Fact Sheet: Making a medicine – Regulatory submission

Regulatory Submission – Marketing Authorisation Application (MAA)

If the results of the Phase III clinical studies show an acceptable risk-benefit relationship, a Marketing Authorisation Application (MAA) can be prepared. All the information (non-clinical, clinical, and manufacturing) is collected and organised in a pre-determined format. This is called a 'dossier' and it is sent to the Regulatory Authorities.

Once the dossier is received, the Regulatory Authority will review the information, and submit questions to be answered by the staff in the regulatory department who sent the document.

Once the Regulatory Authority is satisfied with the results (risk-benefit) they will give their approval for the new medicine to be marketed. The review process usually takes 12-18 months. This period can be shorter in special cases agreed by the Regulatory Authorities, but can be prolonged if there are many questions to answer. The authorities may require more clinical studies before they are prepared to give their approval, and the medicine will not be allowed to enter the market until the Regulatory Authorities are satisfied. Sometimes there are conditions that cannot be accepted by the Regulatory Authorities, and the medicine will not be accepted to go into the market.

Health Technology Assessment

In many countries, studies about the cost effectiveness of the new medicine are also required. These documents will support the government or insurance companies through Health Technology Assessment (HTA) groups to decide and do recommendations about allowing the medicine to be prescribed and paid by the insurance system in the country. One of the well known Health Technology Assessment groups is the National Institute for Health and Care Excellence (NICE) in the UK. NICE recommends whether or not the government should allow the medicine to be prescribed.