KEY CONCEPTS IN E4BT

1) OFF-LABEL and 2) MEDICAL PRESCRIPTION

OFF-LABEL

Off-label use is the practice of prescribing drugs for a purpose outside the scope of the drug's approved purposes, most often concerning the drug's indication. In the United States, the Food and Drug Administration (FDA) requires numerous clinical trials to prove a drug's safety and efficacy in treating a given disease or condition. If satisfied that the drug is safe and effective, the drug's manufacturer and the FDA agree on specific language describing dosage, route and other information to be included on the drug's label. More detail is included in the drug's package insert. However, once the FDA approves a drug for prescription use, they do not attempt to regulate the practice of medicine, and so the physician makes decisions based on her or his best judgment. It is entirely legal in the United States and in many other countries to use drugs off-label. Exceptions to this are certain controlled substances, such as opiates, which cannot be legally prescribed except for approved purposes in the US. In Australia, amphetamines are included in these drugs, which cannot be prescribed off-label.

Some drugs are used more frequently off-label than for their original, FDA-approved indications.

Frequently the standard of care for a particular type or stage of cancer involves the off-label use of one or more drugs. An example is the use of tricyclic antidepressants to treat neuropathic pain. This old class of antidepressants is now rarely used for clinical depression due to side effects, but the tricyclics are often effective for treating pain.

A medical prescription is a written order by a qualified health care professional to a pharmacist or other therapist for a treatment to be provided to their patient. A prescription is a legal document which not only instructs in the preparation and provision of the medicine or device but indicates the prescriber takes responsibility for the clinical care of the patient and the outcomes that may or may not be achieved.

Source: De Giuli E., A. Sala, 2010, *English for Pharmacy*, Milan: Hoepli.

3) ACTIVE IMMUNIZATION or VACCINATION

Active Immunization or Vaccination

The terms vaccination and vaccine derive from the work of Edward Jenner who, over 200 years ago, showed that inoculating people with material from skin lesions caused by cowpox (L. vaccinus, of cows) protected them from the highly contagious and frequently fatal disease smallpox.

Since Jenner's time, the term has been retained for any preparation of dead or weakened pathogens, or their products, that when introduced into the body, stimulates the production of protective antibodies or T cells without causing the disease. In molecular terms, the goal is to introduce harmless antigen(s) with epitopes that are also found on the pathogen.

Vaccination is also called active immunization because the immune system is stimulated to develop its own immunity against the pathogen. Passive immunity, in contrast, results from the injection of antibodies formed by another animal (e.g., horse, human) which provide immediate, but temporary, protection for the recipient.

4) CDC

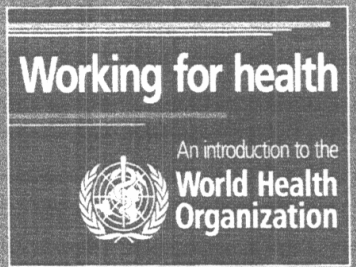
CDC The Centers for Disease Control and Prevention, the US agency charged with tracking and investigating public health trends. The stated mission of the CDC is "To promote health and quality of life by preventing and controlling disease, injury, and disability." The CDC is a part of the US Public Health Services (PHS) under the Department of Health and Human Services (HHS).

5) WHO

About WHO

WHO is the directing and coordinating authority for health within the United Nations system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends.

In the 21st century, health is a shared responsibility, involving equitable access to essential care and collective defence against transnational threats.



Source: De Giuli E., A. Sala, 2010, *English for Pharmacy*, Milan: Hoepli.

6) FDA

The Food and Drug Administration (FDA or USFDA) is an agency of the United States Department of Health and Human Services and is responsible for regulating and supervising the safety of foods, dietary supplements, drugs, vaccines, biological medical products, blood products, medical devices, radiation-emitting devices, veterinary products, and cosmetics.

7) THE LANCET

The Lancet is one of the world's best-known and most respected general medical journals, with editorial offices in London and New York, The Lancet was founded in 1823 by Thomas Wakley, who named it after the surgical instrument called a lancet, as well as an arched window ("to let in light").
The Lancet has taken a stand on several important medical issues. Recent examples include criticism of the World Health Organization, rejecting claims of the efficacy of homeopathy as a therapeutic option, disapproval during the time Reed Exhibitions hosted arms industry fairs, and a call in 2003 for tobacco to be made illegal.

Source: De Giuli E., A. Sala, 2010, *English for Pharmacy*, Milan: Hoepli.