**Pharma Integrity Template to Notify the HPRA
of a Planned Advisory Board**

**This template has been produced as a free resource by Pharma Integrity.**

Effective 1st January 2021, all Market Authorisation Holders and affiliates in Ireland must notify the HPRA when they intend to hold an advisory board meeting which meets the criteria below:

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| Advisory Boards Held in Ireland |
| Details of Meeting | Notify the HPRA? | Comment |
| * Local Irish affiliate involvement\* in its planning/organisation
* Irish-based advisors
 | Ues | HPRA may attend as an observer |
| * No local Irish affiliate involvement in its planning/organisation – all done by Global.
* Irish-based advisors
 | Yes | Notification to HPRA only – HPRA will not attend, but may request a report on the meeting afterwards |
| * No local Irish affiliate involvement in its planning/organisation
* No Irish-based advisors
 | No | HPRA will not attend |
| Advisory Boards Held Outside Ireland |
| Details of Meeting | Notify the HPRA? | Comment |
| * Local Irish affiliate involvement\* in its planning/organisation
* Irish-based advisors
 | Yes | HPRA reserves the right to attend and may request a report on the meeting afterwards |
| * No local Irish affiliate involvement in its planning/organisation – all done by Global.
* Irish-based advisors
 | No | HPRA will not attend |

\*Companies should note that Local Irish Affiliate involvement in advisory boards includes any of the following:

* Planning the advisory board
* Selecting the advisors
* Issuing the invitations to the advisors on its own letterhead/email, etc.
* Involvement in arrangements for the advisory board – e.g., making or assisting with hotel bookings, travel arrangements, room booking, hospitality, providing a medical writer, etc.
* Hosting the advisory board
* Running the advisory board
* Attending the advisory board
* Paying the advisors

The HPRA will decide based on the information provided whether they will attend or observe the meeting (companies will be notified of their decision in advance).

Information should be submitted to the HPRA a minimum of six weeks in advance. The need for genuine exceptions should be clearly communicated to the HPRA.

The following form allows companies to easily compile the information that the HPRA require. Companies must additionally provide a copy of the company’s SOP governing the conduct of advisory boards. We recommend that you delete the first three cover pages of this document before submission.

Pharma Integrity strongly recommend companies to be mindful of the following:

* Advisory boards are held solely for the purpose of the company obtaining advice and answering legitimate questions which cannot be answered through other means. There must be no promotion of medicinal products or products in development, whether direct or indirect. To do so would be a breach of both regulations and the industry codes of practice.
* Multiple advisory boards on the same topic should be avoided unless a clear need can be demonstrated, e.g., due to geographical variances, legitimate difference in need or opinion between stakeholder categories.
* Participants at advisory boards should be chosen solely based on their ability to provide the advice required to meet the objectives of the advisory board. The number of participants should be limited to that which is required to meet the expected outcomes of the meeting, allow for all participants to have an active participation, and make a meaningful contribution.
* Invitations should be clear as to the purpose of the advisory board, the nature of advice that is being sought from invitees, what their expected role is, and the amount of work expected to be undertaken.
* Only that information which is essential to the ability of participants to provide the insight and advice required to meet the objectives of the meeting should be shared. To share surplus information raises concerns with regards disguised promotion.
* The agenda should allow adequate time for discussion (the IPHA Code stipulates a minimum of 60% of time must be allotted to discussion).
* Sponsors remain responsible for ensuring that discussions during an advisory board do not mislead participants (intentionally or unintentionally) about the rational use, benefits or risks associated with a medicinal product.

The HPRA recommends that attendees of advisory boards are notified in advance that:

* The HPRA may attend advisory board meetings, in full or in part, for the purpose of checking compliance with relevant medicines legislation.
* The HPRA’s attendance at any advisory board meeting is not intended to regulate or apply oversight to the attendees (advisors) at the meeting; it is intended to evaluate the company’s running and management of the meeting.
* The HPRA will not actively participate in the meeting – if it does attend an advisory board meeting, it will be only as an observer.
* This is one aspect of the HPRA’s surveillance monitoring of the pharmaceutical industry, and the HPRA’s attendance at any advisory board meeting in no way implies that a non-compliance issue exists with that particular company.

If you require support in preparing an advisory board meeting, or if you would like us to take care of all the arrangements and facilitate an in-person or virtual advisory board meeting for your company, contact us via email using Info@PharmaIntegrity.com, or by telephone to +353 (0)1 531 0674.

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| **A blue and green text on a black background  Description automatically generated** | **Pharma Integrity template for advisory board submissions to the HPRA**Complete fields as fully as possible. It is advised to make it clear where decisions are still to be finalised (i.e. are still draft). |
| **Company Details** |
| Name of advisory board sponsor | Click or tap here to enter text. |
| Address of advisory board sponsor | Click or tap here to enter text. |
| Contact person name | Click or tap here to enter text. |
| Contact person email address | Click or tap here to enter text. |
| Contact person telephone number | Click or tap here to enter text. |

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| **Meeting Details** | **HPRA Response/Comments** |
| Name / title | Click or here to enter text. | Click or tap here to enter text. |
| Date | Click or tap here to enter text. | Click or tap here to enter text. |
| Timings  | Click or tap here to enter text. | Click or tap here to enter text. |
| Venue (if being conducted in person) – state “virtual” if being held online | Click or tap here to enter text. | Click or tap here to enter text. |
| Clinical / therapeutic area of concern | Click or tap here to enter text. | Click or tap here to enter text. |
| MAH medicinal product(s) the advisory board is concerned with | Click or tap here to enter text. | Click or tap here to enter text. |
| Objectives, including the nature of advice that is being sought | Click or tap here to enter text. | Click or tap here to enter text. |
| Agenda (note if draft or final; may be provided as a supplementary document if preferred.) | Click or tap here to enter text. | Click or tap here to enter text. |

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| **Participants** | **HPRA Response/Comments** |
| Expected number of external participants | Click or tap here to enter text. | Click or tap here to enter text. |
| External participant expertise  | Click or tap here to enter text. | Click or tap here to enter text. |
| Expected number of internal participants | Click or tap here to enter text. | Click or tap here to enter text. |
| Role of internal participants | Click or tap here to enter text. | Click or tap here to enter text. |
| Fees paid to external participants (including provisions for any associated travel and accommodation expenses that may be paid directly to participants) | Click or tap here to enter text. | Click or tap here to enter text. |
| Hospitality provisions provided by the company for participants (meals, drinks, registration fees, travel, accommodation) | Click or tap here to enter text. | Click or tap here to enter text. |

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| **Declaration & Signature** |
| *To the best of my knowledge and belief, the particulars stated in this document are true and accurate.* |
| Name | Click or tap here to enter text. |
| Signature |  |
| Position | Click or tap here to enter text. |
| Date | Click or tap to enter a date. |

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| **Documents attached** |
| Agenda (if not described above) | [ ]  |
| Company SOP governing the conduct of advisory boards  |[ ]

This form, along with applicable attachments, must be emailed to advertisingcompliance@hpra.ie at least six weeks in advance of the meeting date. You do not require a response from the HPRA to proceed, this is a notificatio