CASE/0236/07/24

COMPLAINANT v ALNYLAM

Allegations regarding two collaborative working projects

CASE SUMMARY

This case was in relation to two joint working projects between Alnylam and a specialist NHS centre. The complainant made numerous allegations regarding both projects which the Panel considered broadly related to the lack of clarity in the published executive summaries regarding the significant contribution from the parties, that one of the joint projects was a switching service disguised as joint working, that relevant documents had not been certified at the appropriate time, and that there had been a failure to correctly disclose transfers of value in relation to these projects.

The outcome under the 2021 Code was:

Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 20.3 (x3)	**Failing to meet the requirements for collaborative working in relation to the summaries of the collaborative working agreement**

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 5.1 (x2)	**Requirement to maintain high standards at all times**
No Breach of Clause 8.3 (x2)	**Requirement to certify certain non-promotional material**
No Breach of Clause 19.1 (x2)	**Requirement that no gift, pecuniary advantage or benefit may be supplied, offered or promised to health professionals or to other relevant decision makers in connection with the promotion of medicines or as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine**
No Breach of Clause 20.2	**Requirement that collaborative working must have and be able to demonstrate the pooling of skills, experience and/or resources from all of the parties involved**
No Breach of Clause 20.3 (x6)	**Requirement that:** • **Collaborative working must not constitute an inducement to prescribe** • **Collaborative working must have a summary of the collaborative working agreement publicly available before arrangements are implemented** • **The summary of the collaborative working agreement must be certified**

No Breach of Clause 20.4 (X2)	**Requirement that joint working between one or more pharmaceutical companies and the NHS and others which is patient centred and always benefits patients, is an acceptable form of collaborative working, providing it is carried out in a manner compatible with the relevant requirements of the Code**
No Breach of Clause 20.5 (x3)	**Requirement that transfers of value in connection with collaborative working must be publicly disclosed annually**
No Breach of Clause 23.1	**Requirement that donations are freely given for the purpose of supporting healthcare with no consequent obligation on the recipient organisation to provide goods or services to the benefit of the pharmaceutical company in return**
No Breach of Clause 23.2	**Requirement that donations to healthcare organisations do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific medicines**
No Breach of Clause 31.1 (x3)	**Requirement that disclosures must be made annually in respect of each calendar year**

This summary is not intended to be read in isolation.
For full details, please see the full case report below.

FULL CASE REPORT

A complaint was received about Alnylam, from an anonymous, contactable complainant who described themselves as a health professional.

COMPLAINT

The complaint wording is reproduced below with some typographical errors corrected:

"**Alleged funding of a switching service under the disguise of Joint Working.**

Complaint 1

Please see Joint working Project Summary as per available on [URL provided]

"[Named NHS specialist centre and Alnylam UK (Alnylam) Joint Working Project: [named disease] Therapeutic Review"

NP-UK_00304 – DOP October 2023.

The relevant part of the short executive summary is below:

"Executive Summary

Alnylam and the [named specialist centre] will enter a collaboration (Joint Working Agreement (JWA)) to increase the capacity of the [named specialist centre] to support implementation of therapeutic reviews for adult patients with [named disease]. The prescribing HCP at the [named specialist centre] will review each patient's current therapy and may elect to prescribe a different therapy that is more beneficial to the patient. This project will be independent of the prescription decision, which will be carried out by the prescribing HCP at the [named specialist centre]. The project will commence in April 2023. The project term is 12 months*"*

"The prescribing HCP at the [named specialist centre] will review each patient's current therapy and may elect to prescribe a different therapy that is more beneficial to the patient."

- It is unclear from the description as what is the company contribution vs NHS contribution or if there is any third party involvement.
- Searching the internet on Disclosure UK website, Alnylam's declaration [reference number redacted] mentions £39,898.00 spent on collaborative working. This is the
  only collaborative working declared in 2021, 2022 and 2023. No information is provided in the executive summary as to the reasons for provision of this funding.
- This funding seems to be for running a therapy review service via a prescribing HCP – this points towards an inducement to prescribe?
- The executive summary does not provide any details of the NHS contribution or clarity around any significant contribution of pooled resources or any requirement for the baseline to be measured.
- A collaborative working requires transparency. However, the level of transparency is very opaque. On searching the internet for the company drugs and NICE recommendations, the timing of the provision of funds is in line with NICE recommendations (published 15th February 2023) for 'vutrisiran' one of the two company owned drugs used for treatment of the condition at this centre as per the NICE publication.
  • The NICE guidance resource impact report mentions 87%-91% market share for vutrisiran (new) in the next 5 years with the switch from the older company drug – patisiran.
    - *"**Assumptions: 4.2** The resource impact template assumes that: • **87% of people currently receive patisiran**; 6% receive inotersen and 7% receive best supportive care. • **91% of people will receive treatment with vutrisiran from 2027/28 with 0% receiving patisiran**, 4% of people receiving inotersen and 5% receiving best supportive care".*

- This further confirms that the therapy review is a switching service to reach very high levels of conversion for the new drug and the company has actively participated in this service by providing funds.

  NP-UK_00304 further mentions:

  "*The project will commence in April 2023. The project term is 12 months*"

- If the Project commenced in April 2023, however, the Date of preparation of NP-UK_00304 mentions October 2023. It seems that the summary of this alleged joint working has been produced 6 months post commencement of the project.

  Furthermore, NP-UK_00304 also mentions:

  "This document was originally produced by Alnylam and the [named specialist centre] on March 1st, 2023." –

- This leads to a further understanding that this summary was not certified as the final summary document. The Two dates on this one document leads to an understanding that the project was not a genuine joint working but a provision of a grant or a service or worse – an inducement to prescribe. The cover up seems to be classified as a joint working – after starting of the program.

  Additional Possible reasons for multiple versions of the document

- Multiple projects seem to being classified as Joint Working at the same centre with a suspected longer duration and possibly a larger amount of funding – please see next joint working executive summary NP-UK-00396 | June 2024.

  Complaint 2 – Another joint working at the same centre with more resources.

  NP-UK-00396 | June 2024

  "[Named specialist centre] and Alnylam UK (Alnylam) Joint Working Project: [named disease] Genetic Counsellor"

- The Project seems to provide 2 additional headcount – a genetic counsellor and an additional lab technician for 37 months!
- The Project start date as per NP-UK-00396 is mentioned as November 2023. The Date of preparation is June 2024 – This repeats the above mentioned issues ie:
  - the final summary does not seem to be certified before the start of project,
  - the current date of prep is 8 months after the start of the project.
  - Is this also an afterthought joint working?

- There was no declaration on the amount of funding provided by the company as per the disclosure UK website or clarity around the significant contribution from the NHS other than receiving 2 head counts for a service that the NHS already should be providing. – There seems to be a failure to disclose the funding amount for the project that started in November 2023 and the updated document is from June 2024.
- Total disclosures by the company under collaborative working is a single line item 2021-23 whereas the company website has 3 executive joint working summaries – This leads to believe that there is a systematic failure of disclosures. This warrants further scrutiny on the disclosure from this company.

- As per the company website, a majority (2/3) joint working projects seem to be directed at one centre at one NHS trust which would additionally point towards inducement to prescribe.

  It is alleged that the company has breached several clauses not limited to:

Clause Breaches

Breach of Clause 31.1 - Failing to make disclosures annually in respect of each calendar year in the first six months after the end of the calendar year in which the transfers of value were made.

Breach of Clause 20.3 - Failing to certify final summaries of the collaborative working before start of service.

Breach of Clause 20.5 - Failing to disclose transfers of value made by companies in connection with collaborative working must be publicly disclosed.

Breach of Clause 23 - Provision of grant for switching service disguised as therapy review

Breach of Clause 19 – Prohibition on inducement and inappropriate payments

Breach of Clause 9.1 – Failure to maintain high standards

Breach of Clause 2 – Alleged provision of funds for company planned switch service disguised as a therapy review. Non-disclosure of Collaborative working with disclosure UK. Inducement to Prescribe. – Bringing the industry into disrepute."

Further information provided by the complainant

The complainant provided further information in relation to the complaint, reproduced below:

"In search of additional evidence for this case, I would like to submit two additional materials as evidence from online searches.

Please find attached NP-UK-00209 dated March 2023 which seems to be the precursor of the currently available summary for the alleged Therapeutic Review/Switching service NP-UK-00304 dated Oct 2023.

The difference in these documents relate to the duration of the project - the older document has 9 months whereas the newer has it for 12 months.

If the documents NP-UK-00209 is to be believed and the project was completed in December 2023, it has been 8 months since the completion with no results being posted (breach of clause 20).

The second attachment NP-UK-00322 | November 2023, similarly, is a precursor to the current NP-UK-00396 | June 2024. Again the duration has been increased from 27 months to 37 months.

Both these documents prove changes to the final agreed funding provision disguised as joint working. NP-UK-00209 is headlined as "[named specialist centre]-joint-working-executive-summary-nurse-provision.pdf" which confirms provision of a nurse which both document summaries are unambiguous about.

All in all, the two disguised joint working has provided funding for a nurse, a genetic counsellor and a lab technician. Provision of these 3 additional headcounts at the same one centre can easily be seen as an inducement to prescribe."

When writing to Alnylam, the PMCPA asked it to consider the requirements of Clauses 2, 5.1, 19.1, 20.3, 20.5, 23.1 and 31.1, as cited by the complainant. In addition, the company was also asked to consider Clauses 8.3, 20.2, 20.4 and 23.2 of the 2021 Code.

ALYNLAM'S RESPONSE

The response from Alnylam is reproduced below with some typographical errors corrected:

"Thank you for your letter dated 22 July 2024, which Alnylam UK Limited (**Alnylam**) acknowledged receipt of by email on 22 July 2024.

Your letter detailed a complaint brought under the 2021 ABPI Code of Practice (the **Code**) regarding two joint working projects and enclosed a copy of the complaint as submitted by the complainant. We acknowledge the request to consider the requirements of several clauses of the Code in light of the evidence provided by the complainant.

Thank you also for your emails dated 15 and 16 August 2024, the latter containing further information you received from the complainant in relation to the above complaint.

Alnylam is the UK affiliate of Alnylam Pharmaceuticals Inc., a global pharmaceutical company specialising in the discovery and development of RNA interference medicines.

Alnylam takes compliance with the Code very seriously and is committed to adhering to the Code. In developing the two joint working projects that are the subject of the complaint, Alnylam carefully considered the principles of the Code, including the specific requirements that establish joint working as a specific type of collaboration between the NHS and the pharmaceutical industry. Alnylam also consulted the ABPI guidance document "Joint Working - A toolkit for industry and the NHS" (the **Toolkit**) and the ABPI guidance document "Working together - A guide for the NHS, healthcare organisations and pharmaceutical companies" (the **Working Together Guide**). These resources provided invaluable direction to ensure the projects were designed and executed with the utmost integrity and compliance.

Complaint

The complaint makes several specific allegations in relation to two joint working projects between Alnylam and a highly specialised NHS centre. The first project

is titled Therapeutic Review (**Project 1**) and the second project is titled Genetic Counsellor (**Project 2**).

The evidence put forward by the complainant to support the allegations is the publicly available information about the two joint working projects. This information comprises the joint working executive summaries published on the websites of both Alnylam and the NHS centre and the disclosed transfer of value (**ToV**) data available on Disclosure UK. By way of additional information, the complainant provided some additional versions of the executive summaries on 15 August 2024.

The PMCPA has asked Alnylam to respond in relation to the requirements of Clauses 2, 5.1, 8.3, 19.1, 20.2, 20.3, 20.4, 20.5, 23.1, 23.2, 31.1 of the Code.

Alnylam response

Alnylam's response is below.

Introduction

Please refer to section 1 of the Confidential Annex for an introduction to Projects 1 and 2 that contextualises the joint working projects.

The following documentation in relation to Project 1 and Project 2 is enclosed with this letter:

- joint working agreement (including the project initiation document in appendix A to the joint working agreement (**PID**));
- variation agreement relating to joint working agreement;
- executive summaries published online (including all versions), corresponding certificates and the qualifications of the signatories;
- minutes from meetings of each project steering committee.

As requested, we enclose copies of the summaries of product characteristics (SmPCs) of relevant medicinal products.

Our response is divided into two sections, one for each project. In each section, we respond to the four broad allegations raised by the complainant in relation to each project:

1. requirements for joint working projects;
2. prohibition on inducements to prescribe;
3. certification of joint working executive summaries; and
4. annual disclosure of transfers of value in connection with the joint working projects.

Project 1: Therapeutic Review Joint Working

Requirements for collaborative working (Clause, 20.2, Clause 20.3, Clause 20.4)

The complainant makes several allegations as regards the validity of Project 1 as a joint working project under Clause 20 of the Code.

The complaint states that there is a lack of clarity as regards:

- Alnylam's contribution and the NHS' contribution under Project 1;
- the significant contribution of pooled resources under Project 1;
- if there is any third party involvement.

The summary of Project 1 set out in section 2 of the Confidential Appendix clearly sets out the significant contributions of both parties to Project 1. Furthermore, we note that a well-established principle of joint working projects is that the significant contribution from each party need not be financial in nature. The Toolkit states *"[c]ontribution of resources may come in various forms, including people, expertise, equipment, communication channels, information technology and finance.*" The Working Together Guide further states that *"[r]esources may come in various forms, including people, expertise, equipment, communication channels, information technology and finance*."

Project 1 represents the pooling of resources by Alnylam and the Expert Centre, with each party making a significant contribution to the project, Alnylam's in the form of a financial contribution and the Expert Centre's in the form of its significant time and expertise as the only highly specialised commissioning service that manages and treats all patients in the relevant disease area in the UK. This conforms to the principle of pooling resources and reiterates the significant non-financial contributions made by the Expert Centre, which are in line with the ABPI Toolkit and Working Together Guide.

Enclosure 1 and the executive summary viewed by the complainant show that there is no third party involvement, which is questioned by the complainant in the first bullet point on page 1 of the complaint.

The complaint also questions whether there was a requirement under Project 1 for the baseline to be measured. We confirm that Project 1 was duly monitored against the project objectives throughout its term. In this regard, Alnylam and the Expert Centre worked together throughout the term of the project to monitor its delivery:

- the Expert Centre gathered anonymised, aggregated, outcome-focused data throughout the project; and
- this data was reported at meetings of the Project 1 Steering Committee on 3 August 2023, 23 November 2023 and 28 March 2024 and was used to ensure that the project was monitored against the outcomes agreed at the outset.

The complaint questions the reasons for the funding. In this regard, the purpose of Project 1 was to increase the capacity of the Expert Centre to carry out therapeutic reviews for adult patients within scope of the project. Alnylam's contribution funded additional nurse resource to support the:

(i) scheduling of the therapeutic reviews (the reviews which would take place irrespective of whether Project 1 was implemented); and
(ii) process post- therapeutic review.

The Expert Centre did not have the resource to fully manage any additional workload stemming from the therapeutic reviews including supporting and assessing patients post-therapeutic review. This represented an unmet need for patients at the Expert Centre that the project sought to address. Highlighting the unmet need that Project 1 aimed to address reinforces the project's patient-centric focus and its alignment with improving healthcare services.

The complainant makes allegations in relation to the timing of the start of Project 1 in light of the publication of NICE's technology appraisal guidance for vutrisiran, an Alnylam therapy, for treating [named disease]. The complaint goes on to reference some extracts from the NICE resource impact report, associated with the NICE guidance, related to the estimated impact that vutrisiran will have in the market following adoption of the guideline.

The NICE technology appraisal guidance was published on 15 February 2023, before Project 1 was agreed. This document sets out NICE's decision to recommend vutrisiran as a treatment for patients with [named disease]. The conclusions are based on the scientific evidence put forward by Alnylam during the technology appraisal process. The estimated number of patients receiving vutrisiran in the future included in NICE's resource impact report referred to in the complaint is based on the superiority of vutrisiran compared to patisiran demonstrated by the data, as set out in the NICE assessment, so unrelated to and independent of Project 1.

Project 1 itself does not affect the outcome of the therapeutic review, which would routinely be carried out by the Expert Centre on an annual basis for all patients irrespective of the project. In the therapeutic review, available therapies are assessed based on clinical criteria and any new NICE recommendations would be taken into account objectively. However, to reiterate, it is critical to note that Project 1 does not influence nor set-up the therapeutic reviews themselves, and that the market impact projections are unrelated to the project.

The complainant accuses the joint working of being opaque. However, this is not true. The background section of the PID for Project 1 acknowledges the existence of the NICE recommendation for vutrisiran, so there was full transparency about this development. The acceleration of therapeutic reviews at the Expert Centre enabled relevant patients to be reviewed in a shorter period of time, without impacting or influencing prescription decisions themselves.

The complaint goes on to criticise the level of transparency in relation to Project 1. As set out later in this response, Alnylam has complied with the requirements of the Code relating to transparency of joint working projects by publishing summaries of both projects prior to commencement of the applicable project and disclosing all transfers of value. Alnylam is not required to make public any other documents relating to the project. As Project 1 concluded in March 2024, Alnylam had until the end of August 2024 to publish a summary of the outcomes of the project to be within the recommended timeline of 6 months upon finalisation of the joint working as set out in the Working Together Guide. Alnylam published the summary on its website on 29 August 2024. The summary comments on the outcomes and experience of the joint working, enabling others to learn from the

initiative. Reaffirming compliance with transparency requirements and the intent to share outcomes for the benefit of broader learning.

The complaint alleges that Project 1 is a switching service. This is not correct.

Project 1 did not purport to set-up nor affect the therapeutic review or clinical decision-making. The therapeutic review was conducted by Expert Centre clinicians alone based on clinical criteria without Alnylam's involvement, and it would have taken place anyway irrespective of Project 1. The project only shortened the time for patients to be reviewed. Clinicians in the Expert Centre were not required or incentivised to move patients from a particular therapy to another and Alnylam did not monitor the prescriptions that were written during the therapy reviews in connection with Project 1.

The complaint alleges that Project 1 breaches the requirements of Clause 20 of the Code in that it is not a genuine joint working project but is a provision of a grant. The evidence provided shows that this is a fully complaint project:

- both the Expert Centre and Alnylam have contributed to the project with time, people, expertise (the former) and finance (the latter);
- the Expert Centre has gathered data in accordance with the terms of the joint working agreement;
- the parties have monitored the development of Project 1 once initiated and the Project Steering Committee has met regularly to assess the progress of the project; and
- Alnylam has been able to ensure that the Expert Centre was contributing to Project 1 as agreed; otherwise, it would have terminated the agreement in accordance with clause 6 of the joint working agreement and would have the right to be refunded the unused portion of the financial contribution in accordance with clause 6.4 of the joint working agreement.

Emphasising the robust monitoring and evaluation mechanisms in place ensures compliance and mutual contribution throughout the project.

For the reasons set out in this section, Alnylam considers that Project 1 is a fully complaint joint working project and was set up and conducted in line with the requirements of Clause 20 of the Code. Therefore, it is not necessary to consider the requirements of Clauses 23.1 and 23.2 of the Code as cited by the complainant, relating to donations and grants. Alnylam refutes the allegation that Project 1 is not a genuine joint working but a provision of a grant and, as a result, the breaches of these clauses.

In conclusion, Alnylam refutes the alleged breaches of Clause 20.2, 20.3, 20.4, 23.1 and 23.2 of the Code.

Prohibition on inducement to prescribe (Clause 19.1, Clause 20.3)

The complaint alleges that Project 1 breached the prohibition on providing inducements to prescribe. The complaint states that "[t]his funding seems to be for running a therapy review service via a prescribing HCP – This points towards inducement to prescribe."

The complainant has provided no explanation to support this allegation. The funding was provided to the Expert Centre and there was no resulting benefit to any HCP or other relevant decision maker. Project 1 is separate to the therapeutic review itself conducted by the Expert Centre. The project does not fund the therapeutic review and this therapeutic review would have taken place anyway, without the existence of Project 1.

The financial resources provided by Alnylam under Project 1 are to fund the staff requirements associated with the project, specifically the hiring of a full-time band 6 nurse. This nurse was not a prescribing nurse and was not involved in the therapeutic review itself but assisted with the pre- and post-therapeutic review activities stemming from the accelerated therapeutic review timetable. These activities include assessing the experience of patients by completing the "Pre & Post" patient satisfaction questionnaire with each patient in relation to their experience throughout the process and coordinating clinical logistics to meet the needs of patients prescribed with a different therapy and conducting six-month review appointments. To reiterate, the nurse funded by Project 1 had no role in prescribing. The project is structured to ensure that the duties of the funded nurse and the Expert Centre under Project 1 are separated. This prevents there being any risk of any potential inducement to prescribe.

In view of the above, Alnylam refutes the alleged breaches of Clause 19.1 and Clause 20.3.

Certification of executive summary (Clause 8.3, Clause 20.3)

The complaint makes several allegations in relation to the certification of the executive summary for Project 1, and provides two versions of the executive summary. The first version was enclosed with the initial complaint and a second earlier version (that is no longer available on the Alnylam website) was found while "*in search for additional evidence for this case*" and provided to the PMCPA on 15 August 2024. In relation to these allegations, we refer to the three versions of the Project 1 executive summary that have been made publicly available, NP-UK-00198, NP-UK- 00209 (the version provided by the complainant on 15 August 2024 to the PMCPA) and NP-UK- 00304 (the version provided by the complainant with the initial complaint). Each version underwent rigorous review and certification processes to ensure compliance with the ABPI Code. The documented certifications, detailed below, affirm that all necessary steps were taken to uphold the integrity and transparency of the project.

The complainant cites the text of the third version in the initial complaint and, based on the dates set out in this third version, alleges that:

- the summary was produced 6 months after the start of the project;
- the summary was not certified as the final summary document.

In the complainant's communication of 15 August 2024, the complainant refers to the second version and states that "*The difference in these documents relate to the duration of the project - the older document has 9 months whereas the newer has it for 12 months. If the documents NP-UK- 00209 is to be believed and the*

project was completed in December 2023, it has been 8 months since the completion with no results being posted (breach of clause 20)." This is not correct as explained below.

The facts set out below explain the entire sequence of events and show that all requirements were met in relation to the certification of the executive summaries related to Project 1.

The first version was made publicly available on the Alnylam website on 3 April 2023. This is the start date for Project 1 as it is the date that the nurse was allocated to the project (evidence of this can be provided upon request). This version was certified on 21 March 2023 by a UK Final Medical Signatory. The start date for the project was 3 April 2023 as opposed to 1 March, despite this date being listed in the project documentation. This is because there was a delay to the start of the project following execution of the joint working agreement for Project 1. The first version was available until 5 May 2023.

The second version was published on the same site on 5 May 2023. This version made a very small amendment to the way in which the parties at the top of the summary were named. The small amendment was to ensure consistency between the summary and the joint working agreement as regards the way in which the parties were named. The second version was certified on 3 April 2023 by a UK Final Medical Signatory. The second version replaced the first version online and was available until 16 November 2023.

The third version was published on the same site on 16 November 2023, replacing the second version. This version resulted from a variation to the terms of the joint working agreement agreed between Alnylam and the Expert Centre on 27 September 2023. It was certified on 5 October 2023 by a UK Final Medical Signatory. The third version replaced the second version online and is the version of the summary that is available to date.

In summary, Alnylam confirms that:

- The first version was made publicly available before the start date of the project; and
- The first, second and third versions were all certified in final form before being made publicly available.

Therefore, Alnylam refutes the alleged breaches of Clause 8.3 and Clause 20.3 in relation to the certification of the executive summaries relating to Project 1.

Disclosure of ToV (Clause 20.5, Clause 31.1)

The complaint states "searching the internet on Disclosure UK website, Alnylam's declaration mentions £39898 spent on collaborative working. This is the only collaboration declared in 2021, 2022 and 2023."

As Project 1 did not commence until April 2023 there were no ToVs from Alnylam to the Expert Centre in connection with Project 1 in the calendar years 2021 or

2022. This timeline clarifies the period in question and eliminates any ambiguity regarding previous years' disclosures.

The joint working agreement for Project 1 was signed on 3 March 2023 and the project start date was 3 April 2023, even if the start date listed in the joint working agreement was 1 March 2023. We note that, as mentioned above, there was a delay to the start of Project 1, it did not commence until 3 April 2023, the date when the nurse was appointed to the role. Alnylam confirms that in 2023, one sole payment of £39,898 was made to the Expert Centre on 18 December 2023 in connection with this project. This payment corresponds to the ToV of £39,898 to the [named NHS trust] disclosed under the category of "Collaborative Working" in Alnylam's annual disclosure report for the calendar year 2023. This is in line with Alnylam's Transparency Reporting Methodological Note applicable to the 2023 annual ToV disclosure (**2023 Methodological Note**) which states that "[t]oV will be declared according to the year in which the payment or transfer takes place, that is the date of the wire transfer to the recipient occurs as opposed to the date of the event or supporting agreement."

Therefore, in respect of Project 1, Alnylam refutes the alleged breach of the requirement to publicly disclose transfer of value made by companies in connection with collaborative working annually as set out in Clause 20.5 and Clause 31.1 of the Code. Alnylam's commitment to transparency and compliance is further evidenced by our adherence to these disclosure requirements.

Project 2: Genetic Counsellor Joint working

Requirements for collaborative working (Clause, 20.2, Clause 20.3, Clause 20.4)

The complainant makes several allegations as regards the validity of Project 2 as a joint working project under Clause 20 of the Code.

The complaint states that "[t]he Project seems to provide 2 additional headcount – a genetic counsellor and an additional lab technical for 37 months".

As set out in the summary of Project 2 and the documentation enclosed, this statement does not accurately reflect Project 2. The project involves collaboration between Alnylam and the Expert Centre to increase the availability of genetic counselling for patients and the families of patients within scope. The project does involve the funding of a part-time genetic counsellor and a lab technician. However, the period in which these individuals are funded under Project 2 is 24 months and not 37 months (even if the duration of the project is 37 months). The reason for the extension to 37 months was due to a delay in the first recruitment stage; effectively a delay to the start of the project.

The complainant further states that there is no "clarity around the significant contribution from the NHS other than receiving 2 head counts for a service that the NHS already should be providing".

The contribution of the Expert Centre under Project 2 is set out in detail in section 3 of the Confidential Appendix. As set out above in relation to Project 1, a well-

established principle of joint working projects is that the significant contribution from each party need not be financial in nature. As the Expert Centre is the only centre in the UK specialising in the relevant rare disease, its expertise is unique and paramount to the development and delivery of Project 2.

Without Project 2, the Expert Centre would not have adequate funding to make timely genetic counselling services available to all individuals that may benefit from it. The considerably limited availability of genetic counselling at the Expert Centre represents an unmet need which Project 2 aims to address.

Alnylam considers that this project is a compliant joint working project set up and conducted in line with the requirements of Clause 20 of the Code. Therefore, we do not consider it necessary to consider the requirements of Clauses 23.1 and 23.2 of the Code as cited by the complainant, relating to donations and grants, and Alnylam refutes the alleged breaches of these clauses.

Prohibition on inducement to prescribe (Clause 19.1, Clause 20.3)

The complaint states that "a majority (2/3) joint working projects seem to be directed at one centre at one NHS Trust which would additionally point towards inducement to prescribe."

This allegation that Project 2 breaches the prohibition on inducements to prescribe is speculative and unsupported by any evidence.

As mentioned, the funding provided by Alnylam under Project 2 is to fund the salaries of a part-time genetic counsellor and a lab technician, recruited externally from the Expert Centre. No element of Project 2 relates to prescribing decisions. There is no aspect of this project that could be construed as an inducement to prescribe.

The Expert Centre is the only NHS commissioned centre of its kind in the UK and undertakes the vast majority of activities that relate to all aspects of the relevant rare disease area, from providing advice and support, to genetic testing, to clinical management of patients.

Given the national role of the Expert Centre and that it is the only Centre commissioned by NHS to manage this rare disease in the UK, partnering with this centre would enable all relevant patients across the UK to have equitable access to the service and experience the benefits of the Project. This is an element outside of Alnylam's control but necessary for the project to positively benefit patients. In any event, Alnylam and the Expert Centre carefully structured and monitored the project to ensure the parties remained at arm's length and the project remained independent of prescribing decisions.

Certification of executive summary (Clause 8.3, Clause 20.3)

The complainant makes specific allegations in relation to the executive summaries for Project 2. Two versions of the Project 2 executive summary have been made publicly available, NP-UK-00322 and NP-UK-00396.

The complaint cites the text of the second version in the initial complaint and, based on the dates set out in this second version, questions:

- whether the final version of the summary was certified before the start of Project 2; and
- why the date of preparation on NP-UK-00396 is 8 months after the start of the project.

In the complainant's communication of 15 August 2024, the complainant refers to the second version , merely alleging that "[a]*gain the duration has been increased from 27 months to 37 months*."

These allegations raised by the complainant are based on incomplete information available to the complainant in relation to Project 2. Based on the facts set out below, it is clear that all requirements were met in relation to the certification of the executive summaries related to Project 2. Each version underwent rigorous review and certification processes to ensure compliance with the ABPI Code. The documented certifications, detailed below, affirm that all necessary steps were taken to uphold the integrity and transparency of the project.

The first version was made publicly available on the Alnylam website on 16 November 2023, prior to the start date of Project 2 (30 November 2023) and was certified on 7 November 2023 by a UK Final Medical Signatory. This version was available online until 10 July 2024.

The second version was published on the same site, replacing the first version, on 10 July 2024 as a result of the variation to the terms of the joint working agreement agreed between Alnylam and the Expert Centre on 2 July 2024. The second version was certified on 28 June 2024 by a UK Final Medical Signatory. The second version is the version of the summary that is available online to date.

In summary, Alnylam confirms that:

- The first version was made publicly available before the start date of the project; and
- both the first and second versions were certified in final form before being made publicly available.

Therefore, Alnylam refutes the alleged breaches of Clause 8.3 and Clause 20.3 in relation to the certification of the executive summaries relating to Project 2.

Disclosure of Transfer of Value (Clause 20.5, Clause 31.1)

The complainant states that "there was no declaration on the amount of funding provided by the company as per the disclosure UK website" and "total disclosures under collaborative working is a single line item in 2021-23 whereas the company website has 3 executive joint working summaries – This leads to believe that there is a systematic failure of disclosures."

The “single-line item” referred to in the complaint is addressed in the Project 1 section and is the sole ToV made by Alnylam to the Expert Centre in 2023 in relation to Project 1.

Although the joint working agreement for Project 2 was signed in 2023, no transfers of value have been paid from Alnylam to the Expert Centre in connection with Project 2 to date; therefore none have been disclosed. This complies with the process set out in Alnylam’s 2023 Methodological Note. The Methodological Note states that “[t]oV will be declared according to the year in which the payment or transfer takes place, that is the date of the wire transfer to the recipient occurs as opposed to the date of the event or supporting agreement.”

Alnylam therefore refutes the alleged breach of the requirement to publicly disclose ToVs made by companies in connection with collaborative working annually as set out in Clause 20.5 and Clause 31.1 of the Code.

Alnylam is very disappointed that the complainant alleges a “systematic failure of disclosures”. This allegation is baseless and unsupported by any evidence. Alnylam UK has always complied with the requirements for disclosures, as evidenced by the extensive disclosures reported on [URL provided] by Alnylam within the required timeframes.

Cumulative effect of the Projects do not amount to an inducement to prescribe

In the additional information provided on 15 August 2024, the complainant states that: *“All in all, the two disguised joint working has provided funding for a nurse, a genetic counselor and a lab technician. Provision of these 3 additional headcounts at the same one centre can easily be seen as an inducement to prescribe.”* We object and disagree with the baseless allegation.

Above, we explain why each project on its own does not amount to an inducement to prescribe. Similarly, when considered jointly, the cumulative effect of the project do not give rise to an inducement to prescribe for the following reasons:

- the joint workings are legitimate and “true” joint workings, with clear and specific deliverables from both parties entering the joint workings;
- Alnylam has carefully monitored the completion of the phases / milestones and tasks by the Expert Centre, as it can be seen from the regular meetings by the Steering Committee;
- none of the roles funded by Alnylam under the Joint Workings have prescription capabilities or make any recommendations or otherwise influence prescription decisions.
- the Expert Centre is the only centre commissioned by NHS to manage this rare disease in the UK; partnering with this centre is necessary to implement a project that (i) truly improves patient care in this relevant rare disease area and (ii) enables all relevant patients across the UK to have equitable access to the service and experience the benefits of the joint workings. In order to maximise the benefit of the projects to the largest possible number of patients with this rare disease, it is unavoidable to partner with the Expert Centre. This is something outside of Alnylam’s

control.

Final remarks

In addition to the clauses of the Code set out in the sections above, the complainant alleged a breach of Clause 2 (upholding confidence in the industry) and Clause 5.1 (high standards must be maintained at all times). Alnylam considers that it has maintained high standards at all times. Further, Alnylam does not consider that this matter could bring discredit on the pharmaceutical industry.

We hope that the detail included in this response together with the level of project documentation enclosed demonstrates to the PMCPA the culture of transparency and compliance that Alnylam aims to foster. Alnylam remains committed to upholding the highest ethical standards and maintaining the trust and confidence of the healthcare community.

Once again, we appreciate the opportunity to address these concerns and reiterate our commitment to compliance with the Code."

Further response from Alnylam

Further information was provided by Alnylam in response to a request for additional information by the Panel. The response from Alnylam is reproduced below:

"Similar to our initial response, we refer to the [named specialist centre] as the Expert Centre in this letter to protect the privacy of the clinicians at the [named specialist centre].

We set out answers to your three questions related to Project 1 below.

1. *With respect to Project 1 (Therapeutic Review), Alnylam's response and certain sections of the Joint Working Agreement(JWA) and Project Initiation Document (PID) indicate that the therapeutic reviews were separate to Project 1 (page 6 of Alnylam's response letter) and would be carried out prior to the start of the project (paragraph 2.2 of JWA and section 'Project Plan, Timelines & Milestones' of the PID). However, the PID also describes the therapeutic reviews as both a resource (section 'Project Resources') and principal activity of the [named specialist centre] (section 'Principal Activities and Accountabilities'). Please confirm whether the therapeutic reviews are part of the joint working project and hence a resource provided by the [named specialist centre]?*

The term 'therapeutic review' has been used in two contexts; a broad and narrow context. In the broader context, the term is used to describe the end-to-end therapeutic review service. The end-to-end service includes scheduling appointments, conducting pre-assessment tests, patient reviews with an expert [named disease] clinician and post-review follow-up.

In the narrower context, the term is used to describe the specific review of patients by the specialist clinicians at the Expert Centre, including any patient management or prescribing decisions taken by such clinicians at or following review.

The resource provided by the Expert Centre to enable the therapeutic reviews (in the broader context) to take place in an accelerated timeframe does fall within the Expert Centre's contribution to Project 1.

Activities performed by such resource included:

(i) scheduling appointments;
(ii) pre-review assessments;
(iii) creating the pre- and post- patient satisfaction questionnaire;
(iv) expert clinicians attending the accelerated patient reviews.

As this is a rare disease area and patients are managed by specialist experts in [named disease], the unique composition of pre-clinical assessments and specialist patient reviews are a significant contribution to the Project.

The section headed 'Project Plan, Times & Milestones' of the PID sets out the tasks which took place following the project start date. The therapeutic review activities (in the broader context) took place after the project start date and, accordingly, are listed in this section. The Expert Centre did carry out therapeutic reviews prior to this project. However, the objectives of Project 1 were to accelerate the time in which patients were reviewed and provide better patient care and management post review by the clinician.

In hindsight, we acknowledge that the documentation could have better defined therapeutic reviews in the broad and narrow context. We will carefully consider this in any future joint working documentation.

2. *Furthermore, whilst we note Alnylam's submission that the therapeutic review was undertaken independently by the [named specialist centre] please confirm what framework or documents Alnylam had visibility of with respect to the conduction of these therapeutic reviews, including its approval and provide a copy of any such documents.*

To ensure independence of patient management and prescribing decisions:

(i) the Expert Centre led and had control over the patient therapeutic reviews (in the narrow context);
(ii) Alnylam did not have visibility over the Expert Centre's framework for carrying out the therapeutic reviews nor any documents specific to the discussions at the therapeutic reviews (in the narrow context).

At the time, the parties acknowledged that it was still important for Alnylam to monitor:

(i) the progress and outcomes of the project; and
(ii) whether resources dedicated to the project were being utilised correctly.

To this end, Alnylam did receive updates from the Expert Centre on the number of therapeutic review consultations conducted per month (in alignment with PID (Project Plan, Timeline & Milestones (phase 3) and clause 4.2 of the Joint Working Agreement). This information was collected either via the template set-out in Appendix D of the Joint Working Agreement for Project 1 or discussed at the steering committee meetings.

3. *Alnylam's response letter states that the additional nurse resource funded by it would support the "scheduling of the therapeutic reviews" (page 4 of Alnylam's response letter). The PID refers to the "scheduling and recall of relevant patients" to be "prior steps carried out by the [named specialist centre] independently" (section 'Project Plan, Timelines & Milestones' of the PID). Please clarify whether the nurse funded by Alnylam was involved in scheduling the review or whether their activity was limited to the post-therapeutic review period and what their exact responsibilities were.*

Scheduling therapeutic review consultations was an on-going task throughout the second phase of the project. Therefore, once appointed, this specific activity was conducted in part by the Expert Centre and in part by the nurse.

The Expert Centre was already scheduling consultations prior to the existence of Project 1, but the Expert Centre did not have the resources to carry out <u>all</u> scheduling of patient therapeutic reviews in the accelerated timeline. Therefore, the Expert Centre did schedule reviews prior to the project starting as part of their normal process, however, this responsibility was, in part, assumed and accelerated by the nurse once in post, in line with Project 1's objectives.

To clarify, the nurse funded by Alnylam was involved in the following activities:

(i) booking patient therapeutic review appointments;

(ii) supporting patients prescribed with a different therapy, such as:
- performing an assessment on the patient's [named disease] status;
- counselling the patient on the new therapy;
- assessing serum vitamin A levels;
- prescribing and counselling patients on any additional supplements required by prescription of alternative therapy;

(iii) completing the "Pre & Post" satisfaction questionnaire with each patient.

Thank you for providing Alnylam the opportunity to clarify the position. We do hope that the responses set out in this letter are helpful. We acknowledge that certain areas of the documentation could have described the parties' intentions more clearly. We will carefully consider these points in any future joint working documentation and reiterate our commitment to compliance with the Code."

PANEL RULING

This case was in relation to two joint working projects between Alnylam and a specialist NHS centre. The complainant made numerous allegations in relation to both projects which the Panel considered broadly related to the lack of clarity in the published executive summary regarding the significant contribution from the NHS, that one of the joint projects was a switching service disguised as joint working, that relevant documents had not been certified at the appropriate time, and that there had been a failure to correctly disclose transfers of value in relation to these projects.

The Panel noted the requirements for joint working and collaborative working were set out in Clause 20. Clause 20.1 described joint working as a limited form of collaborative working as set out in Clause 20.4. The latter stated that joint working, which was patient centred and always benefitted patients, was an acceptable form of collaborative working providing it was carried out in a manner compatible with Clause 20 and other relevant requirements of the Code. The Supplementary Information to Clause 20.4 reproduced the Department of Health's definition of joint working between the NHS and the pharmaceutical industry, as situations where for the benefit of patients, one or more pharmaceutical companies and the NHS pool skills, experience and/or resources for the joint development and implementation of patient centred projects and share a commitment for successful delivery. Each party must make a significant contribution, and the outcomes must be measured. The pooling of skills, experience and/or resources for collaborative working was a requirement of Clause 20.2.

The Panel bore in mind that the complainant bore the burden of proof and in relation to each project the complainant's evidence was limited to the executive summary.

The Panel considered the allegations against each project separately.

Joint Working Project 1 ('Project 1')

Allegation 1: In relation to the executive summary-*"It is unclear from the description as what is the company contribution vs NHS contribution or if there is any third party involvement"*

The complainant cited information from the published executive summary for Project 1 and alleged that it was unclear from the description within this summary as to what was the company contribution versus NHS contribution, or if there was any third-party involvement.

The complainant had provided information from, and a link to, an executive summary which was dated October 2023. Alnylam submitted that three versions of the executive summary for Project 1 had been made publicly available, and that the version provided by the complainant was the most recent. The Panel therefore based its ruling on this version.

Clause 20.3 of the Code stated in part, that collaborative working must *"have a summary of the collaborative working agreement publicly available before arrangements are implemented"*. While neither Clause 20 nor its supplementary information set out what should be included in the summary, the supplementary information listed points to be included in the written agreement, including an outline of the financial arrangements along with the roles and responsibilities of each party.

The Panel considered that although these related to the written agreement, the purpose of the summary was to reflect key aspects of the arrangements bearing in mind the principle of transparency. The Panel noted PMCPA guidance, in the form of a Q&A, stated:

> "*Do the financial arrangements for joint working need to be included in the Executive Summary?*
>
> *Yes. Joint working is a form of 'collaborative working', which requires the publication by the company of a summary of the collaborative working agreement. The agreement should include an outline of the financial arrangements. Clause 20 and its supplementary information provide more details on collaborative working*."

The Panel acknowledged that the Code did not specify exactly what information should appear in this publicly available summary, but it should be a summary of the collaborative working agreement. The Panel considered that whether a summary of a joint working agreement was a fair summary would depend on a number of factors including the nature of the joint working activity and its complexity bearing in mind the overall principle of transparency.

The Panel observed that the executive summary for Project 1 included the following information:

- the name of the project,
- a short summary of the project including its objective
- the commencement date and expected duration, and
- a short summary of the expected benefits to patients, the NHS specialist centre and Alnylam.

The Panel considered that there was very little detail provided within the executive summary for Project 1. The executive summary referred to a *"collaboration (Joint Working Agreement) to increase the capacity of the [named specialist centre] to support implementation of therapeutic reviews for adult patients with [named disease]"*. There was no further information summarising the contributions made by the company or the NHS, whether financial or non-financial, or the parties' roles and responsibilities.

Alnylam submitted that Project 1 was a collaboration to increase capacity at the specialist NHS centre to support already-existing therapy reviews for adult patients with [named disease]. By providing additional resource to support the specialist NHS centre pre- and post- the existing therapy framework, the aim was for patients to be reviewed within a shorter timeframe and, if appropriate, prescribed the most optimal therapy faster. Alnylam submitted that its contribution to the joint working was to fund the staff requirements associated with the project, specifically the hiring of a full-time band 6 nurse who would assist with pre- and post-therapy review activities. The Panel noted that Appendix A of the joint working agreement, within the section titled Project Manager, referred to an Alnylam project manager and stated that the time associated with project management support forms part of the Alnylam contribution. According to Alnylam the specialist NHS centre's contribution corresponded to experience, expertise, people and time, and included recruitment of the above-mentioned nurse and scheduling of relevant patients for the therapy reviews, preparing a 'pre & post' patient satisfaction questionnaire and carrying out monitoring and evaluation activities, and attending review meetings. The Panel noted that Alnylam's supplementary response additionally listed pre-review assessments and expert clinicians attending the accelerated patient reviews as part of the NHS centre's contribution and made clear that the NHS centre's contribution included carrying out the

therapy review. The Panel noted that none of this information was provided in the executive summary. The Panel noted that there appeared to be some inconsistencies between Alnylam's response and the Joint Working Agreement as to what exactly the contributions of the different parties entailed.

In the Panel's view, the executive summary did not adequately summarise the joint working arrangement, including an outline of the financial arrangements or the roles and responsibilities of the parties. The Panel ruled **a breach of Clause 20.3** in this regard.

Allegations 2 and 3: *"Searching the internet on Disclosure UK, Alnylam's declaration mentions £39,898.00 spent on collaborative working. This is the only collaborative working declared in 2021, 2022 and 2023. No information is provided in the executive summary as to the reasons for provision of this funding*"

The complainant stated that the only declaration on Disclosure UK from Alnylam in relation to collaborative working was £39,898 and that this was the only collaborative working declared in 2021, 2022 and 2023. It appeared to the Panel that the complainant was alleging that other transfers of value in relation to this collaborative working had not been disclosed.

Alnylam submitted that Project 1 did not commence until April 2023 and there had been no transfer of value to the NHS specialist centre in the calendar years of 2021 and 2022. One sole payment of £39,898 had been made to the NHS trust in connection with Project 1 in 2023, which was in-line with Alnylam's methodological note that a transfer of value would be declared according to the year the payment or transfer is made and not the date of the event or supporting agreement.

The complainant had the burden of proving their complaint on the balance of probabilities. The Panel noted that the complainant had provided no evidence to support the allegation that additional payments had been made in relation to Project 1 in 2021-2023 that had not been disclosed and so the Panel ruled **no breach of Clause 20.5 and Clause 31.1.**

In the Panel's view the complainant was additionally alleging that there was no information in the executive summary which would explain the reasons for the provision of £39,898 as declared on Disclosure UK. In the Panel's view this was closely related to the subject matter of allegation 1, above, where the Panel had determined that the executive summary did not adequately summarise the joint working arrangement, including an outline of the financial arrangements or the roles and responsibilities of the parties. The Panel decided that its reasons and ruling above at allegation 1 applied equally here and it ruled **a breach of Clause 20.3**.

Allegation 4: "*This funding seems to be for running a therapy review service via a prescribing HCP – This points towards an inducement to prescribe?"*

The complainant alleged that the funding provided by Alnylam seemed to be for running a therapy review service via a prescribing health professional which pointed towards an inducement to prescribe. The complainant did not provide any detailed reasons to support their position and appeared to base their concern on the narrow principle of the joint working project involving a therapy review service via a prescribing health professional. The Panel bore in mind that the complainant had to establish their case on the balance of probabilities and in this regard

had provided a copy of the executive summary dated October 2023, but had provided no additional evidence. It was not for the Panel to infer reasons on behalf of the complainant. The Panel also noted the complainant's use of the phrase 'points towards' which was similar in meaning to 'suggestive of', rather than a matter that could clearly be established on the balance of probabilities.

Alnylam submitted that funding was provided to the NHS specialist centre with no resulting benefit to any health professional or other relevant decision maker. It further submitted that Project 1 was separate to the therapy review itself which was conducted by the specialist centre and not funded by the project. The Panel noted that the Joint Working Agreement was not always consistent with Alnylam's submission on this point as carrying out the therapeutic reviews was listed as a principal activity of the specialist centre within the Project Initiation Document (PID). Further, Alnylam's supplementary response listed "expert clinicians attending the accelerated patient reviews" as part of the NHS centre's contribution. Alnylam submitted that the therapy reviews would have taken place without the existence of Project 1. Alnylam further submitted that the nurse funded by Alnylam's contribution was not a prescribing nurse and was not involved in the therapy review itself but assisted with the pre- and post-therapy review activities stemming from the accelerated therapy review timetable. The Panel considered that it was clear that irrespective of whether the specialist centre's contribution to the joint working project was the therapy review, or whether the joint working project was limited to acceleration of the therapy review and did not include the review itself, a prescribing health professional was involved in the therapy review. In the Panel's view even if the therapy review had sat outside the joint working project Alnylam would still have to satisfy itself that the activity complied with the Code, including that it was not an inducement to prescribe as it would be unacceptable to facilitate or accelerate an activity that was potentially in breach of the Code.

The Panel noted that the Joint Working Agreement, under "Nature and scope of each Party's contributions to the joint working", stated: *"It is expressly agreed that Alnylam's support of the Joint Working Project and provision of the Support in accordance with this Agreement is not intended to have, in any way or manner, any influence on prescribing or purchasing decisions [named specialist centre] has made or may make in the future, including those relating to Alnylam, its affiliates or to Alnylam's products, nor is it intended to reward any previous purchasing or prescribing decisions. Furthermore, the Support is made exclusively to [named specialist centre] as an institution, and not to individual employees or representatives of [named specialist centre] (including in particular, any physicians or other health care professionals)".* It further stated in relation to the project Steering Committee that: *"It is unequivocally agreed between the Parties that the Steering Committee has no influence on decisions relating to the direct care of patients"*.

The Panel noted that the PID stated in 'Project Summary': *"The project will not affect prescription decisions. During the therapeutic review, the prescribing HCP will review the current therapy provided to the patient and may elect to prescribe a different therapy that is more beneficial to the patient. This project will be entirely independent of the prescription decision."* The PID further established that the therapy reviews were pre-existing, stating: *"At present, relevant patients have a therapeutic review scheduled every 12 months. This joint working project will support the acceleration of the scheduling and completion of therapeutic reviews. The aim is to complete all therapeutic reviews for relevant parties within the 9 month term of this joint working project".*

The Panel noted that the lack of influence of Alnylam on prescription decisions was repeated several times throughout the PID document:

> *"Importantly prescribing decisions remain with the independent medical team of HCPs at the [named specialist centre] without Alnylam's involvement. This Joint Working will not influence in any way prescription doses"*.
>
> *"…During an independent therapeutic review, a [named specialist centre] clinician will assess the patient and decide whether their current therapy plan is optimal or whether they would best benefit from a different therapy. This therapeutic review and prescribing decision will be undertaken by the [named specialist centre] alone and without any involvement of Alnylam"*.
>
> *"…This project will not affect prescription decisions. It will take effect after an independent therapeutic review with a HCP and the [named specialist centre]. The prescription decisions will be made by a prescribing HCP at the [name specialist centre] independently and without any involvement from Alnylam."*

The Panel did not have the therapy review documentation before it but considered that from the Joint Working Agreement it was clear that Alnylam had no input or influence on prescribing decisions, which remained at the discretion of the prescribing clinician.

Whilst the Panel was concerned with certain aspects of the joint working arrangements, the Panel considered that the complainant had not established why the involvement of a prescribing health professional meant that the joint working project was an inducement to prescribe.

The Panel noted the requirements of Clauses 19.1 and 20.3.

Clause 19.1 of the Code stated that *"No gift, pecuniary advantage or benefit may be supplied, offered or promised to health professionals or to other relevant decision makers in connection with the promotion of medicines or as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine, subject to the provisions of Clauses 10.4 and 19.2".*

Clause 20.3 of the Code stated, in part, that collaborative working must *"not constitute an inducement to health professionals or other relevant decision makers to prescribe, supply, recommend, buy or sell a medicine"*.

The Panel noted that Clauses 20.3 on this point and Clause 19.1 each applied to inducements to individual health professionals and considered that the complainant had failed to discharge their burden of proof in this regard. Therefore the Panel ruled **no breach of Clauses 19.1 and 20.3**.

Allegation 5: "*The executive summary does not provide any details of the NHS contribution or clarity around any significant contribution of pooled resources or any requirement for the baseline to be measured"*

The complainant alleged that the executive summary for Project 1 did not provide any details of the NHS contribution or clarity around any significant contribution of pooled resources or any requirement for the baseline to be measured. In the Panel's view the allegation explicitly

concerned the adequacy of the executive summary rather than a broader allegation about the acceptability of the joint working project.

The Panel bore in mind its description of the executive summary in question and its references to the relevant parts of the Code and supplementary information at allegation 1 above. The supplementary information to Clause 20 stated the collaborative working agreement should cover, among other things, the roles and responsibilities of the NHS, the pharmaceutical company and other organisations and how the success of the project will be measured, when and by whom; all aspects of input should be included.

In the Panel's view, the first part of this allegation regarding the failure of the executive summary to detail the parties' contributions amounted to the same matter as alleged in allegation 1, above, where the Panel had determined that the executive summary did not adequately summarise the joint working arrangement, including an outline of the financial arrangements or the roles and responsibilities of the parties. The matter was therefore covered by the Panel's ruling in allegation 1.

With regard to the second part of the allegation, that the executive summary did not mention 'any requirement for the baseline to be measured,' the Panel acknowledged that, as outlined above at allegation 1, the Code did not specify exactly what information should appear in the publicly available summary, but it should be a summary of the collaborative working agreement.

The Panel noted Alnylam's submission that Project 1 was duly monitored against the project objectives throughout its term, and monitoring data was reported at meetings of the Project 1 Steering Committee which was used to ensure that the project was monitored against the outcomes agreed at the outset.

The Panel noted that the Joint Working Agreement outlined how the progress of Project 1 would be monitored. The Monitoring and Evaluation Plan in the PID referred to the specialist centre gathering information on changes to relevant patient satisfaction/experience levels resulting from the therapeutic review and support provided to patients prescribed a different therapy, and costs saved in relation to the therapeutic review of patients. Noting the supplementary information to Clause 20, the Panel considered that there might be a difference between monitoring an activity and making baseline measurements, and further accepted that a requirement for baseline measurements might, depending on the nature of the project, be an important part of measuring a project's success, and good governance.

Noting the above, in the Panel's view it was not necessarily unacceptable, in the particular circumstances of this project, and in the absence of any reasons from the complainant, to not include details of any requirement for baseline measurements in the summary of the joint working agreement. The Panel considered that the allegation clearly concerned the executive summary rather than the joint working project itself. Therefore, the Panel considered that the complainant had not established that any requirement to take baseline measurements as part of its monitoring activities needed to be included in the publicly available summary of the joint working project, and it ruled **no breach of Clause 20.3** in this regard.

The Panel noted that Clause 20.2 required collaborative working arrangements to demonstrate the pooling of skills, experience and/or resources from all parties involved, with each party making a significant contribution and a shared commitment to delivery.

In this case and as set out above, the Panel's view was that the complainant's allegation that there was a lack of clarity around any significant contribution of pooled resources specifically related to the executive summary. Accordingly, the **Panel made no ruling in respect of Clause 20.2** on the basis that there was no specific allegation that the joint working project itself did not have pooled skills, experience or resources, and/or that either party's contribution was not significant. The clause had been raised by the case preparation manager. The matter in relation to the executive summary had been ruled on at allegation 1 above.

Allegation 6: "This further confirms that the therapy review is a switching service to reach very high levels of conversion for the new drug and the company had actively participated in this service by providing funds" and "provision of grant for switching service disguised as therapy review"

The complainant's reasons for alleging that the therapy review was a switching service included that the timing of the provision of funds from Alnylam was in line with NICE recommendation for one of its medicines, vutrisiran, one of its two medicines used for treating the condition at the NHS specialist centre. The complainant referred to the NICE impact report which outlined predicted market share for this medicine of 87-91% in the next five years. The complainant alleged that this further confirmed that the therapy review was a switching service aimed at converting a high number of patients to the new medicine, and that Alnylam had actively participated in this service by providing funds.

Alnylam submitted that Project 1 did not affect the outcome of the therapy reviews which would be routinely carried out by the specialist centre on an annual basis irrespective of the joint working project. It submitted that, within the therapy reviews, available therapies were assessed based on clinical criteria and any NICE recommendations would have been taken into account objectively. It further submitted that clinicians in the specialist centre were not required nor incentivised to switch patients from a particular therapy to another, and Alnylam did not monitor the prescriptions that were written during the therapy reviews.

Alnylam submitted that it considered Project 1 to be a fully compliant joint working project which was set up and conducted in line with the requirements of Clause 20 of the Code. Therefore, it did not consider it necessary to consider the requirements of Clauses 23.1 and 23.2 relating to donations and grants.

The Panel noted its comments above in allegation 4 about where the therapy review sat within the context of the overall joint working project and Alnylam's submissions on this point. In the Panel's view even if the therapy review sat outside the joint working project Alnylam would still have to satisfy itself that the activity complied with the Code, including that it was not an inducement to prescribe as it would be unacceptable to facilitate or accelerate an activity that was potentially in breach of the Code. The Panel noted that the only reference to a switching service in the Code was in the supplementary information to Clause 23 which stated:

> *"Clauses 19.1 and 23.1 prohibit switch services paid for or facilitated directly or indirectly by a pharmaceutical company whereby a patient's medicine is simply changed to another. For example, it would be unacceptable if patients on medicine A were changed to medicine B, without any clinical assessment, at the expense of a pharmaceutical company promoting either or both medicines. It would be acceptable for a company to promote a simple switch from one product to another but not to assist a health professional in implementing that switch even by means of a third party.*

A therapeutic review is different to a switch service. A therapeutic review which aims to ensure that patients receive optimal treatment following a clinical assessment is a legitimate activity for a pharmaceutical company to support and/or assist. The result of such clinical assessments might require, among other things, possible changes of treatment including changes of dose or medicine or cessation of treatment. A genuine therapeutic review should include a comprehensive range of relevant treatment choices, including non-medicinal choices, for the health professional and should not be limited to the medicines of the sponsoring pharmaceutical company. The decision to change or commence treatment must be made for each individual patient by the prescriber and every decision to change an individual patient's treatment must be documented with evidence that it was made on rational grounds."

Although in this case, the therapy review had been provided as part of a joint working project, in the Panel's view the supplementary information to Clause 23 was directly relevant when considering whether the therapy review or its accelerated provision was acceptable as part of the joint working arrangements.

The Panel noted that Alnylam had submitted a copy of the NICE technology appraisal guidance document titled 'Vutrisiran for treating [named disease]', dated February 2023. The recommendations stated:

"Vutrisiran is recommended, within its marketing authorisation, as an option for treating [named disease]. It is only recommended if the company provides vutrisiran according to the commercial arrangement.

If people with the condition and their clinicians consider vutrisiran to be 1 of a range of suitable treatments, discuss the advantages and disadvantages of the available treatments. After that discussion, if more than 1 treatment is suitable, choose the least expensive. Take account of administration costs, dosage, price per dose and commercial arrangements."

A section titled 'Why these recommendations were made', stated:

"[Named disease] is usually treated with patisiran [Alnylam's product]*, which is already recommended in NICE's highly specialised technologies guidance on patisiran.*
Vutrisiran works in a similar way, but it is given as an injection under the skin instead of into a vein.
Evidence from a clinical trial and an indirect comparison shows that vutrisiran works as well as patisiran."

"….Taking the number of vials used per person in the pharmacy data and administration costs into account, a cost comparison suggests vutrisiran is cost saving compared with patisiran. So vutrisiran is recommended."

The complainant submitted a copy of the NICE Resource impact report, "Vutrisiran for treating [named disease]", published February 2023, associated with the above NICE technology appraisal guidance.

The report stated the following with respect to the estimated number of people in England receiving vutrisiran:

	2023/24	2024/2025	2025/2026	2026/2027	2027/28
Market share for vutrisiran (%)	87	88	89	90	91

The report similarly detailed the estimated reduction in the number of visits needed with IV infusion services based on the estimated number of patients taking vutrisiran.

The resource impact template assumptions included that 87% of people currently receive patisiran, 6% receive inotersen and 7% receive best supportive care and that 91% of people will receive treatment with vutrisiran from 2027/28 with 0% receiving patisiran, 4% of people receiving inotersen and 5% receiving best supportive care.

The Panel considered that, based on NICE recommendations, patients may be switched to vutrisiran from patisiran if suitable following a discussion of the advantages and disadvantages and if a commercial arrangement was in place. The NICE Impact Report appeared to assume that no patisiran patients would receive that product by 2027/2028. Further, the Panel considered that Alnylam would likely have been aware of the Impact report dated February 2023 which predated the first version of the executive summary published 1 March 2023.

The Panel noted that Alnylam did not have visibility over the Expert Centre's framework for carrying out the therapeutic reviews nor any documents specific to the discussions at the therapeutic reviews (in the narrow context) and thus such documentation was not before the Panel. The Panel was concerned that Alnylam was therefore unable to satisfy itself that the arrangements for the therapeutic review complied with the Code.

When considering this matter the Panel bore in mind that:

a. Patients underwent an independent therapy review with a clinician at the NHS specialist centre before any medication changes were made.
b. Specialist centre had led and had control over the patient therapeutic reviews.
c. Alnylam had no influence over prescribing decisions made as part of the therapy review.

The Panel was concerned about the lack of visibility into the framework of the therapy reviews and the timing of the project and considered that Alnylam should have satisfied itself that the specialist centre was conducting a genuine therapeutic review as outlined in the supplementary information to Clause 23. However, as with any complaint, the complainant had the burden of proving their complaint on the balance of probabilities. The Panel did not have any evidence before it that this was not a genuine therapeutic review. Alnylam did not have access to the relevant documentation. Taking all of the above into account, the Panel considered, on balance, that the complainant had not established that the timing of the publication of the NICE guidance rendered Project 1 a switching service as alleged. There was no data before the Panel about the number of patients that had been prescribed vutrisiran as a result of the therapeutic review. The Panel bore in mind that the Project Outcome Summary stated that in addition to the initial patient review 67% received an additional six month follow up and noted that according to the Joint Working Agreement such post therapeutic support was provided to those patients prescribed a different therapy.

The Panel firstly considered the matter in relation to Clauses 23.1 and 23.2 which applied to donations and grants and were cited by the complainant. Alnylam submitted that it considered

Project 1 to be a fully compliant joint working project which was set up and conducted in line with the requirements of Clause 20 of the Code. Therefore, it did not consider it necessary to consider the requirements of Clauses 23.1 and 23.2 relating to donations and grants. The Panel bore in mind that the complainant had not explained why they considered the arrangements to be a grant as defined in Clause 23.1, namely a fund, benefit-in-kind or service freely given for the purpose of supporting healthcare, scientific research, or education, with no consequent obligation on the recipient organisation to provide goods or services to the benefit of the pharmaceutical company in return. The Panel considered that it was clear in the Joint Working Agreement that the NHS specialist centre was contractually obliged to contribute to the arrangements and therefore it did not consider that the joint working project satisfied the definition of a grant. The Panel therefore ruled **no breach of Clauses 23.1 and 23.2** accordingly as they were not applicable.

The Panel therefore decided to rule on the matter of whether the timing of the publication of the NICE guidance rendered Project 1 a switching service as alleged, under Clause 5.1. The Panel bore in mind its comments above, and whilst noting concerns about the arrangements, considered, on balance, that there was insufficient evidence about what actually had occurred such that the complainant had not established their case on the balance of probabilities and it ruled **no breach** of that Clause accordingly.

Allegation 7: "It seems that the summary of this alleged joint working has been produced 6 months post commencement of the project"

The complainant alleged that the project commenced in April 2023 but that the date of preparation on the published executive summary states October 2023, which indicated that the summary had been produced 6 months post commencement of the project.

Alnylam submitted that three versions of the executive summary for Project 1 had been made publicly available and that each version underwent rigorous review and certification. The first version of the summary was made publicly available on 3 April 2023. Alnylam considered this to be the start date of the project as it was the date that the nurse was allocated to the project. It further submitted that the start date for the project was 3 April 2023 as opposed to 1 March, which was listed in the project documentation. This had been due to a delay to the start of the project following the execution of the joint working agreement.

Alnylam submitted that a second version was published on 5 May 2023 due to a change in the way in which the parties were named. The third version (the version provided by the complainant) was published on 16 November 2023, after being certified on 5 October 2023. This update was due to a variation in the terms of the joint working agreement.

Clause 20.3 of the 2021 Code states in part, that collaborative working must *"have a summary of the collaborative working agreement publicly available before arrangements are implemented"*.

The Panel considered that the executive summary provided by the complainant was not the original summary which had been publicly available since 3 April 2023 which Alnylam submitted was the start date of the project. Whilst the Panel queried whether this could be classed as "before arrangements are implemented", the complainant had alleged that the summary of the

joint working had been produced 6 months after the start of the project which was not so. On the basis of this narrow allegation, the Panel ruled **no breach of Clause 20.3**.

Allegation 8: "…this summary was not certified as the final summary document"

The complainant alleged that the published executive summary stated *"This document was originally produced by Alnylam and the [named specialist centre] on March 1st 2023".* The complainant alleged that this led to an understanding that the summary was not certified as the final summary document.

The Panel noted that as above, Alnylam had submitted that three versions of the executive summary for Project 1 had been made publicly available and that each version underwent rigorous review and certification

Clause 8.3 states, among other things, that the following material must be certified in advance: *"material relating to collaborative working as described in Clause 20 and its supplementary information"*.

Clause 20.3 states: *"Material relating to collaborative working must be certified, including the summary of the collaborative working agreement".*

Alnylam submitted certificates corresponding to the three versions of the executive summary:

a. Version 1 had been certified on 21st March 2023. Alnylam submitted this was placed on the website on 3rd April 2023
b. Version 2 had been certified on 3rd April 2023. Alnylam submitted this was placed on the website on 5th May 2023.
c. Version 3 had been certified on 5th October 2023. Alnylam submitted this was placed on the website in 16th November 2023.

Whilst the Panel was concerned about the delay in updating the website following the certification of a new version of the executive summary, all three versions had been certified prior to use. On the basis of the narrow allegation, the Panel ruled **no breach of Clauses 8.3 and 20.3**.

Allegation 9: "The two dates on this one document leads to an understanding that the project was not a genuine joint working but a provision of a grant or a service or worse – an inducement to prescribe. The cover up seems to be classified as a joint working – after starting of the program"

The complainant alleged that the two dates on the published executive summary "*leads to an understanding that the project was not a genuine joint working but a provision of a grant or a service or worse – an inducement to prescribe*".

The Panel noted that as above, Alnylam had outlined the reason behind the two dates in the published executive summary due to there being more than one version of the executive summary.

It was not explicitly clear which two dates in the executive summary the complainant was referring to. The version provided by the complainant contained three dates:

a. "*This project will commence in April 2023"*
b. *"This document was originally produced by Alnylam and the [named specialist centre] on March 1st, 2023"*
c. *Date of preparation October 2023*

The Panel understood that Alnylam had updated the executive summary due to the following reasons:

a. Version 2 updated the name of the parties to ensure consistency with joint working agreement.
b. Version 3 updated the project term from 9 to 12 months due to a delay in completing the reviews within a 9 month timeframe.

In the Panel's view these changes and the resulting reference to different dates did not imply that the project was not genuine joint working as alleged. The Panel noted the complainant had made a very narrow allegation in relation to whether the project was genuine joint working. The Panel considered that the complainant had not established why this reference to two dates lead to an understanding that the project was not genuine joint working. They had failed to discharge their burden of proof in relation to this aspect of their complaint. Therefore, the Panel ruled **no breach of Clause 20.4** on the narrow ground alleged**.**

Allegation 10: "It has been 8 months since completion with no results being posted"

In a follow-up email, the complainant alleged, based on the information provided in the first version of the publicly available summary, that the project should have completed in December 2023 and it had been 8 months since completion with no results being posted.

Alnylam submitted that initially the project was to commence in March 2023 and run for 9 months. However, there had been a delay to the start of the project which did not commence until 3rd April 2023 and the project term was extended by an additional period of 3 months finishing in March 2024. Alnylam submitted a copy of the project outcome summary which was dated August 2024 and listed the project completion date as March 2024. Alnylam submitted that it had until the end of August 2024 to publish a summary of the outcomes of the project to be within the recommended timeline of 6 months upon finalisation of the joint working as set out in the Working Together Guide. It published the summary of outcomes on its website on 29 August 2024 (which was after the date of complaint).

The supplementary information to Clause 20 stated that the collaborative working agreement should cover, amongst other things, that *"outcomes should be published by all parties as soon as possible and usually within six months of the project's completion…".* The Panel noted that Section 4.1.3 of the Joint Working Agreement provided that the parties acknowledge and agree that 'they are committed to publishing an executive summary of the outcomes from the joint working project'.

From the evidence before it, the Panel considered that a project outcome summary had been published within 6 months of the project completion date. The complainant had failed to discharge their burden of proof in relation to this aspect. Therefore, the Panel ruled **no breach of Clause 20.3.**

Joint Working Project 2 ('Project 2')

Allegation 11: "Final summary does not seem to be certified before the start of the project, the current date of prep is 8 months after the start of the project, is this also an afterthought joint working?"

The complainant alleged that the published executive summary stated the start date of Project 2 was November 2023, but that the date of preparation in the executive summary was June 2024. The complainant alleged that the final summary did not seem to have been certified before the start of the project, that the date of preparation on the document was 8 months after the start of the project and queried whether this was also an afterthought joint working.

The version provided by the complainant stated the following:

a. "*The project will commence in November 2023"*
b. *"June 2024"* – which the Panel took to be the date of preparation for the document

Alnylam submitted that two versions of the executive summary for Project 2 had been made publicly available and that each version underwent rigorous review and certification. The first version of the summary was made publicly available on 16 November 2023 prior to the start date of Project 2 which was 30 November 2023. A second version was published on 10 July 2024 as a result of a variation to the terms of the joint working agreement between Alnylam and the specialist centre. Alnylam submitted this variation was an extension to the project duration due to difficulties in recruiting a genetic counsellor.

Clause 8.3 stated, among other things, that the following material must be certified in advance: *"material relating to collaborative working as described in Clause 20 and its supplementary information"*.

Clause 20.3 stated: *"Material relating to collaborative working must be certified, including the summary of the collaborative working agreement".*

Alnylam submitted certificates corresponding to the two versions of the executive summary:

a. Version 1 had been certified on 7 November 2023. Alnylam submitted this was placed on the website on 16 November 2023
b. Version 2 had been certified on 28 June 2024. Alnylam submitted this was placed on the website on 10 July 2024 and remained online at the time of the complaint.

The Panel noted that the version of the executive summary provided by the complainant was version 2 as provided by Alnylam and considered that as the complainant referred to the start of the project the allegations applied to versions 1 and 2 of the executive summary. Noting the project start date, the Panel considered that version 1 of the published summary had been certified prior to the start of the project. The Panel noted Alnylam's submission that the variation to the terms of the joint working agreement was agreed on 2 July 2024 and that version 2 of the executive summary was certified on 28 June. The Panel, therefore considered that version 2 had been certified prior to the start of the variation and ruled **no breach of Clauses 8.3 and 20.3** in relation to versions 1 and 2 of the executive summary.

Allegation 12: "There was no declaration on the amount of funding provided by the company as per the disclosure UK website" and "There seems to be a failure to disclose the funding amount for the project that started in November 2023 and the updated document is from June 2024"

The Panel considered that the statements above made by the complainant amounted to an allegation that Alnylam had failed to disclose funding in 2024 for a project that had commenced in 2023.

Alnylam submitted that although Project 2 had commenced in November 2023, at the date of complaint no transfers of value had yet been made to the specialist centre in connection with this project and therefore none had been disclosed. This was in-line with Alnylam's methodological note that a transfer of value would be declared according to the year the payment or transfer is made and not the date of the event or supporting agreement. The Panel noted that Clause 31.1 required, amongst other things, disclosure to be made in the first six months after the end of the calendar year in which the transfers of value were made.

From the information before it, the Panel considered that disclosure of transfers of value made in relation to Project 2 on Disclosure UK was not required at the date of complaint. The complainant had failed to discharge their burden of proof in relation to this aspect. Therefore, the Panel ruled **no breach of Clauses 20.5 and 31.1.**

Allegation 13: "[No] clarity around the significant contribution from the NHS other than receiving 2 head counts for a service that the NHS already should be providing"

The complainant alleged that there was no clarity around the significant contribution from the NHS. In the Panel's view the allegation concerned the clarity of the executive summary rather than a broader allegation about whether the NHS contribution to the joint working as a whole was significant.

The complainant had provided a link to an executive summary which was dated June 2024. Alnylam submitted that two versions of the executive summary for Project 2 had been made publicly available, and that the version provided by the complainant was the most recent. The Panel therefore based its ruling on this version.

The Panel bore in mind its references to the relevant parts of the Code, its supplementary information and guidance published by the PMCPA, in the form of a Q&A, at allegation 1 above. The supplementary information to Clause 20 stated the collaborative working agreement should cover, among other things, the roles and responsibilities of the NHS, the pharmaceutical company and other organisations; all aspects of input should be included. The Panel acknowledged that the Code did not specify exactly what information should appear in this publicly available summary, but it should be a summary of the collaborative working agreement.

The Panel observed that the executive summary for the Project 2 included the following information:

- the name of the project,
- a short summary of the project including its objective
- the commencement date and expected duration, and
- a short summary of the expected benefits to patients, the NHS specialist centre and Alnylam.

The Panel considered that there was no information provided within the executive summary for Project 2 about the contributions made including an outline of the financial arrangements, or the roles and responsibilities of the NHS.

Alnylam submitted that Project 2 was a collaboration to:

- increase the availability of genetic counselling in line with consensus on best practice to (i) all patients diagnosed with a [named disease] gene variant; (ii) relatives of these individuals, regardless of whether they also had been diagnosed with a gene variant; and
- increase the capacity of the genetic testing service at the specialist centre to process genetic tests.

Alnylam submitted that its contribution to the joint working was to fund hiring of a part-time genetic counsellor and a full-time lab technician to assist with the above. As with Project 1, the Panel noted that Appendix A of the joint working agreement within the section titled Project Manager, referred to a Alnylam project manager and stated that the time associated with project management support forms part of the Alnylam contribution. According to Alnylam the NHS specialist centre's contribution corresponded to experience, expertise, people and time, and included staff capacity to advertise and recruit individuals to the genetic counsellor and lab technician role, training of these individuals and the provision of diagnostic and management services to genetically diagnosed patients. The Panel noted that none of this information, with respect to the NHS contribution, was summarised in the executive summary.

In the Panel's view, the executive summary did not adequately summarise the joint working arrangement, including an outline of the financial arrangements and the roles and responsibilities of the parties, particularly the NHS. The Panel ruled **a breach of Clause 20.3** in this regard.

Overall

Allegation 14: "Total disclosures by the company under collaborative working is a single line item 2021-2023 whereas the company website has 3 executive joint working summaries- this leads to believe that there is a systemic failure of disclosures"

The Panel noted its rulings of no breach above in relation to disclosures of transfers of value for Projects 1 and 2.

The complainant had not provided any evidence or information on what other transfers of value Alnylam should have disclosed in relation to joint working nor evidence to support there being a *"systemic failure of disclosures".* The complainant had failed to discharge their burden of proof in relation to this aspect. Therefore, the Panel ruled **no breach of Clauses 20.5, 31.1 and 5.1**.

Allegation 15: "Both these documents [referring to executive summaries] prove changes to the final agreed funding provision disguised as joint working"

The Panel understood the complainant to be alleging that because there had been changes made to the published summaries for both joint working projects, this meant that the projects were disguised joint working.

The Panel noted its comments above regarding the amendments made to the published summaries:

- The executive summary for Project 1 had first been amended to change the way in which the parties were named to ensure consistency with the joint working agreement, and secondly to extend the term of the project from 9 to 12 months due to a delay in completing the reviews within the initial timeframe.
- The executive summary for Project 2 had been amended to extend the term of the project from 24 to 37 months, due to difficulties in recruiting a genetic counsellor.

The Panel noted that the Joint Working Agreements for both projects stated the following with respect to extending the term of agreements: *"Any agreement to extend the Term must be set out in writing and effected through a signed amendment to this Agreement."*

The Panel had been provided with amendment agreements signed by both Alnylam and the specialist centre agreeing to the extension of the project term for both projects. In the Panel's view it appeared that Alnylam had genuine reasons for each amendment and that these consequent changes to the executive summaries did not imply that the projects were *"disguised as joint working"* as alleged. The Panel noted the complainant had made a very narrow allegation. The Panel considered that the complainant had not established why changes to the joint working provision, as outlined in the published summaries, meant that the projects were disguised as joint working. They had failed to discharge their burden of proof in relation to this aspect of their complaint. Therefore, the Panel ruled **no breach of Clause 20.4** on the narrow ground alleged**.**

Allegation 16: "A majority of joint working projects (2/3) seem to be directed at one centre at one NHS trust which would additionally point towards an inducement to prescribe" and *"Two disguised joint working projects has provided funding for a nurse, a genetic counsellor and a lab technician. Provision of these 3 additional headcounts at the same once centre can easily be seen as an inducement to prescribe"*

The Panel considered that the statements above made by the complainant both amounted to an allegation that the provision of two joint working projects, which resulted in providing three additional headcounts, to the one centre, was an inducement to prescribe.

The Panel referred to its ruling in relation to allegation 4, about whether the arrangements for Project 1 were an inducement to prescribe.

Alnylam submitted that no element of Project 2 related to prescribing decisions. It further submitted that the specialist centre is the only centre commissioned by the NHS to manage this condition in the UK, and that by partnering with them, it would enable all patients across the UK to have equitable access to the service and experience the benefits of the project.

The Panel noted that the Joint Working Agreement, under "Nature and scope of each Party's contributions to the joint working", stated: *"It is expressly agreed that Alnylam's support of the Joint Working Project and provision of the Support in accordance with this Agreement is not intended to have, in any way or manner, any influence on prescribing or purchasing decisions [named specialist centre] has made or may make in the future, including those relating to Alnylam, its affiliates or to Alnylam's products, nor is it intended to reward any previous*

purchasing or prescribing decisions. Furthermore, the Support is made exclusively to [named specialist centre] as an institution, and not to individual employees or representatives of [named specialist centre] (including in particular, any physicians or other HCPs)". It further stated in relation to the project Steering Committee that: *"It is unequivocally agreed between the Parties that the Steering Committee has no influence on decisions relating to the direct care of patients"*.

The Panel noted that the PID stated in 'Project Summary': *"The genetic counsellor will not recommend, advise or discuss individual available treatments."* This information was repeated in the published executive summary for the project.

The Panel noted that the lack of influence of Alnylam, and its funded counsellor, was repeated throughout the PID document:

> *"The funding provided by Alnylam will contribute to increasing the resources of the [named specialist centre] but will not relate to the cost of the physical tests themselves or impact any prescription decisions"*
>
> *"The genetic counsellor will not provide information in relation to available individual treatments for [named disease] and will refer individuals requesting information on individual treatment to clinicians at the [named specialist centre]/their local practice"*.

The Panel considered that it was helpful when considering the acceptability of individual projects that companies bear in mind the overall number and nature of their financial arrangements with an organisation that fall within the scope of the Code and the overall impression created by the arrangements. It was not, in principle, necessarily unacceptable to have more than one joint working project with the same NHS organisation. The Panel acknowledged Alnylam's submission that the specialist centre involved in the two joint working projects was the sole NHS commissioned centre for managing this specific rare condition. The Panel did not consider it unreasonable for Alnylam to have entered into two different joint working projects with the centre, especially as there appeared to be little overlap in the objectives of the two projects.

Whilst the joint working projects had provided three additional headcounts to the specialist centre, it was clear to the Panel from the documentation that none of these roles had any influence on prescribing decisions.

In the Panel's view, the complainant had not established that directing two joint working projects to one centre, or providing funding for three additional headcounts at one centre in the particular circumstances of this case meant that in relation to individual health professionals there had been an inducement to prescribe. The complainant had provided little evidence and no detailed reasons to support their position. Therefore, the Panel ruled **no breach of Clauses 19.1 and 20.3**

High standards

In the Panel's view, transparency in relation to joint working was an important means of building and maintaining confidence in the pharmaceutical industry. Companies were expected to have a robust governance framework in place to support Code compliance.

The Panel took account of its breach rulings above in relation to the joint working summaries. Transparency was a key principle underpinning self-regulation and was important in maintaining public trust. The Panel considered that the effect of these matters was such that high standards had not been maintained. The Panel therefore ruled a **breach of Clause 5.1**.

Upholding confidence in the industry

Clause 2 was a sign of particular censure and reserved for such use. The Panel had broad concerns about the arrangements but did not consider that in relation to the matters that fell within the narrow allegations the complainant had demonstrated that Alnylam had brought discredit upon, and reduced confidence in, the pharmaceutical industry. The complainant had not established that Alnylam was using joint working as an inducement to prescribe as alleged. The Panel therefore **ruled no breach of Clause 2**

* * * * *

During its consideration of this case the Panel had serious concerns about the arrangements for Project 1 but noted that these were not matters raised by the complainant and therefore were not the subject matter of its rulings above. The Panel raised these concerns with Alnylam.

[On receipt of the case report, Alnylam have agreed to address these concerns.]

Complaint received **17 July 2024**

Case completed **13 February 2026**