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MCA involvement in public health

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Pharmacist and chemists as analysts play key roles in the regulation of human medicines in the UK. Both pharmacists and chemists, as civil servants working in MCA, fulfil the following roles:

- advising on medicines policy
- assessment of marketing authorisation
- applications and variations
- management
- pharmacovigilance
- medicines inspection and enforcement
- medicines testing
- pharmacopoeial services.

Pharmacists and chemists also play key roles in advising Ministers or as members of the main Medicines Act Section 4 Committees, such as CSM, and its sub-committees, such as the Sub-Committee on Chemistry, Pharmacy and Standards.

This discourse will focus on the role played by pharmacists and chemists as assessors of marketing authorisation applications for human medicines.

European Marketing Authorisation Applications (MAA's) are divided into three main sections: Chemistry / Pharmacy / Biology (Part II), pre-clinical toxicology(Part III), and clinical (Part IV). These data sets support the three main tenets of world-wide medicines legislation: quality, safety and efficacy. A significant proportion of Part II of a dossier consists of analytical methodology and attendant validation used to control the drug substance, the drug product and in support of studies on the biological disposition of drug substance in man and animals.

Assessment of the quality of a human medicine must be taken in relation to safety and efficacy; quality *per se* cannot be assessed in isolation. Aside from compliance with national and European pharmaceutical legislation pharmaceutical assessment must identify areas of quality in relation to safety and efficacy which are minor and seek, in concert, with the Licence Applicant to resolve these issues and/or identify major issues which if unresolved would constitute a serious risk to public health. Major issues or objections are taken up with the applicant directly.

Pharmaceutical assessment of MAA's is a team effort combining pharmaceutical, toxicology and clinical assessment, inspection and enforcement and post and post-licensing issues.

The role of the pharmacists and chemists in regulation of human pharmaceutical products is fully affirmed.