient active ingredient ⁷

Internet Sales

- In over 50% of cases, medicines purchased over the Internet from illegal sites that conceal their physical address have been found to be counterfeit.

Public health risks

- Use can result in treatment failure and contribute to increased resistance (eg. in the case of antimalarials that contain insufficient active ingredient) or even death.
- Unlike substandard medicines where there are problems with the manufacturing process by a known manufacturer, SFFC medicines are made by people with the intent to mislead.
- The extreme difficulty in tracing the manufacturing and distribution channels of SFFC medicines makes their circulation on markets difficult to stop.
- Even a single case of a SFFC medicine is unacceptable since it indicates that the pharmaceutical supply system in which it was detected is vulnerable.
- It undermines the credibility of national health and enforcement authorities.

Contributory factors

- Some people seek medicines that are sold more cheaply.
- These are often available from non-regulated outlets.
- People might also purchase medicines from non-regulated outlets if supplies of medicines at regular health facilities do not meet demand.
- Counterfeiting medicines can be very lucrative. Since many countries have not yet enacted deterrent legislation, counterfeiters often do not fear prosecution.
- The growth in international trade of pharmaceutical ingredients and medicines adds a further dimension of complexity to this issue.
 - For example, trade through brokers and free trade zones where regulation is lax or absent (and medicines are repackaged and relabelled to conceal the country of origin) is increasing.

Response

- Stringent regulatory control of medicines and enforcement by national medicines regulatory authorities contributes significantly to the prevention and detection of SFEC medicines.
- WHO provides direct country and regional support for strengthening medicines regulation.

Quality control in Drug sector in India

- The Drugs and Cosmetics Act, 1940
- Drug and Cosmetics Rule, 1945
- Central Drug Standard Control Organization (CDSCO):
 - Quality control of the imported drugs
 - Coordination of the activities of States/UTs
 - Approval of new drug proposed to be manufactured or imported.
 - Laying down standards and regulatory measures.
 - Acting as the Central License Approving Authority .

Take Home Message....

- (Try to) Avoid use of OTC (Over the counter) by self and advise other to avoid.
- (Try to) Avoid use of 'magic' formulations by self and advise other to avoid.
- (Try to) Prescribe (when you come into practice) generic medicines rather than branded products.