

The development of Sativex[®] – a natural cannabis-based medicine

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History of the development

Cannabis has been used medicinally for 4000 years [1–4] in a variety of cultures and was re-introduced into British medicine in 1842 by W. O'Shaughnessy [5]. It remained in the British pharmacopoeia until 1932, when cannabis, extract of cannabis and tincture of cannabis were among 400 medicines removed, though all three remained in the British Pharmaceutical Codex of 1949 [5].

However, following the 1961 UN Single Convention on Narcotic Drugs, cannabis and cannabis derivatives became scheduled products and were subject to special measures of control and parties could ban their use altogether. Following the 1971 UN Convention on Psychotropic Substances, the UK enacted the Misuse of Drugs Act 1971. Cannabinol and its derivatives, including Δ^9 -tetrahydrocannabinol (Δ^9 -THC), appeared in Schedule I to the Convention, and their regular medical use was prohibited. The introduction of the Misuse of Drugs Regulations in the UK in 1973 listed cannabis and cannabis products in Schedule 4 (now Schedule I in current legislation), thereby prohibiting medical use altogether [5].

Early research

Although the medicinal properties of cannabis had been well documented for a number of years, the constituent(s) responsible for therapeutic efficacy had, until recently, not been identified. The discovery, isolation (and subsequent synthesis) of the principal cannabinoid present in cannabis, Δ^9 -THC, by Raphael Mechoulam and Yehiel Gaoni in 1964 [6] ensured that interest in cannabinoid chemistry remained and led to an expansion of cannabinoid research.

Despite the scheduling and prohibition of cannabis and the ban on medical use of cannabis-based products in the 1970s, research into the pharmacology and toxicology of Δ^9 -THC continued through the 1970s and 1980s, mainly by the National Institute of Health (NIH) in the USA.