



British Society for the
History of Pharmacy

The evolution of pharmacy: Theme E, Level 2 The history of UK medicines regulation



Early medicines regulation

Before the middle of the nineteenth century there were no effective controls over the sale of medicines, and only limited progress was made in ensuring their safety and efficacy (see **control of harmful substances**). A number of sudden deaths were reported following the introduction of chloroform as an anaesthetic, as a result of which a British Medical Association (BMA) working party suggested in 1880 the setting up of an independent body to assess drug safety. However, this related only to anaesthetics, was not a permanent body, and had only limited impact.

Concern about the content of patent medicines led to two BMA publications, *Secret Remedies* (1909) and *More Secret Remedies* (1912) which prompted the establishment of a Parliamentary Select Committee to examine the issues. This Committee recommended, amongst other things, the setting up of legal controls over the sale and advertising of medicines. However the First World War intervened and most of the proposed legislation was dropped. The Venereal Disease Act of 1917, and later the Cancer Act of 1939, prevented the advertising and promotion of medicines for these conditions.

Control of manufacturing

Before the Medicines Act of 1968 medicines were classified as poisons, with a new category of dangerous drug introduced in 1920 and therapeutic substances in 1925. Some legislation to control the quality, sale and promotion of medicines existed before then, but its impact was very limited. The first edition of the British Pharmacopoeia (BP) appeared in 1864, and this laid down standards for the manufacture of common established drugs. However, there were inevitably long delays between a new drug becoming available and its appearance in the BP.

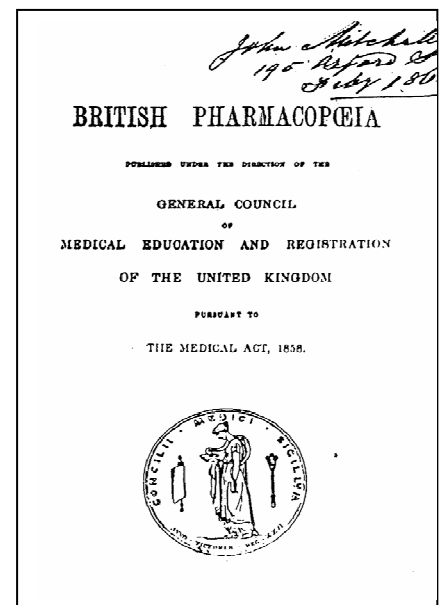
The Therapeutic Substances Act 1925 introduced regulations concerning the manufacture of biological substances; it was strengthened in 1956.

But legislation did not keep pace with the enormous progress that was made in the middle of the twentieth century in the discovery of new medicines, and it had little relevance to the therapeutic revolution that was taking place.

The thalidomide disaster

The **thalidomide** disaster in 1961 was the major watershed that transformed medicines regulation in the UK. Thalidomide first went on sale in 1956 as a sedative and hypnotic. It was widely prescribed during the late 1950s and early 1960s for insomnia, because it was seen to be vastly safer than barbiturates.

However, following anecdotal reports of benefits in the treatment of vomiting in early pregnancy, it was heavily promoted for the relief of morning sickness in the first few months of pregnancy. But in 1959 reports started to appear of babies being born with malformed limbs (a condition known as phocomelia) and other associated internal malformations. At a conference in November 1961 a possible link between these serious birth defects and thalidomide was highlighted, as a result of which the drug was withdrawn. Within nine months or so the epidemic of malformations returned to background levels.





Response to the disaster

In a bid to prevent a similar occurrence, the **Committee on Safety of Drugs** (CSD) was set up in 1963. It had no legal powers but worked effectively with the pharmaceutical industry to advise on clinical trials and the marketing of new medicines. This committee also set up a system of **adverse drug reaction reporting** for drugs by means of reply-paid yellow cards; this became known as the "Yellow Card Scheme".

A White Paper in 1967 recommended legislation rather than a voluntary system to control medicines and the **Medicines Act** received Royal Assent in October 1968. This Act established the requirement that, from 1 September 1971, all medicines, for both human and animal use, already on the UK market had to be reviewed, whilst any new products had to be first approved and licensed before being allowed onto the UK market.

Regulatory bodies

Responsibility for this role initially lay with the Medicines Division of the Department of Health for human medicines. Rising demands and delays in licensing led to the creation of the Medicines Control Agency (MCA) in 1989, one of the executive agencies of the Department of Health arising out of the Government's *Next Steps* initiative. MCA then merged with the Medical Device Agency to become the Medicines and Healthcare products Regulatory Agency (MHRA) in 2003. Responsibility for veterinary medicines fell to MAFF, now DEFRA, the Department for Food, Environment and Rural Affairs, and it too saw the creation of an executive agency, the Veterinary Medicines Directorate. The European Medicines Agency (EMA) was set up in 1995 to co-ordinate and provide regulatory support to EU member states and the European medicines advisory committees for both human and veterinary medicines.



UK medicines regulation today

Medicines today must meet the strict criteria of safety, quality and efficacy before they can be marketed in the United Kingdom. Consideration of these factors forms the basis of the marketing authorisation application which manufacturers send to one of the regulatory authorities. These are the Medicines and Healthcare products Regulatory Agency for human medicines, and the Veterinary Medicines Directorate (VMD) for veterinary medicines. These agencies assess medicines prior to marketing to ensure that the benefits outweigh the risks.

FIND OUT MORE

Links to other sheets:

Theme E, levels 1 and 3

Further reading:

Applebe, Gordon E.: *From arsenic to thalidomide: a brief history of medicine safety*, (*Making Medicines* 243-260 Pharmaceutical Press, London, 2005)

Griffin, John P, *The evolution of human medicines control from a national to an international perspective*, (*Adverse Drug React. Toxicol. Rev.* 1998, 17(1) 19-50 Oxford University Press)

Kayne, Steven B. & Jepson, Michael H. (eds) *Veterinary Pharmacy*, (Pharmaceutical Press, London, 2004)

Shah, R R, *Thalidomide, drug safety and early drug regulation in the UK*, (*Adverse Drug React. Toxicol. Rev.* 2001, 20(4) 199-255 Oxford University Press).