Department of Health & Social Care

Minutes – Advisory Committee on Borderline Substances

14 and 15 March 2022 | By teleconference

S40

Attendees:

Alison Smith (AS) - Chair
Stuart Lakin (SLk)
Rosemary Stennett (RS)
Stephen Lewis (SL)
[redacted]
Anne Daly (AD)
Andrea Hilton (AH)
Ghazala Yousuf (GY)
Emily Walters (EW)
[redacted]
Evelyn Ward (EWard)
Charlotte Ellerton (CE)
Ian R White (IRW)
Amit Arora (AA)
Una Cuthbert (UC)
[redacted]

Apologies:

[redacted]
Emma Emmerson (EE)

1. **Introductions and apologies**
   On Monday 14 March, there were apologies from Emma Emmerson. On Tuesday 15 March there were also apologies from Emma Emmerson, Evelyn Ward and Amit Arora.

2. **Declaration of interests**
   AS read out the declaration of interests. The interests declared are at appendix A.

3. **Minutes of the 15 and 16 November 2021 meeting**
   The minutes were agreed and no amendments were raised.

4. **Business**

a. **For enteral use only (Alison Smith)**
   The Committee were informed that the British Specialist Nutrition Association (BSNA) had contacted the DHSC Nutrition Legislation Team (NLT) about Article 5(2) of Commission Delegated Regulation 2016/128, specifically the use of the statement "For enteral use only" (the positive wording). This Article sets out a list of mandatory particulars required on the labels of FSMPs with Article 5(2)(h) specifically requiring 'where appropriate, a warning that the product is not for parenteral use' (the negative wording).

   Manufacturers are stating the positive wording on their labels because the ACBS advise of patient safety issues with the negative wording. However, the NLT were requiring industry to use the negative wording as they understood this to be the requirement of Article 5(2)(h). Therefore, NLT were not issuing acknowledgements letters for labels using the positive wording and, as acknowledgement letters are a mandatory requirement of ACBS submissions, manufacturers were hindered from submitting to ACBS.

Following a series of correspondence between NLT and BSNA, the DHSC legal team reviewed the requirements of the legislation and concluded that the positive wording is considered to have an equivalent meaning to that of the negative wording. Therefore, NLT has decided it will acknowledge labels that state the positive wording but will also continue to acknowledge labels that use the negative wording.

The Committee were informed that it can accept labels using either the positive or the negative wording.

A letter from the NLT to the BSNA outlining the detail was shared at appendix 3.

b. **Consultation on ready-to-drink ONS (Alison Smith)**

Following the November meeting, AS informed the Committee that members working on the response to the ONS consultation had reviewed all the responses to the questions (i) How far do you agree that standardising pack sizes of ready-to-drink ONS to 125ml and 200ml will improve the prescribing of these products and reduced prescribing error? and (ii) Do you know of any reasons for or against a ready-to-drink ONS product needing to be presented in different sizes?

Members reviewed the quantitative data for the close-ended answers and the qualitative data for the open-ended answers. The team noted that most respondents used the open-ended questions as an opportunity to not only explain their answers to the closed questions but to remark on various related matters, providing a wealth of information that has never previously been available.

The group is undertaking thematic analysis of the data. Members separately reviewed the answers and formulated their own themes. The team then discussed the themes they had identified and agreed to group them into overarching themes. These themes and a description of them was circulated at appendix 4 of the meeting papers, which is repeated here.

1. Understanding and communication of prescribing practice

Definition: Healthcare professional understanding of the differences in prescribing practice between hospital and primary care settings is often poor resulting in confused communication about required nutritional products and the volume needed to support nutritional and clinical requirements.

- Improved communication and understanding of prescribing practice in different settings would help to reduce prescribing errors, waste and cost whilst helping to improve or maintain patients' nutritional state.

2. Patient safety

Definition: There is a need for both an appropriate range of ONS and prescriptions of the right product and volume to enable the safe management of varying nutritional and clinical needs.

- Reduce the risk of nutritional and/or clinical harm by ensuring prescription of the correct ONS product
- Reduce the risk of nutritional and/or clinical harm by ensuring there is neither over nor under prescribing of the volume of ONS
- Ensure there is an appropriate range of ONS energy/nutrient density and volume to support patient choice, preference and compliance

- Ensure there is an appropriate range of ONS energy/nutrient density and volume to enable patients' clinical and nutritional needs to be safely met e.g.
  - o Higher volume (200ml) ONS available to support hydration
  - o Lower volume (125ml) nutritionally complete ONS to support those requiring fluid restrictions, or with anorexia resulting from disease-related malnutrition or at risk of this due to acute illness
  - o Use of 125ml and 200ml ONS to meet different IDDSI requirements

3. **Evidence base for ONS pack size**

Definition: The evidence for over and under prescribing of ONS volume and incorrect prescription of ONS product in the UK is anecdotal with little described in the peer reviewed literature. There is only anecdotal suggestion that restricting the volume of ONS products would reduce prescribing errors.

NOTE: There is published peer reviewed evidence for use of low volume, energy and nutrient dense ONS as an effective intervention for disease-related malnutrition in adults.

Gerda H. van den Berg, Robert Lindeboom, Wil C. van der Zwet, (2015) The effects of the administration of oral nutritional supplementation with medication rounds on the achievement of nutritional goals: A randomized controlled trial, Clinical Nutrition, 34;1:15-19

Background & aims: Oral nutritional supplements (ONS) are often considered for hospitalized patients with acute severe malnutrition, however the compliance to the supplements is known to be variable. The aim of our study was to investigate whether providing a lower volume of ONS at a higher frequency during medication rounds would improve the intake of the supplements. Methods: In this randomized controlled trial, 234 malnourished inpatients (mean age 71.2 years, 55% male, median LOS 10 days) were randomized to receive ONS (300 kcal and 12 g Protein per 125 ml serving) in one of three different schemes. The usual care group (n = 88) was offered ONS 125 ml twice per day in between meals. This was compared to two intervention groups that were offered ONS during medication rounds: intervention group 1 (n = 66) received 125 ml of ONS twice per day, at 12 and 17 o'clock, and intervention group 2 (n = 80) received 62 ml of ONS four times a day, at 8, 12, 17 and 20 o'clock. Follow-up was performed until discharge or until ONS was no longer needed, with a maximum follow-up period of 30 days. The primary outcome measure was the percentage of patients who consumed at least 75% of the prescribed volume of ONS. Results: No significant differences were observed between the control groups and intervention group 1 (risk difference of −16.0% (95% CI −33.2–1.2). However, the percentage of patients consuming at least 75% of the prescribed ONS was higher in intervention group 2, with a risk difference 23.4% (95% CI 7.8–39.0%) and a mean increased intake of 35 ml (84 kcal) per day, $p < 0.001$). Median time ONS were taken was 5 days (range 1–17). Conclusion: A higher frequency of a lower volume of ONS during medication rounds increased the compliance of patients needing ONS.

Atkinson, Emma; Atkinson, Judith. (2021) Nutrition and oncology: best practice and the development of a traffic light system. British Journal of Nursing, 30;10:S16-S23

Malnutrition is common in oncology patients, with age, disease stage and tumour type all influencing malnutrition risk. There are several detrimental effects of malnutrition in oncology patients, including weight loss, which is associated with negative oncological outcomes, and reduced survival. The causes of malnutrition in this group may be multifactorial and include effects from the tumour itself, altered metabolism, increased nutritional requirements, and cancer treatments and their associated side effects, which can impact on an individual's ability and desire to eat. Nutritional screening to identify early nutritional risk is essential and should involve the use of a validated screening tool, with commonly used tools usually assessing nutritional risk and weight loss over a period of months, for example a 3- to 6-month period. It is also important to consider weight changes over a shorter time period to identify rapid weight changes. Multidisciplinary teamworking is essential in tackling malnutrition, with collaborative working between the dietitians and the nutrition nurses shown to be beneficial in the authors' practice to develop community pathways and improve their service and manage increasing patient numbers. Malnutrition within oncology can often be managed with additional supplementation with oral nutritional supplements or enteral nutrition, where indicated. A low-volume, energy-dense, high-protein supplement can help to meet nutritional needs and to achieve dietetic aims, with compliance improved by the use of a low-volume product.

Willem F. Nieuwenhuizen, Hugo Weenen, Paul Rigby, Marion M. Hetherington (2010) Older adults and patients in need of nutritional support: Review of current treatment options and factors influencing nutritional intake, Clinical Nutrition, 29;2:160-169

Background & aims: Many older adults and patients do not achieve sufficient nutritional intake to support their minimal needs and are at risk of, or are suffering from, (protein-energy) malnutrition. Better understanding of current treatment options and factors determining nutritional intake, may help design new strategies to solve this multifactorial problem. Methods: Medline, Science Citation Index, ScienceDirect and Google databases (until December 2008) were searched with the keywords malnutrition, elderly, older adults, food intake, energy density, variety, taste, satiety, and appetite. Results: 37 Factors affecting nutritional intake were identified and divided in three categories; those related to the environment, the person, and the food. For older adults in nursing homes, encouragement by carers and an appropriate ambiance seem particularly important. Meal fortification, offering variety, providing frequent small meals, snacks and particularly Oral Nutritional Supplements (ONS) between meals are other possibilities for this group. Product factors that stimulate intake include palatability, high energy density, low volume, and liquid format. Conclusion: The current review gives a comprehensive overview of factors affecting nutritional intake and may help carers to improve nutritional intake in their patients. The product factors identified here suggest that especially small volume, energy and nutrient dense ONS can be effective to improve nutritional intake.

Stange, I. et al. (2013) 'Effects of a Low-Volume, Nutrient- and Energy-Dense Oral Nutritional Supplement on Nutritional and Functional Status: A Randomized, Controlled Trial in Nursing Home Residents', Journal of the American Medical Directors Association, 14(8), p. 628. doi: 10.1016/j.jamda.2013.05.011.

Objectives Although oral nutritional supplements (ONS) are known to be effective to treat malnutrition in the elderly, evidence from nursing home populations, including individuals with dementia, is rare, especially with regard to functionality and well-being. A known barrier for ONS use among elderly is the volume that needs to be consumed, resulting in low compliance and thus reduced effectiveness. This study aimed to investigate the effects of a low-volume, energy- and nutrient-dense ONS on nutritional status, functionality, and quality of life (QoL) of nursing home residents. Setting Six nursing homes in Nürnberg and Fuerth, Germany. Participants Nursing home residents affected by malnutrition or at risk of malnutrition. Intervention Random assignment to intervention (IG) and control group (CG), receiving 2 × 125 mL ONS (600 kcal, 24 g protein) per day and routine care, respectively, for 12 weeks. Measurements Nutritional (weight, body mass index [BMI], upper arm and calf circumferences, MNA-SF) and functional parameters (handgrip strength, gait speed, depressive mood [GDS], cognition [MMSE], activities of daily living [Barthel ADL]) as well as QoL (QUALIDEM) were assessed at baseline (T1) and after 12 weeks (T2). ONS intake was registered daily and compliance calculated. Results A total of 77 residents (87 ± 6 y, 91% female) completed the study; 78% had dementia (MMSE <17) and 55% were fully dependent (ADL ≤30). Median compliance was 73% (IQR 23.5%–86.5%) with median intake of 438 (141–519) kcal per day. Body weight, BMI, and arm and calf circumferences increased in the IG (n = 42) and did not change in the CG (n = 35). Changes of all nutritional parameters except MNA-SF significantly differed between groups in favor of the IG (P < .05). GDS, handgrip strength, and gait speed could not be assessed in 46%, 38%, and 49% of participants at T1 and/or T2, because of immobility and cognitive impairment. In residents able to perform the test at both times, functionality remained stable in IG and CG, except for ADLs, deteriorating in both groups. From 10 QoL categories, "positive self-perception" increased in IG (78 [33–100] to 83 [56–100]; P < .05) and tended to decrease in CG (100 [78–100] to 89 [56–100]; P = .06), "being busy" significantly dropped in CG (33 [0–50] to 0 [0–50]; P < .05). Conclusion Low-volume, nutrient- and energy-dense ONS were well accepted among elderly nursing home residents with high functional impairment and resulted in significant improvements of nutritional status and, thus, were effective to support treatment of malnutrition. Assessment of function was hampered by dementia and immobility, limiting the assessment of functionality, and highlighting the need for better tools for elderly with functional impairments. ONS may positively affect QoL but this requires further research.

Various sub-themes have been identified and will be further grouped into the overarching themes.

The next steps is to review industry's responses to the questions mentioned above. These have to be reviewed separately as the majority of manufacturers chose not to complete the online survey where the information from other sources was captured.

The Committee acknowledged the work that had been undertaken, discussed the themes at length and was in agreement with those themes and the intended approach. However, the Committee opined that the work appears it will be resource intensive and that more resource may be required.

The group will report back at the July meeting.

c. **Types of applications** [redacted]

At the November meeting, the Committee discussed draft definitions for the different types of applications proposed by the ACBS-BSNA Working Group, which is working to revamp the ACBS guidance. For type 1 applications, the Committee agreed evidence needs to be well-established. However, industry does not think evidence for type 1 products can be well-established owing to their immaturity and proposed that the Committee revert to the old definition. The BSNA's proposal on this matter was circulated at appendix 5 of the meeting papers.

The Committee discussed the definitions for the type 1 route but could not reach an agreement. However, much like the discussion on this subject at the meeting in November 2021, the Committee are in agreement that the type 1 route needs to be much more thorough and the process rigorous, and perhaps that such applications need to be considered on a case-by-case basis. The Committee must be able to satisfy itself that type 1 products are truly clinically effective and can substantiate this using a body of evidence so that the position is conclusive, as opposed to being considered based on only one study showing efficacy.

❖ [redacted] to inform the ACBS-BSNA Working Group of the outcome of the discussion.

d. **Trial of the new application form** [redacted]

[redacted] informed that the ACBS-BSNA Working Group had intended to trial a draft of the new application form at this meeting. However, the applications that had completed the trial form unfortunately did not make the agenda for this meeting as applications were added to the agenda using the rule of first-come-first-served, which is custom and practice.

The Working Group hopes to trial the draft of the new form at the July meeting.

e. **Recruitment** [redacted]

[redacted] informed that the Department is preparing to recruit new members to the Committee. The intention is to fill four posts: two posts are to replace AH and UC as their terms, after ten years on the Committee, end in July, one to fill the vacant post left by the late Vera Todorovic and one additional member.

The Department intend to recruit a metabolic dietitian, a primary care professional, a medicines management or prescribing support dietitian and a pharmacist. These professions are either to replace like-for-like with those leaving or to bolster the capacity of the Committee in areas where it is needed most according to the current nature of the work and types of applications coming through. The Committee agreed with the approach.

The Department hopes to advertise at the end of March and asked that members circulate the adverts via their networks in order to galvanise interest as recruitment for the Committee has been notoriously difficult in the past. The Committee agreed.

❖ [redacted] to inform members when the adverts go live.

f. **Meeting of 12 July 2022** [redacted]

The Committee agreed to hold the meeting scheduled for Tuesday 12 July 2022 in person.

❖ [redacted] to arrange the meeting.

g. **Meeting date for March 2023** [redacted]

The Committee agreed to schedule a meeting for 13 and 14 March 2023.

❖ [redacted] to schedule the meeting.

5. Product submissions

Product submissions were discussed. A record of this conversation is at appendix B.

Table of actions

Action	Responsible
❖ [redacted] to inform the ACBS-BSNA Working Group of the outcome of the discussion regarding the types of applications	[redacted]
❖ [redacted] to inform members when the adverts go live.	[redacted]
❖ [redacted] to arrange the meeting for July 2022	[redacted]
❖ [redacted] to schedule the meeting for March 2023	[redacted]

Appendix A – Declarations of interest

Name	Name of organisation	Nature of interest
Ghazala Yousuf	Harley Dietitians Ltd	Company Director and Consultant Dietitian - Harley Dietitians Ltd work may be commissioned or funded by commercial organisations/companies, educational establishments, companies, organisations, charities, or individuals who may produce or have an interest in medical nutrition. Examples of work carried out by Harley Dietitians Ltd include research, publications, training, conference/webinar speaker, and provision of specialist nutritional dietary advice for Paediatrics.
Amit Arora	UHNM. NHS	"No conflict or interest in any products or topics as such. I have been appointed as Vice President for the British Geriatrics Society which is not really a conflict but am declaring an interest in older people health care. I have been appointed as a trustee for the British Lymphology Society, but not a conflict of interest I think. I remain a member of other advisory bodies and committees."

Appendix B – Product submissions

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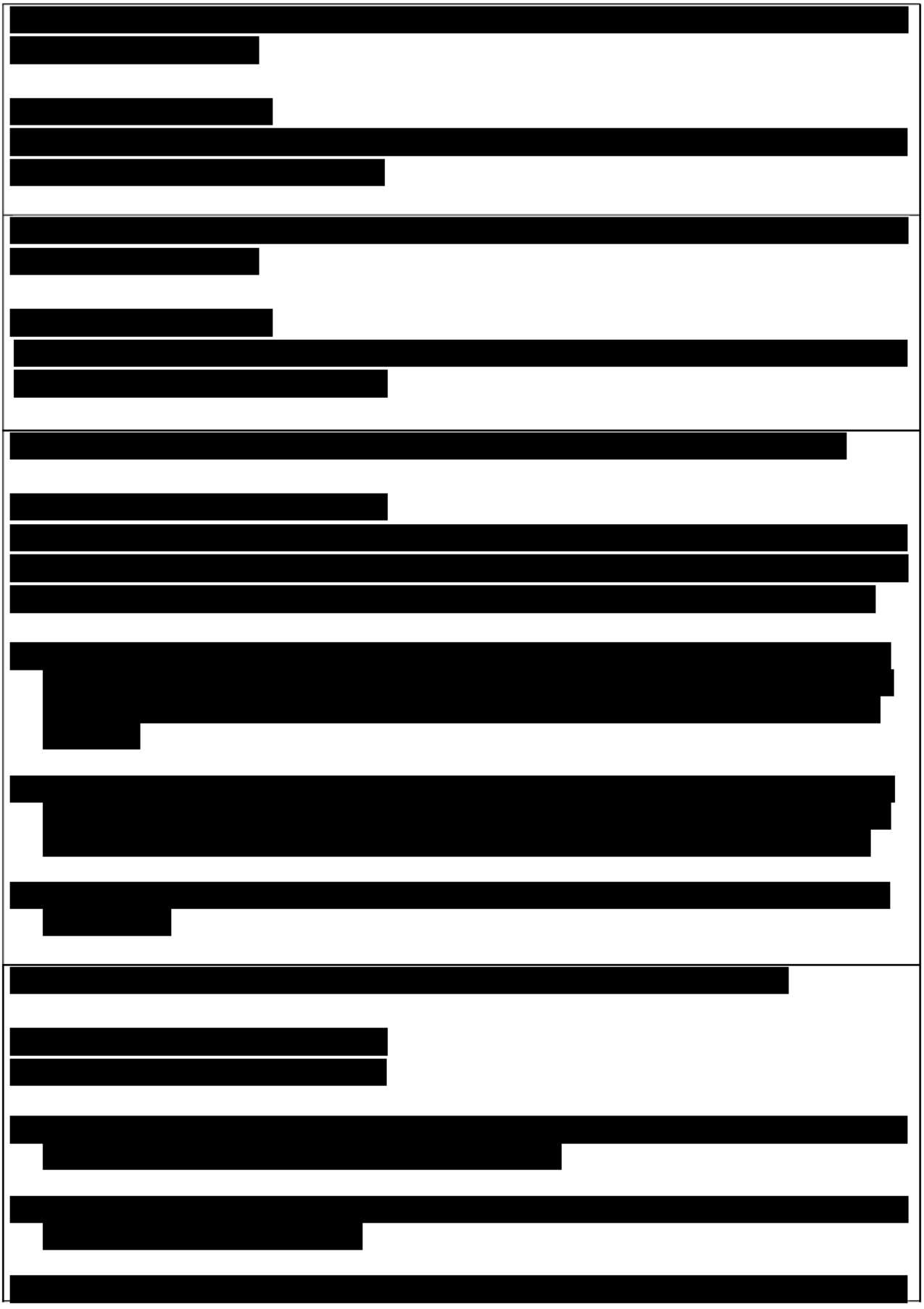

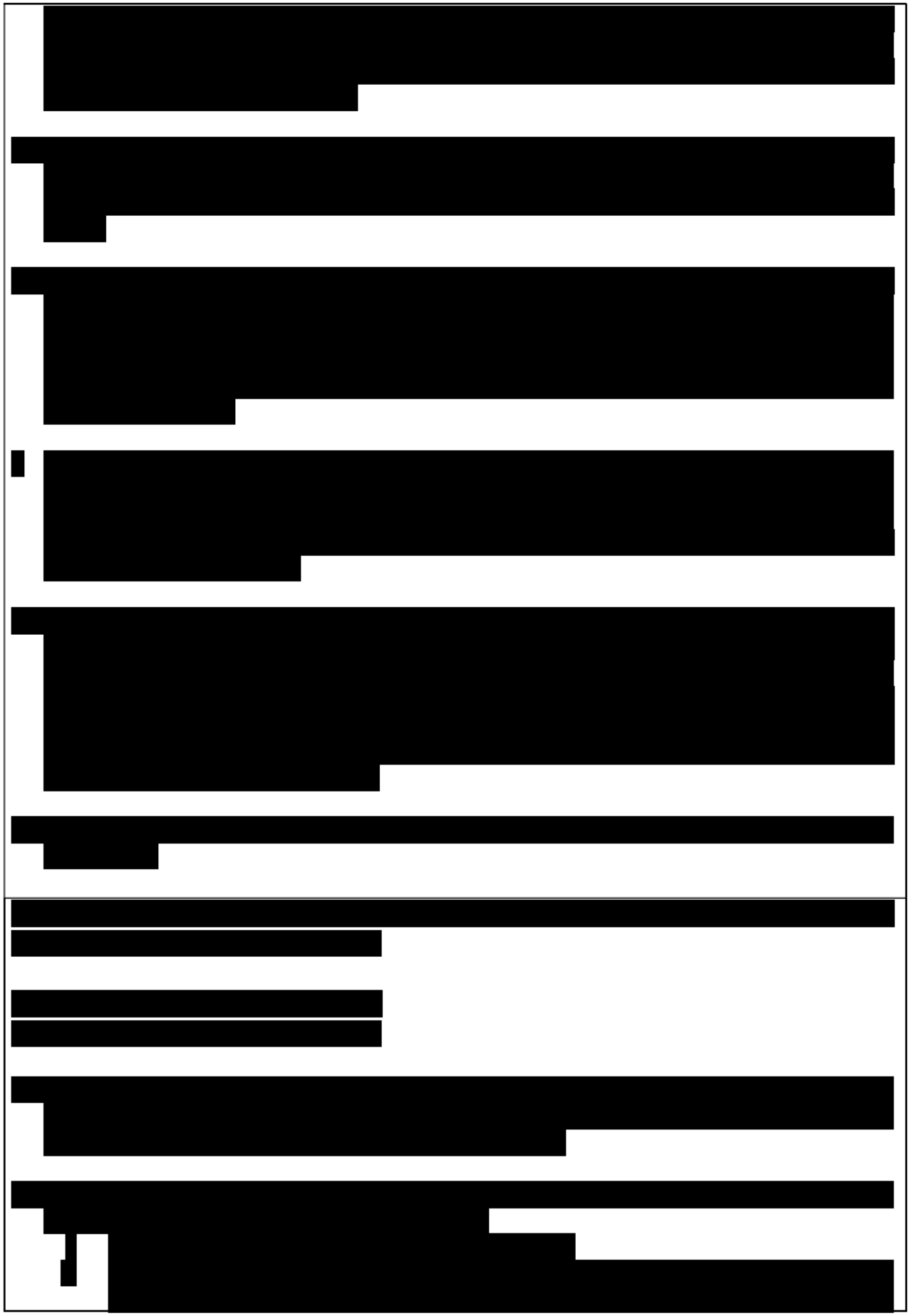

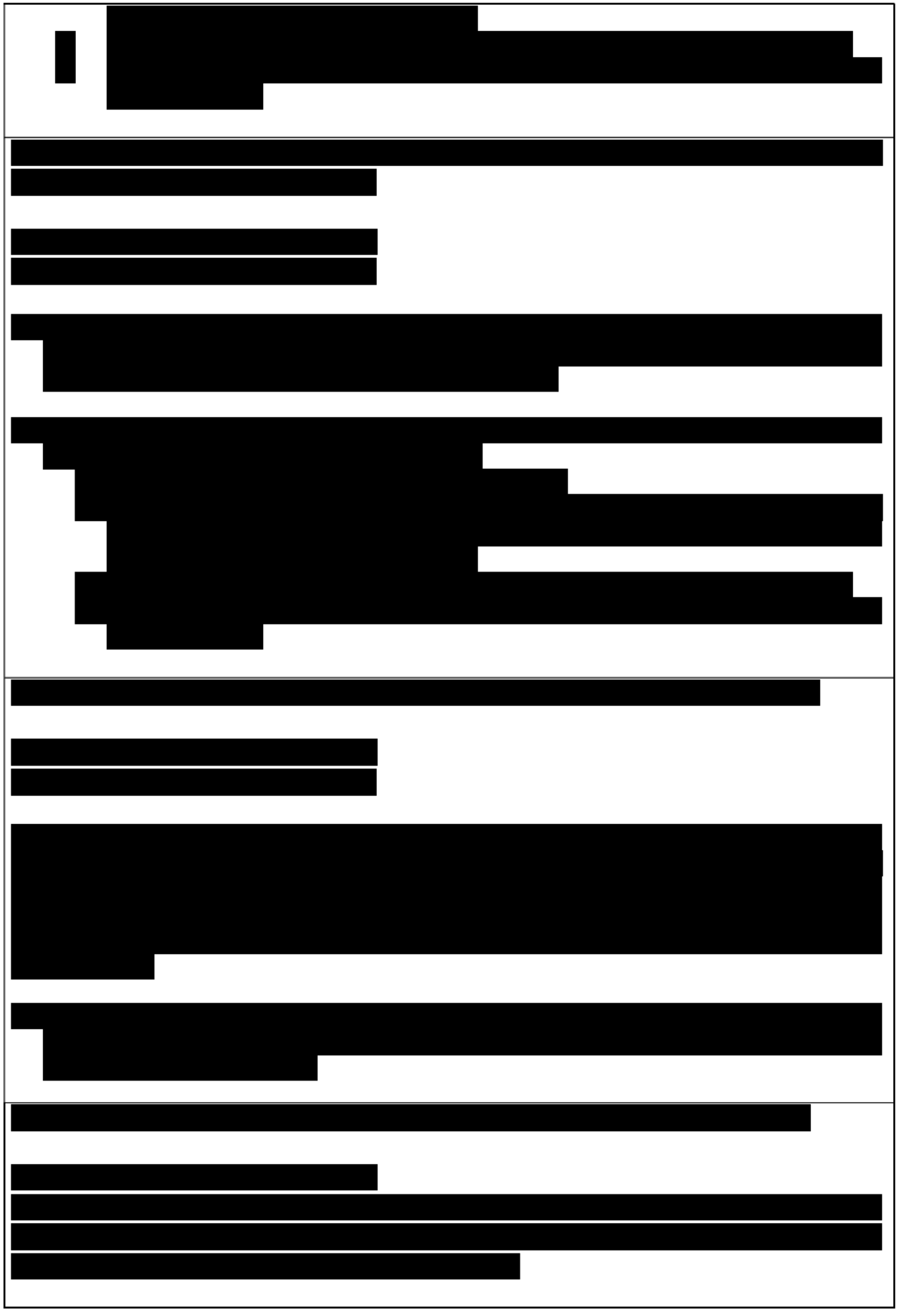

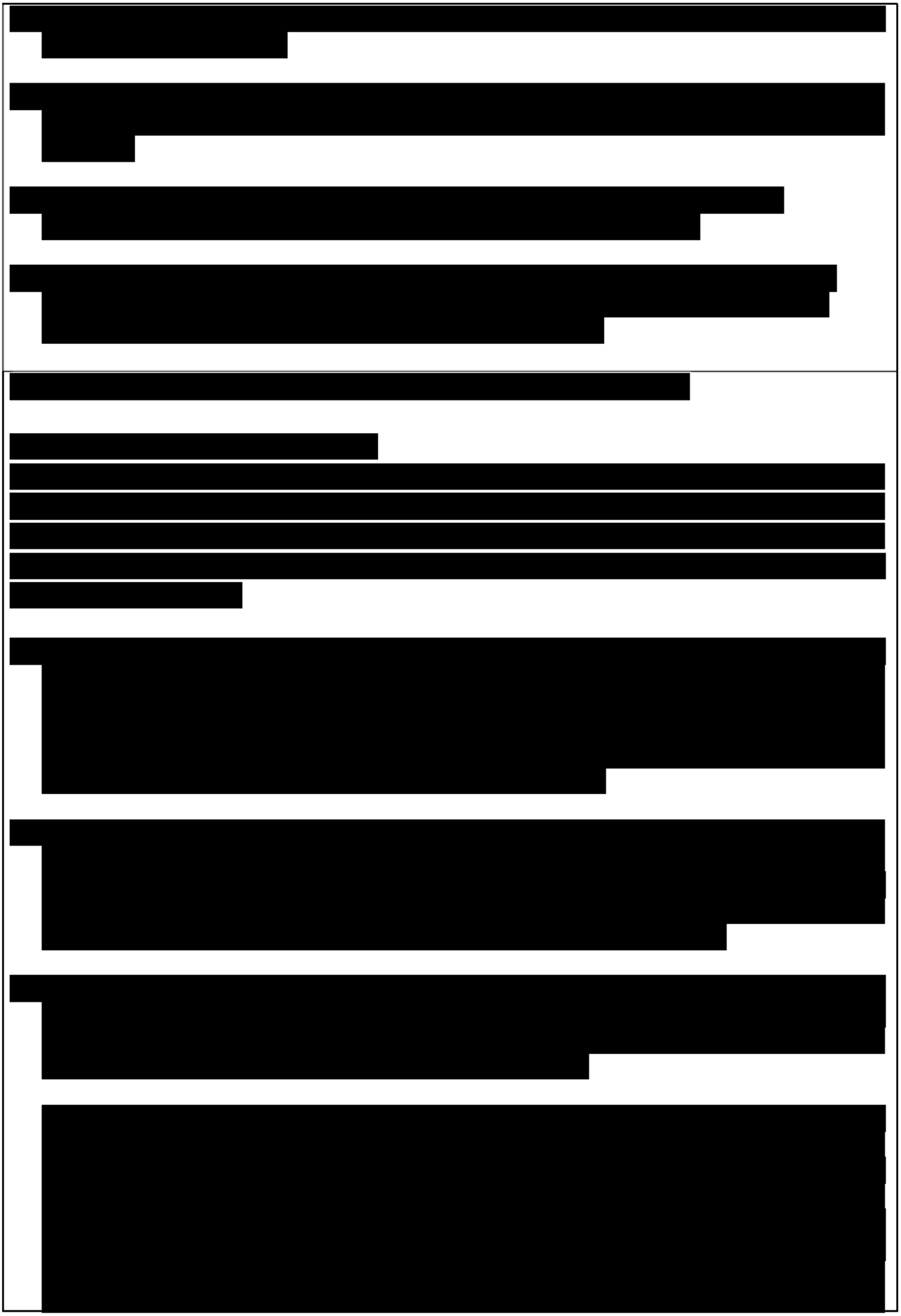

[redacted]