

## Appeals and hearings



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### Appeals and hearings

Questions received from regulatory authorities in response to registration submissions may be simple requests for clarification of the data. All too often, however, such questions constitute an outright rejection which brings with it a formal right of appeal. It is important to recognise the distinction from the outset, for appeals can be extremely costly and delay the product launch by many months. Companies may therefore wish to seek the assistance of specialists such as us, who have a track record of success in winning appeal cases.

Appeals require more than just a knowledge of the science to succeed. A constructive approach to developing arguments in support of the case is an essential prerequisite. In preparing written responses a positive style of writing can be enormously beneficial in engendering a sense of confidence and giving reassurance that the case has been fully considered.

We are well versed in all these arts as well as in the pharmaceutical sciences. We thrive on challenges and enjoy using all our scientific skills to achieve a positive outcome for all our clients. Our experience with many different appeals, hearings, representations, arbitration and litigation cases is second to none and we believe our success rate, at over 90%, speaks for itself.

### Preparation for an appeal

#### The briefing

The process starts with a thorough briefing from the client, in order for us to understand the issues to be addressed; this may involve a meeting with the authorities to hear at first-hand the views of the assessors.

#### The written representation

All the questions raised by the authorities are thoroughly reviewed and possible resolutions are brainstormed by our multidisciplinary team. Each specialist acts as a foil to the others and convincing arguments are developed to the stage where they can be presented to the authorities with confidence, fully backed by sound, scientific evidence.

#### The appeal team

Careful consideration is given to the choice of experts who will join the select team to represent the company at the formal hearing. Under the leadership of one of our senior executives, the team is fully briefed on appeal procedures and trained in the skills of positive presentation.



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#### **The presentation**

Much of the success of an appeal depends upon the quality of the presentation made to the Committee. Effective visual aids are designed to address the key issues in a convincing and visually appealing manner.

#### **The rehearsals**

By the time the experts are ready to attend the oral hearing they are fully rehearsed and act as a team rather than individuals. All the contributors know exactly what is expected of them and answers to every question expected to be raised by the Committee have been fully agreed and tested during at least one prior mock appeal.

#### **The oral hearing**

When the day finally arrives, the team guided by our experts feels confident and has a determination to win. The presentation to the Committee is polished and their responses are positive and slick. A successful outcome is to be expected.

#### **Mock appeals**

All appeal cases we undertake automatically go through a mock appeal. But we also offer mock appeals as an independent service to companies wishing to conduct their own appeals.

The mock appeal is a full dress rehearsal mimicking both the procedure and the 'feel' of the actual event. A team of experts play-acts the role of the Committee members in similar surroundings.

The company's appeal team is encouraged to come fully prepared as for the real thing. No contact is allowed with the mock Committee until the team is invited into the appeal chamber under conditions as tense as on the day. All the formalities of the actual appeal day are observed for this rehearsal.

The mock appeal typically occupies a full day. The morning is engaged in the 'play-acting'. The company team makes its presentation in support of the case and is questioned intensely by the mock Committee, during which their responses and behaviour are both closely monitored.

After a relaxing and well-earned lunch, the afternoon session commences. This is a leisurely affair compared with the morning and involves a detailed analysis of the performance of the team. The two sides join forces and together analyse the performance to strengthen the case

Few people who have been put through the rigours of a mock appeal forget the experience. Many have said, by comparison, that the real thing was 'a doddle'. Mock appeals achieve three major objectives: they are fun; highly educational and, above all, achieve success.

### **Contact us:**

For a more detailed discussion on how we can help you, contact us on **+44 (0)1628 530554** or email us on **info@wainwrightassociates.co.uk**