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# When I use a word . . . Medicines regulation: 1540 and all that

The 1540 Pharmacy Wares, Drugs and Stuffs Act, also called the Apothecary Wares, Drugs and Stuffs Act, promulgated by Henry VIII, who had founded the College of Physicians in 1518, gave physicians the right to search apothecaries' shops for faulty wares. If the search unearthed medicines that were defective in any way, they were to be destroyed. The act gave physicians power over apothecaries, who were also prohibited from supplying medicines unless under a physician's prescription or a written note from the purchaser. It also provided income for the King's purse, since there was a fine for failing to comply with the act. It would be some time before quality, efficacy, and safety became the main concerns of medicines regulators.

Jeffrey K Aronson

## The purposes of medicines regulation

The chief purpose of medicines regulators today is to try to ensure that the medicines that pharmaceutical companies manufacture and purvey meet certain standards of quality, efficacy, and safety. This principle was enshrined in the UK's 1968 Medicines Act,[1] and can be found in a later amendment to the act, the 2012 Human Medicines Regulations,[2] which includes a description of the functions of the Commission on Human Medicines, the successor to the Medicines Commission and its Section 4 committee, the Committee on Safety of Medicines (CSM): "the Commission must (a) give advice with respect to the safety, quality and efficacy of medicinal products; and (b) promote the collection and investigation of information relating to adverse reactions, for the purposes of enabling such advice to be given."

I say that regulators try to do these things, because, despite their very best efforts, they don't always succeed. From time to time medicines are licensed and marketed, only later to be removed from the market because of adverse outcomes that were not revealed in the premarketing phase of development.[3]

However, before these modern concerns emerged, different concerns motivated regulation. Medicines regulation is by no means new; it has been with us almost since medicines first started to be used.[4] Early regulation was mostly concerned with who supplied what,[5] and that was even the case at the start of the 20th century, when the British Medical Association published two volumes of information about patent medicines, their contents and their true costs—*Secret Remedies* (1909) and *More Secret Remedies* (1912)—comparing the prices that manufacturers charged with the true costs of the ingredients.[6]

## The 1540 Pharmacy Wares, Drugs and Stuffs Act

One of the earliest pieces of legislation was the Pharmacy Wares, Drugs and Stuffs Act of 1540, "for Physicians and their Privileges," also called the Apothecary Wares, Drugs and Stuffs Act. Its purpose was to give physicians power over apothecaries.

King Henry VIII had supported the physicians by granting them a charter to establish the College (now the Royal College) of Physicians in 1518, on the request of Thomas Linacre and other leading physicians. The 1540 act gave physicians the power to inspect apothecaries' wares and destroy them if defective. In doing this, they were assisted by "Wardens of the said mystery of Apothecaries within the said City." The penalty for refusing to submit to a search was 100 shillings, of which the King took half, demonstrating another aspect of medicines regulation—profit.

Traditionally, medicines had been purveyed alongside nonperishable commodities—spices, comfits, preserves, and the like—which apothecaries had originally sold. The apothecaries were therefore members of the Guild of Grocers, classed with spicers and pepperers, whose guild had regulated the trade in medicines since the 12th century. However, the apothecaries gradually focused on drugs, and by about the middle of the 14th century an apothecary was one who prepared and sold drugs for medicinal purposes. Although the apothecaries were keen to be recognised as independent practitioners, their requests were refused until 1617, when James I founded the Worshipful Society of the Art and Mistery of Apothecaries. This heightened the tension between physicians and apothecaries, and led the former to publish the *Pharmacopoeia Londinensis* in 1618,[7] which was endorsed by the first Stuart King, James the Sixth of Scotland and the First of England.[8]

The title page of the act is an impressive piece of artwork, rather like a piece of concrete poetry, the text arranged in the form of what looks like a spinning top[9]:

_____ANNO
XXXII_____

_____IN THE PARLYAMENTE
BEGON_____

___at Westminster the xxviii of Apryll, the xxxii yeare of the reygne of the moste____

_____excellente, most hyghe, and most mighty prince, HENRYE the eyght_____

_____by the grace of GOD kyng of ENGLAND, & FRANCE under_____

_____CHRISTE supreme head of the churche of Englande, oure_____

_____most redoubted souerayne lorde there holden and_____

_____afterwards continued by dyuers prorogations vnto_____

_____the xii daye of Apryll in the sayde yeare. In_____

_____the last session thereof begon the same_____

_____xii daye of Apryll, and from the same_____

_____holden vnto the xi day of Maye, _____

_____in the xxxii yeare of his_____

_____maiesties most prosperous_____

_____reigne ..... established_____

_____ordeyned and_____

_____enacted_____

_____ANNO, MDXL_____

The act was published "Ex aedibus Thomae Bartheleti, Cum priuilegio ad imprimendum solum."

The act included a prohibition on selling poisons or medicines except by the order of a physician's prescription or a written note from the purchaser. However, it would be some time before quality, efficacy, and safety became the main concerns of medicines regulators.

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