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The Royal Pharmaceutical Society's Medicines Testing Laboratory

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The Royal Pharmaceutical Society's Medicines Testing Laboratory has been the main official medicines control laboratory for the United Kingdom since 1972, undertaking regulatory analysis and testing of pharmaceuticals at the request of the Medicines Control Agency. Since 1995 MTL has also been a commercial analytical laboratory undertaking contract research and testing on behalf of clients in the private sector, mainly pharmaceutical manufacturers. This dual role as a commercial and regulatory laboratory provides many interesting opportunities to undertake laboratory studies involving the evaluation of the quality of medicines and to play an important role in the protection of the patient.

MTL's role as a regulatory laboratory is to assess the quality of medicinal products on the UK market in order to determine whether they are being manufactured in accordance with their marketing authorisation (product licence). A major part of the laboratory's regulatory work involves surveillance of products which are monitored for compliance with their relevant specifications and other legal requirements (e.g. labelling requirements). The laboratory's work also involves the investigation of potentially defective medicines when they come under suspicion for any reason (e.g. visual defects, or reports of adverse reactions or ineffectiveness). MTL also supports the work of the MCA's enforcement section in their investigations into breaches of the provisions of the Medicines Act.

Generally, products are tested by the methods registered in the marketing authorisation, pharmacopoeial methods or validated in-house procedures and emphasis is placed on critical quality parameters, e.g.

- uniformity of mass or content
- presence of active ingredients
- dissolution (of solid oral dosage forms)
- quantification of drug-related impurities
- appearance and labelling
- content (assay) of active ingredient
- microbiological quality
- assay of functional excipients

A number of major surveillance studies (typically 8 12) of the quality of medicines are undertaken each year on behalf of the Medicines Control Agency. Examples in recent years have included

- Allopurinol Tablets 360 samples
- Naproxen Tablets 90 samples
- Atenolol Tablets 480 samples
- Nifedipine Capsules 118 samples
- Carbamazapine Tablets 193 samples
- Tamoxifen Tablets 99 samples
- Cimetidine Tablets 170 samples
- Herbal products 425 samples

With few exceptions, products tested in the last 3 years complied with the quality specifications against which they were assessed. In certain cases when results fell outside of pharmacopoeial limits, it was necessary to retest the sample according to the method registered in the marketing authorisation if this differed from the pharmacopoeial method. Only when the out-of-specification result is confirmed by the registered method is the product licence holder asked to take appropriate action.

All aspects of the laboratory's regulatory work bring their own challenges and rewards. The product surveillance work provides confidence to government and consumers about the quality of medicinal products on the UK market. The investigation of potentially defective medicines or illegally manufactured products is particularly interesting and challenging. This work is also the most intellectually rewarding since it may result in the removal of unsafe or ineffective products from the market, thereby contributing to the protection of public health.

The commercial work undertaken on behalf of clients in the private sector is similar to that for regulatory clients. However, in addition to the testing of medicinal products for quality assessment, a significant part of MTL's commercial work involves analytical method development and validation to support the clients' research and development programmes. Stability testing of drug substances and of finished products is an essential aspect of the development of new medicines because the data generated allow the storage conditions and shelf-life of the products to be determined. Commercial analytical work undertaken by laboratories like the Medicines Testing Laboratory play an important role in protecting patients by contributing to the process of bringing to the market new medicinal products that are safe, efficacious and produced to a high quality.