

# Activities Prior to Marketing Authorisation Summary

## 1 Key Principles

Provision of off label information is allowable under the following circumstances:

- where there is a legitimate business need
- in response to an external request
- when there is an established expectation



### Remember:

Off-label promotion is **illegal**. Make sure activities and materials cannot be viewed by others as promotion. If in doubt seek advice.

## 2 Legitimate Business Need



Examples of where there may be a legitimate business need include: advisory boards, clinical trial documentation or meetings, HTA submissions, development partnerships, business development enquiries, market research, regulatory submissions, information for prospective employees.

### Scientific Exchange

It is acknowledged by authorities that exchange of information during the development of a product needs to be allowed for certain 'legitimate' reasons. In addition the term 'exchange' implies a two way process in terms of sharing information. It differs from medical education as there is no teaching or training element.



### Discussion by learned society

When part of formal proceedings symposia may include research developments in terms of pipeline products.



### Investigator meetings

Information must be non promotional but may use study 'branding'.



### Information for payers

Provide only to those responsible for making policy and budgetary decisions, and not to potential future prescribers of the product.

### Checklist for Advisory Boards:

- There must be a clear and documented business need for the advice
- The number of advisors invited and attending and the duration must not exceed what is reasonably necessary to achieve the objectives
- They must not be attended by sales representatives or their first line managers
- There must be a clear and documented rationale for the choice of advisors which should stand up to scrutiny
- The agenda must allow enough time for active discussion and input from all of the advisors. Their input must constitute the majority of the agenda.
- Information provided to the advisors must not exceed what is reasonably necessary to achieve the objectives of the advisory board and must be presented in a non promotional way
- Appropriate contracts and agreements must be in place with advisors

## 4 Established Expectation



Examples of where there is an established expectation that companies will share off label information about a product include:

- Business press releases
- HTA submissions
- Horizon scanning to assist budget planning
- Scientific publication of clinical data
- Investor updates
- Congress presentations
- Financial reporting

## 3 Response to an External Request

Usually handled through the medical functions off label information can be given but:

- the enquiry must be unsolicited
- response must not go beyond the scope of enquiry
- response must be non promotional