Dates	Organisation	Legal Status	Primary Purpose	Powers
Pre-1968	None	-	-	-
06/1968 – 08/1971	Committee on Safety of Drugs **(CSD)**	Non Statutory (Voluntary by agreement with the pharmaceutical industry)	To **advise** on drug safety and to create **and administer** a **voluntary** licencing structure	**None** – could ask manufacturers to remove a medicine, could not make them
09/1971 – 10/2005	Medicines Commission	Statutory under Medicines Act 1968 as per Directive 75/318/EEC	To **advise** the licencing authority on issued related to the 1968 Act	Advised the Licencing authority – in particular on the setting up of committees, such as CSM and CRM and on appeals by manufacturers
09/1971 – 10/2005	Committee on Safety of Medicines **(CSM)**	Statutory under Medicines Act 1968	To **advise** the licencing authority on drugs	Advised the Licencing authority on drug efficacy, safety and quality
10/2005 -	Commission on Human Medicines **(CHM)**	Statutory under Medicines Act 1968 (SI 2005 No. 1094) as per Directive 75/318/EEC	**Advisory** - Amalgamated roles of Medicines Commission and CSM (MHRA provides admin support for CHM)	As for Medicines Commission and CSM
2001 – Aug 2014	Committee on Safety of Devices	Non-Statutory (Voluntary arrangement with various devices experts)	To **advise** the Competent Authority on devices	Advisory, no powers, could make recommendations
Sept 2014 -	Devices Expert Advisory Committee **(DEAC)**	Non-Statutory (Voluntary arrangement with various devices experts)	To **advise** the Competent Authority (MHRA) on devices	Advisory, no powers, could make recommendations

09/1971-03/1989	Medicines Division of the Department of Health and Social Security (DHSS)	Statutory under Medicines Act 1968 as per Directive 75/318/EEC	**Administrative agency** for licencing medicines	Responsible for licencing including ability to remove medicines. Mission statement – To promote and safeguard public health through ensuring appropriate standards of safety, quality and efficacy for all medicines on the UK market. from the market
04/1989-03/2003	Medicines Control Agency **MCA**	Statutory under Medicines Act 1968 as per Directive 75/318/EEC	**Administrative agency** for licencing medicines	Responsible for licencing including ability to remove medicines. Mission statement – To promote and safeguard public health through ensuring appropriate standards of safety, quality and efficacy for all medicines on the UK market. from the market
1969 – 08/1994	The Scientific and Technical Board (STB) of the Department of Health, the Medical Devices Directive (MDD) of the Department of Health and the Medical Devices Agency (MDA).	Non-statutory	**Quasi-regulatory** Checking devices were safe and met appropriate standards	To protect public health and safeguard the interest of patients and users by ensuring that medical devices and equipment met appropriate standards of safety, quality and performance and that they complied with relevant rules.
09/1994 - 03/2003	Devices Control Agency (D**CA)**	Executive Agency enforcing statutory provisions.	**Regulatory** Checking compliance with regulatory	To ensuring that medical devices and equipment complied with relevant laws designed to ensure they met appropriate

			standards for devices	standards of safety, quality and performance.
04/2003-	Medicines and Healthcare Regulatory Agency (**MHRA)**	Statutory under Medicines Act 1968 as per Directive 75/318/EEC	**Administrative agency** for medicines licencing & Devices. Merger of MCA and DCA	Responsible for licencing, including ability to remove medicines and devices from the market
10/1975 – 03/1992	Committee for the Review of Medicines (**CRM)**	Statutory under SI 1975/1066 as per Directive 75/318/EEC	To review medicines which were marketed in the UK prior to 22/11/1976 for quality, safety and efficacy	Could convert a Product Licence of Right (PLR) to a full licence or could remove the PLR.

Figure H.3 Key National Organisations in the control of the pharmaceuticals and Medical Devices being reviewed by the IMMMDS Review.

2.2. European regulation of medicines

2.2.1 On 1 January 1973 Great Britain joined the EEC. Under the architecture of the EU, there are different types of legislation passed at EU level which place different requirements on member states, see Figure H.4

Regulations. A Regulation is a binding legislative act. It must be applied in its entirety across the EU.
Directives. A Directive is a legislative act that sets out a goal that all EU member states must achieve. However, each individual member state is responsible for designing and implementing their own laws to achieve these goals.
Decisions. A decision is binding on those to whom it is addressed (e.g. an EU member state or an individual agency/company) and is directly applicable (meaning it does not need any other act of parliament in the relevant member state to make it into a law).
Recommendations. A recommendation is not binding on those to whom it is addressed. A recommendation suggests a course of action without imposing any legal obligation to follow that course of action.
Opinion. An opinion is not binding on those to whom it is addressed. An opinion allows various institutions to state an opinion about a topic, without imposing any legal obligation.

Figure H.4 Types of regulation in the EU