Policy on Interactions with Patients, Care Partners, Patient Advocates and Patient Advocacy Groups

1. PURPOSE

The purpose of this document is to establish a policy for Kyowa Kirin International (KKI) and its Affiliates for complying with laws, regulations and industry codes related to interactions with Patients, Care Partners, Patient Advocates and Patient Advocacy Groups (all hereby referred to as Patients).

2. SCOPE

This policy applies to all KKI staff including consultants, contract workers and temporary staff (KKI staff). This policy also applies to third party vendors acting on behalf of KKI.

This policy is intended to align with the requirements of applicable law and adopted industry codes in the countries in which KKI operates. Where local law or adopted industry codes in a country differ from this policy, the more restrictive rule applies, whether that is this policy or the local requirements.

In exceptional cases where this policy is more restrictive but is also in conflict with the local rules and following this policy would lead to an infringement of the local law or regulation, then the local requirements should be followed.

This policy does not apply to interactions with Healthcare Professionals, Hospitals, and other such Organisations.

3. GENERAL PRINCIPLES

3.1 KKI is committed to ethical and meaningful interactions with Patients. This means that we must ensure all collaborations reflect key principles for engagement of respect, integrity, independence, and transparency, and relevant to the interests of the Patients.

3.12 The KKI Patient Advocacy Director and local Patient Primary Point of Coordination (PPOC) maintain effective relationship building and ensure oversight of all engagements with Patients in their region or local markets. Patients should not be engaged without informing these individuals. For regionally led activities, the KKI Patient Advocacy Director or for locally led activities, the local Patient PPOC, must be consulted at concept phase.

3.13 When conducting an activity with Cross-Border impact, the relevant local Patient PPOC and Affiliate Medical team affected must be informed and consulted before any written or verbal agreements are made to confirm the latest applicable local requirements. Where there is no local Affiliate in the country where the interaction takes place, the KKI Patient Advocacy Director and relevant Cluster Medical team should be consulted.

3.14 Before engaging with Patients, a legitimate need for the interaction must be clearly identified and documented.

3.15 Interactions shall not be entered into with the intent of inducing the administration, consumption, prescription, purchase, recommendation, sale, supply or use of a KKI product.

3.16 KKI must not request that Patients promote or endorse a KKI medicine.

3.17 Mutual respect should form the basis for any partnership with Patients; this means that each partner must give equal value to the views and decisions of the other. All activities and outcomes should be performed with the common goal of benefiting patients.

3.18 KKI shall not influence the opinions or activities of Patients and shall ensure all efforts are taken to preserve the independence of Patient Advocacy Groups regarding their policies, activities, judgement, and views. The objectives and scope of any engagement with Patients must be transparent.

3.19 The objective and scope must be agreed, clearly defined, and documented at the outset of the project. The Patients must understand the reasons and full context of interacting with KKI.

3.20 KKI will seek to inform the Patients of the outcomes of initiatives and interactions they have been involved in.

3.21 KKI will seek to obtain systematic patient input throughout the lifecycle of KKI medicines.

3.22 Engagements with Patients must support healthcare, scientific research, or education.

3.23 KKI shall not seek direct commercial return on investment from any financial or non-financial support provided to Patients but will consider the benefits of an interaction from a societal, Patient-Centric and Healthcare perspective.

3.24 KKI must never request nor require, as a condition of providing funding, that KKI be the sole funder of a Patient Advocacy Group or any of its major programmes and should encourage the Patient Advocacy Group to seek a diversity of funding sources where possible. KKI only provides less than 50% of a Patient Advocacy Group's total income.

3.25 KKI will not directly or indirectly establish or co-create a Patient Advocacy Group, except under exceptional circumstances approved by the Head of Medical Affairs and Compliance.

3.26 KKI shall not provide any advice on personal medical matters but if requested to do so will advise the Patient to consult their healthcare professional.

3.27 Any consultancy interaction with KKI clinical trial participants will be deferred until the Patient's involvement in the clinical trial has ended.

3.28. A KKI employee can provide their experience as a patient as part of a consultancy service to KKI only if they voluntarily come forward and there is a legitimate reason to include their experience in the activity.

3.29 Collection or sharing of Personal Information and/or Sensitive Personal Information should be limited to what is necessary for the agreed purpose of the engagement.

WRITTEN AGREEMENTS

4.1 A Written Agreement (and where applicable consent) must be in place before execution of the activity. If local laws or regulation require additional steps to verify the status of the association or to declare the activity prior to implementation, it is the responsibility of the affiliate to ensure these are followed before the agreements are executed.

4.12 All Written Agreements should be, as a minimum, reviewed and approved by the Legal Department and a director with the authority to contractually commit KKI (or its Affiliates) before submission to the Patient. It is recommended the agreements are reviewed by the KKI Patient Advocacy Director (regional activities) or local Patient Primary Point of Coordination (PPOC) (local activities). Where applicable, certification may also be required to comply with local laws and regulations.

4.13 Fees consistent with but not more than fair market value may be paid to Patients for advice or insights (subject to regional/local laws and regulations) and to Patient Advocacy Groups for supporting healthcare initiatives or research. Where a participant is an employee of a Patient Advocacy Group or is representing a Patient Advocacy Group, the Written Agreement and any fees will be paid to the Patient Advocacy Group and not the individual.

MATERIALS, EDITORIAL CONTROL AND USE OF LOGOS AND PROPRIETARY MATERIALS

5.1 Any materials developed for Patients must conform with the national regulatory requirements in the country in which the Patient resides, must be consistent with the market authorisation for the product in that country and must not be promotional in nature.

5.12 All materials for Patients must be reviewed and approved prior to distribution.

5.13 Any financial or non-financial support provided by KKI shall be clearly acknowledged on all relevant materials and shall be apparent from the outset of the activity (as applicable).

5.14 KKI shall never seek to improperly influence the content of any materials written by Patients. The independence of the Patients must be respected. Improper influence specifically includes attempts to include in materials information favourable to KKI's commercial interests. Correcting a factual inaccuracy would not constitute improper influence.

5.15 Where requested in writing, KKI can contribute to the drafting of Patient Advocacy Group materials from a fair and balanced scientific perspective. This also

applies to materials which are co-created between KKI and the Patient Advocacy Group. Where KKI does provide such drafting support, it is important that is acknowledged on all relevant materials.

5.16 KKI can only use a Patient Advocacy Group's logo and/or proprietary material with the prior written permission of that organisation. When obtaining written permission KKI must be clear on how and for what purpose the organisation's logo and/or proprietary material will be used.

TRANSPARENCY

6.1 In some countries it is a requirement for KKI to make publicly available annually a list of Patients, Patient Advocates, Care Partners and/or Patient Advocacy Groups to which KKI provides financial support and/or significant indirect/non-financial support (including grants and sponsorship and including in relation to events/meetings). Disclosure requirements vary by country, it is important to clarify these with the Local Compliance Contact when providing support to a Patient.

HOSPITALITY, TRAVEL AND ACCOMODATION

7.1 KKI must only provide hospitality, travel or accommodation to persons who qualify as a participant or delegate. This includes Care Partners.

7.12 Travel arrangements for Patients should follow the same guidance as applied to KKI staff.

PATIENT SUPPORT

8.1 KKI can provide Healthcare Professionals with materials and items for patient support which are to be passed on to Patients. The items must:

- Directly benefit patient care (item should be related to either the condition under treatment or general health)
- Be inexpensive
- Not be product branded (unless the name of the medicine is essential for the correct use of the item), but may bear the name of the company providing them
- Not be given out from exhibition stands
- Not be given to administrative staff unless they are to be passed on to Healthcare Professionals
- Be appropriately documented and certified in advance

GIFTS AND ITEMS OF VALUE

9.1 Gifts for personal benefit must not be given, either directly or indirectly to any Patient Advocacy Group or any individual associated with a Patient Advocacy Group.

9.12 Gifts must not be intended to, or be perceived as intending to, incite unlawful or improper influence.