Yukon

ATIPP Request: 24-759

Source of Records: Insured Health &
Strategic Policy and Planning

Health and Social Services

Kane.Sprangers

From: Jason.Durand
Sent: June 13, 2023 2:57 PM
To: MacDonald, Daniel (HC/SC)
Cc: Bettencourt, Sarah (HC/SC); Ung, Christine (HC/SC); Edwards, Clara (HC/SC); Amy.Riske
Subject: RE: [EXT] FPT Pharmaceuticals Executive Group follow up (June 5, 2023) // Groupe exécutif FPT sur les produits pharmaceutiques suivi (5 juin 2023)
Attachments: s.76(1)

Good afternoon Daniel,

s.76(1)

Happy to have a discussion if you want more granular detail on some of this information.

Sincerely,

Jason D

From: MacDonald, Daniel (HC/SC) <Daniel.MacDonald@hc-sc.gc.ca>
Sent: Monday, June 12, 2023 5:51 AM
To: Jason.Durand <Jason.Durand@yukon.ca>
Cc: Bettencourt, Sarah (HC/SC) <Sarah.Bettencourt@hc-sc.gc.ca>; Ung, Christine (HC/SC) <christine.ung@hc-sc.gc.ca>; Edwards, Clara (HC/SC) <clara.edwards@hc-sc.gc.ca>
Subject: RE: [EXT] FPT Pharmaceuticals Executive Group follow up (June 5, 2023) // Groupe exécutif FPT sur les produits pharmaceutiques suivi (5 juin 2023)

Thank you and noted.

Daniel

From: Jason.Durand <Jason.Durand@yukon.ca>
Sent: Monday, June 12, 2023 8:49 AM
To: MacDonald, Daniel (HC/SC) <Daniel.MacDonald@hc-sc.gc.ca>
Subject: RE: [EXT] FPT Pharmaceuticals Executive Group follow up (June 5, 2023) // Groupe exécutif FPT sur les produits pharmaceutiques suivi (5 juin 2023)

Good morning Daniel,

The Yukon will need a few more days ourselves to get information along to you. It is coming along, but we need to verify a few things.

Thank you,

Jason D

From: MacDonald, Daniel (HC/SC) <Daniel.MacDonald@hc-sc.gc.ca>
Sent: Tuesday, May 30, 2023 1:53 PM
To: Mitch.Moneo@gov.bc.ca; Chad.mitchell@gov.ab.ca; Greg.Gettle@health.gov.sk.ca; Robert.shaffer@gov.mb.ca; Patrick.Dicerni@ontario.ca; eric.levesque2@gnb.ca; craig.beaton@novascotia.ca; kdshaw@ihis.org; FLangor@gov.nl.ca; Amy.Riske <Amy.Riske@yukon.ca>; Jeannie_Mathison@gov.nt.ca; cnieuwstraten@gov.nu.ca; scott.doidge@sac-isc.gc.ca; Fortin, Karen <karen.fortin@sac-isc.gc.ca>; Mujoomdar, Michelle (HC/SC) <Michelle.Mujoomdar@hc-sc.gc.ca>; Daniel.desharnais@msss.gouv.qc.ca; dominic.belanger@msss.gouv.qc.ca; RJGILL@ihis.org; nmacphee@gov.pe.ca; smacneill@gov.pe.ca; angie.wong@ontario.ca; leah.Fuder@gov.bc.ca; Patricia.Caetano@gov.mb.ca; mark.thompson@gnb.ca; natalie.borden@novascotia.ca; Marsha Cusack <mdcusack@ihis.org> <mdcusack@ihis.org>; Stephen.Doyle <Stephen.Doyle@yukon.ca>; Jason.Durand <Jason.Durand@yukon.ca>; luke_spooner@gov.nt.ca; ATaylor1@gov.nu.ca; pbarnes@gov.nl.ca
Cc: Belair, Eric (HC/SC) <Eric.Belair@hc-sc.gc.ca>; Nourallah, Laura (HC/SC) <laura.nourallah@hc-sc.gc.ca>; Leblanc, Josee (HC/SC) <Josee.Leblanc@hc-sc.gc.ca>; Edwards, Clara (HC/SC) <clara.edwards@hc-sc.gc.ca>; Ung, Christine (HC/SC) <christine.ung@hc-sc.gc.ca>; Bettencourt, Sarah (HC/SC) <Sarah.Bettencourt@hc-sc.gc.ca>
Subject: [EXT] FPT Pharmaceuticals Executive Group follow up (June 5, 2023) // Groupe exécutif FPT sur les produits pharmaceutiques suivi (5 juin 2023)

Some people who received this message don't often get email from daniel.macdonald@hc-sc.gc.ca. Learn why this is important

(Le français suit)

(On behalf of Eric Bélair, Associate Assistant Deputy Minister, Strategic Policy Branch, Health Canada)

Dear colleagues,

As a follow-up to our May 24 Pharmaceuticals Executive Group (PEG) meeting, I am touching base on the five items that we agreed upon would need further work before we reconvene in mid-June:

1) s.76(1) [redacted]

   Please send your s.76(1) [redacted] and the contact information of your **DG/Director level representative** to Daniel MacDonald (daniel.macdonald@hc-sc.gc.ca), cc. Josée Leblanc (josee.leblanc@hc-sc.gc.ca) by **Monday, June 5 close-of-business**.

   Questions about the s.76(1) [redacted] can also be sent to Daniel and Josée.

b. Daniel MacDonald will call a meeting of the DG/Director level group on Monday, June 12 to discuss the products for the mid-June ADM meeting.

2) For info, Health Canada s.76(1) [redacted]

3) Please confirm your **representatives for the upcoming** s.76(1) [redacted] PEG conversations to Daniel MacDonald (daniel.macdonald@hc-sc.gc.ca), cc. Josée Leblanc (josee.leblanc@hc-sc.gc.ca) by **Monday, June 5, close of business**. Feel free to provide the contact information for more than one representative if it is relevant s.76(1) [redacted]

4) A reminder to please provide any s.76(1) [redacted] discussed on May 24 (presentation re-attached for your convenience) to Daniel MacDonald (daniel.macdonald@hc-sc.gc.ca), cc. Josée Leblanc (josee.leblanc@hc-sc.gc.ca), ideally prior to the DG/Director pre-meeting on June 12.

5) As a few PEG members requested during the last meeting, for your background only, we are attaching a slide from the deck presented to PEG in March 2022 s.76(1) [redacted] s previously discussed by PEG.

Many thanks in advance for your cooperation in advancing our work, and I am looking forward to continuing our discussions,

Eric Bélair
Associate Assistant Deputy Minister / Sous-ministre adjoint délégué
Strategic Policy Branch / Direction générale de la politique stratégique
Health Canada / Santé Canada
343-552-1733
eric.belair@hc-sc.gc.ca

========
(De la part d'Eric Bélair, Sous-ministre adjoint délégué, Direction générale de la politique stratégique, Santé Canada)

Chers collègues,
En suivi de notre réunion du Groupe exécutif FPT sur les produits pharmaceutiques (Groupe exécutif) du 24 mai, je vous contacte à propos des cinq items que nous avons convenu nécessitent du travail supplémentaire avant notre prochaine rencontre à la mi-juin :

1) s.76(1) [redacted]

Veuillez envoyer vos s.76(1) [redacted] et l'information sur votre **représentant au niveau DG/Directeur(trice)** à Daniel MacDonald (daniel.macdonald@hc-sc.gc.ca), cc. Josée Leblanc (josee.leblanc@hc-sc.gc.ca) avant la **fin de la journée lundi le 5 juin**.

Toute question sur le s.76(1) [redacted] peut être dirigée à Daniel et Josée.

b. Daniel MacDonald organisera une rencontre du groupe de niveau DG/Directeur(trice) lundi le 12 juin pour discuter des documents pour la réunion des SMA de la mi-juin.

2) Pour votre information, Santé Canada s.76(1) [redacted]

3) s.76(1) [redacted] à Daniel MacDonald (daniel.macdonald@hc-sc.gc.ca), cc. Josée Leblanc (josee.leblanc@hc-sc.gc.ca) avant la **fin de la journée lundi le 5 juin**. N'hésitez pas à fournir le nom de plus d'un représentant si cela est pertinent s.76(1) [redacted]

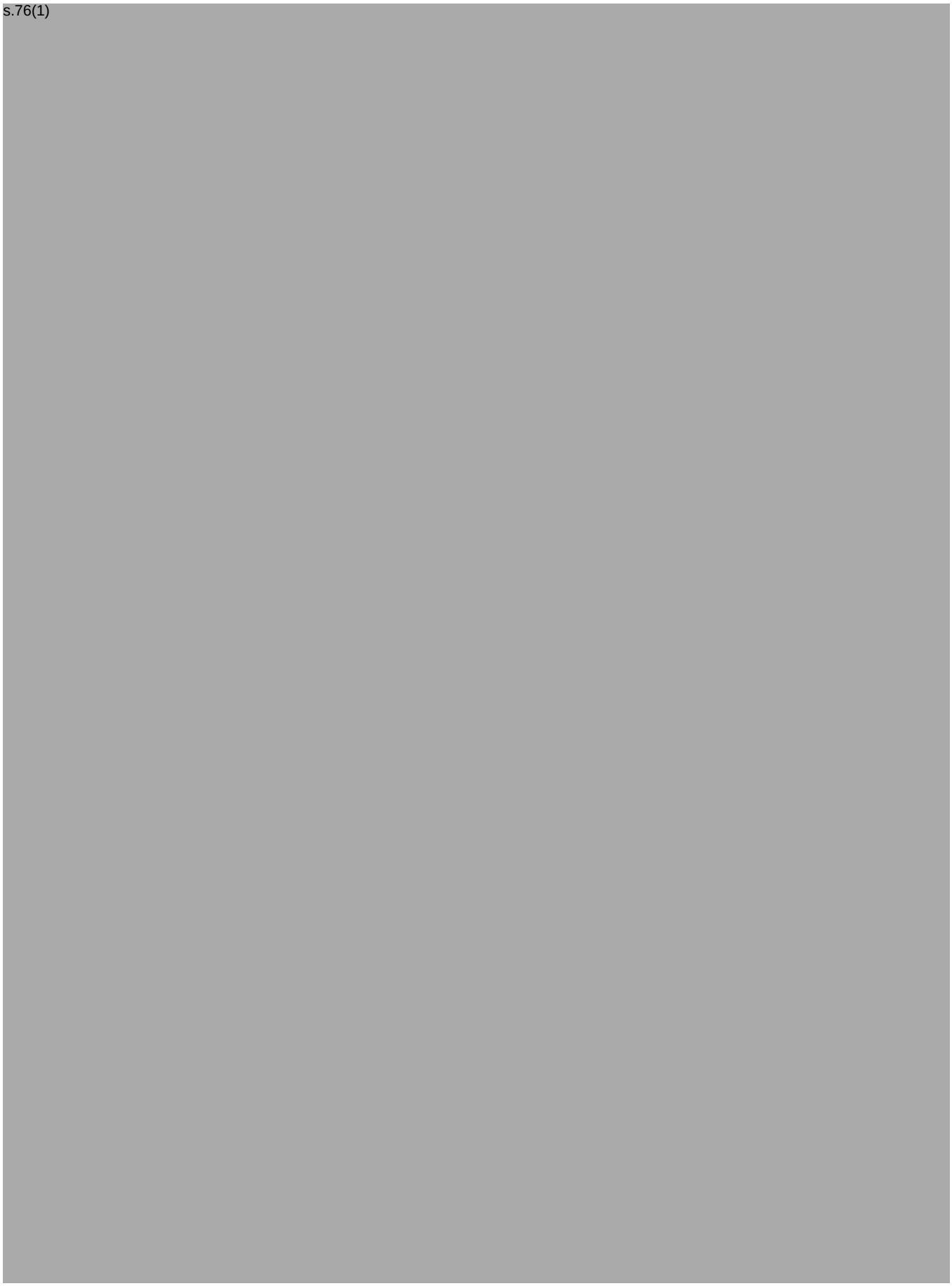
4) Un rappel de fournir tout **commentaire** s.76(1) [redacted] discutés le 24 mai (présentation en pièce jointe à des fins de simplicité) à Daniel MacDonald (daniel.macdonald@hc-sc.gc.ca), cc. Josée Leblanc (josee.leblanc@hc-sc.gc.ca), idéalement avant la pré-réunion des DG/Directeur(s)(trice(s)) le 12 juin.

5) Tel que demandé par plusieurs membres du Groupe exécutif, afin de fournir du contexte seulement, nous joignons la page de la présentation au Groupe exécutif de mars 2022 s.76(1) [redacted] discutées précédemment par le Groupe exécutif.

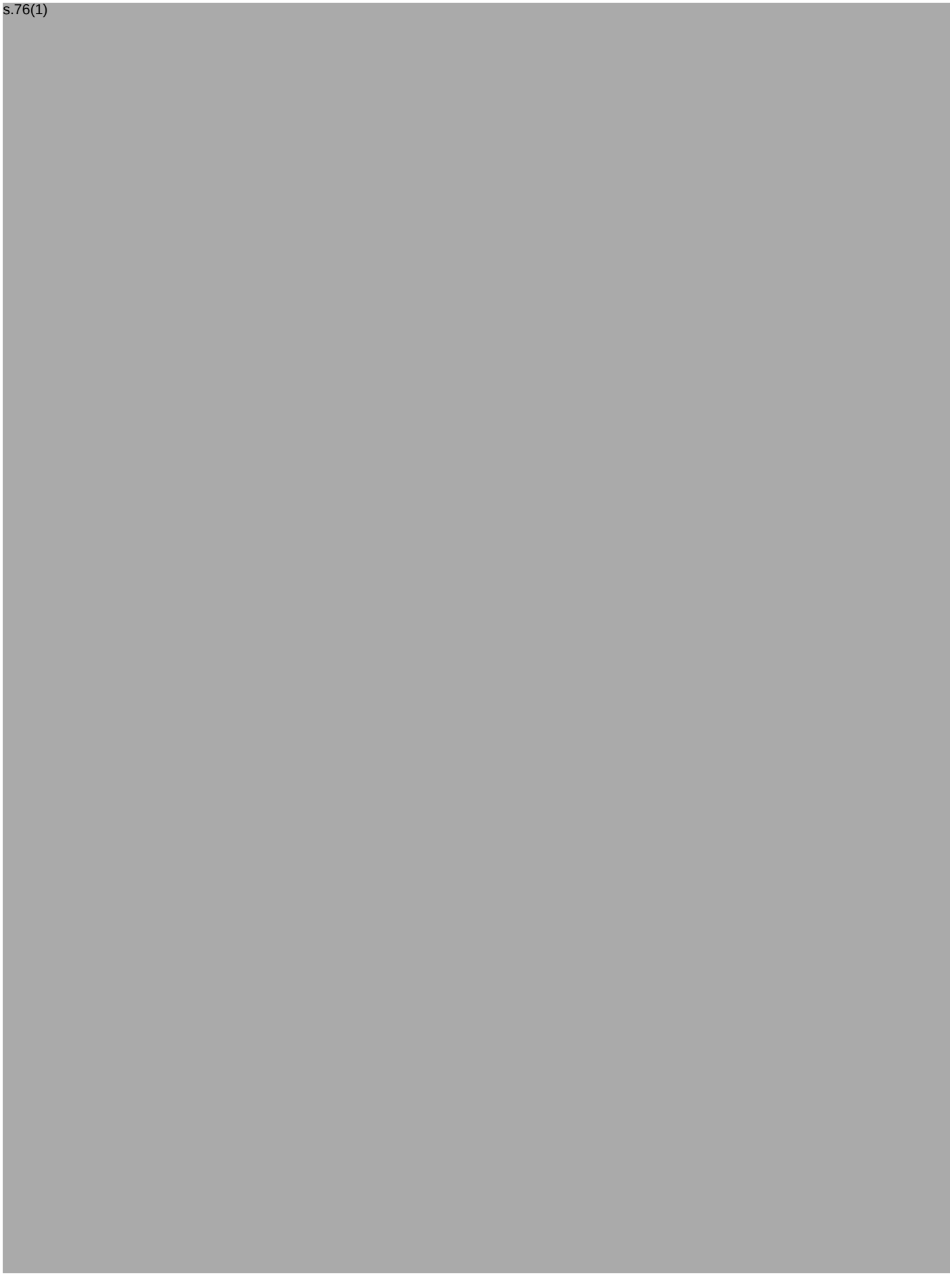
Merci à l'avance pour votre coopération dans l'avancement de nos travaux, et j'attends avec intérêt la suite de nos discussions,

Eric Bélair
Associate Assistant Deputy Minister / Sous-ministre adjoint délégué
Strategic Policy Branch / Direction générale de la politique stratégique
Health Canada / Santé Canada
343-552-1733
eric.belair@hc-sc.gc.ca

s.76(1)



s.76(1)



s.76(1)

From: Boudreau, Michelle (HC/SC)
To: Boudreau, Michelle (HC/SC); Ian.Rongve@gov.bc.ca; Fazlagic, Tijana HLTH:EX; Kierstin.Kashuba@gov.ab.ca; Chad.Ryan@health.gov.sk.ca; Robert.shaffer@gov.mb.ca; patrick.dicerni@ontario.ca; eric.levesque2@gnb.ca; Sheila.MacLeod@novascotia.ca; Kathleen.Coleman@novascotia.ca; alicialmccallum@GOV.PE.CA; PatrickMorrissey@gov.nl.ca; Cathy.Mcneil; Jeannie_Mathison@gov.nt.ca; cnieuwstraten@gov.nu.ca; karen.fortin@sac-isc.gc.ca; "dominic.belanger@msss.gouv.qc.ca"
Cc: Leah.Fuder@gov.bc.ca; Lauren.Bresee@gov.bc.ca; andrea.nagle@gov.ab.ca; Rachel.Cheruvallath@gov.ab.ca; Sherry.Holland@gov.ab.ca; Marina.Facci@health.gov.sk.ca; michelle.pashovitz@health.gov.sk.ca; Jillian.Farrow@health.gov.sk.ca; Alan.Lawless@gov.mb.ca; carey.lai@gov.mb.ca; Angie.wong@ontario.ca; Michelle.Falone@ontario.ca; Evan.Sotiropoulos@ontario.ca; Dan.Coulombe@gnb.ca; rachel.comeau@gnb.ca; mxdemone@gov.pe.ca; tjpaynter@ihis.org; BDBERTELSEN@gov.pe.ca; pbarnes@gov.nl.ca; Jason.Durand; Prev.Naidoo; Robert.Furlong; luke_spooner@gov.nt.ca; ATaylor1@gov.nu.ca; valerie.fontaine@msss.gouv.qc.ca; michelle.mujoomdar@sac-isc.gc.ca; Carter, Luke (HC/SC); Conly, Meghan (HC/SC); Boutin, Jennifer (HC/SC); Lawlor, Brent (HC/SC); MacDonald, Daniel (HC/SC); DRD Secretariat / Secrétariat des MTMR (HC/SC); HC.F DRD / MTMR F.SC; Wilson, Clara (HC/SC); Harris, Natasha (HC/SC)
Subject: PEG follow-up – sharing the Common Set with partners – Suivi du GEPP – partager l'ensemble commun avec les partenaires
Date: February 13, 2025 9:07:27 AM
Attachments: s.76(1) [redacted]

Unclassified / Non classifié

(le français suit)

Dear Colleagues,

As mentioned at our last FPT Pharmaceuticals Executive Group meeting on January 28, Canada's Drug Agency (CDA-AMC) and the Canadian Institute for Health Information (CIHI) have been working on specific DRD projects, but also positioning themselves to coordinate and enable RWE activities more broadly. s.76(1) [redacted]

s.76(1) [redacted]

Thank you for your support in sharing this important information with our Partners to enable further planning related to the RWE Workplan.

Michelle

****

Chers collègues,

Comme nous l'avons mentionné lors de notre dernière réunion du Groupe exécutif FPT sur les produits pharmaceutiques du 28 janvier, l'Agence canadienne des médicaments (AMC) et l'Institut canadien d'information sur la santé (ICIS) ont travaillé sur des projets précis relatifs aux médicaments pour le traitement des maladies rares, mais se sont également positionnés pour coordonner et permettre des activités utilisant des données probantes du monde réel (DPMR) plus largement. s.76(1) [redacted]

s.76(1) [redacted]

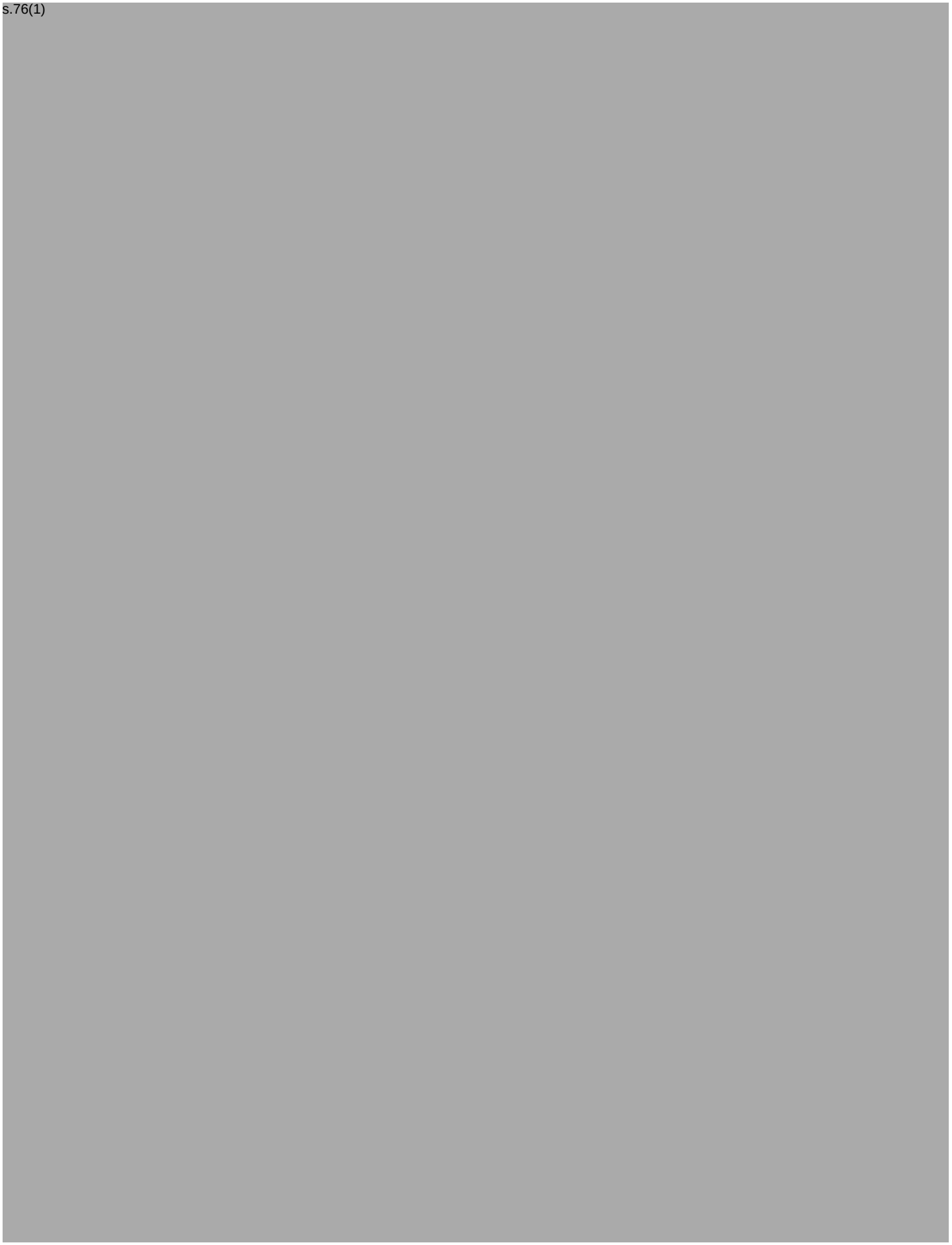
Nous vous remercions de votre soutien dans l'échange de ces renseignements importants avec nos partenaires afin de permettre une planification plus approfondie liée au plan de travail des données probantes du monde réel.

Michelle

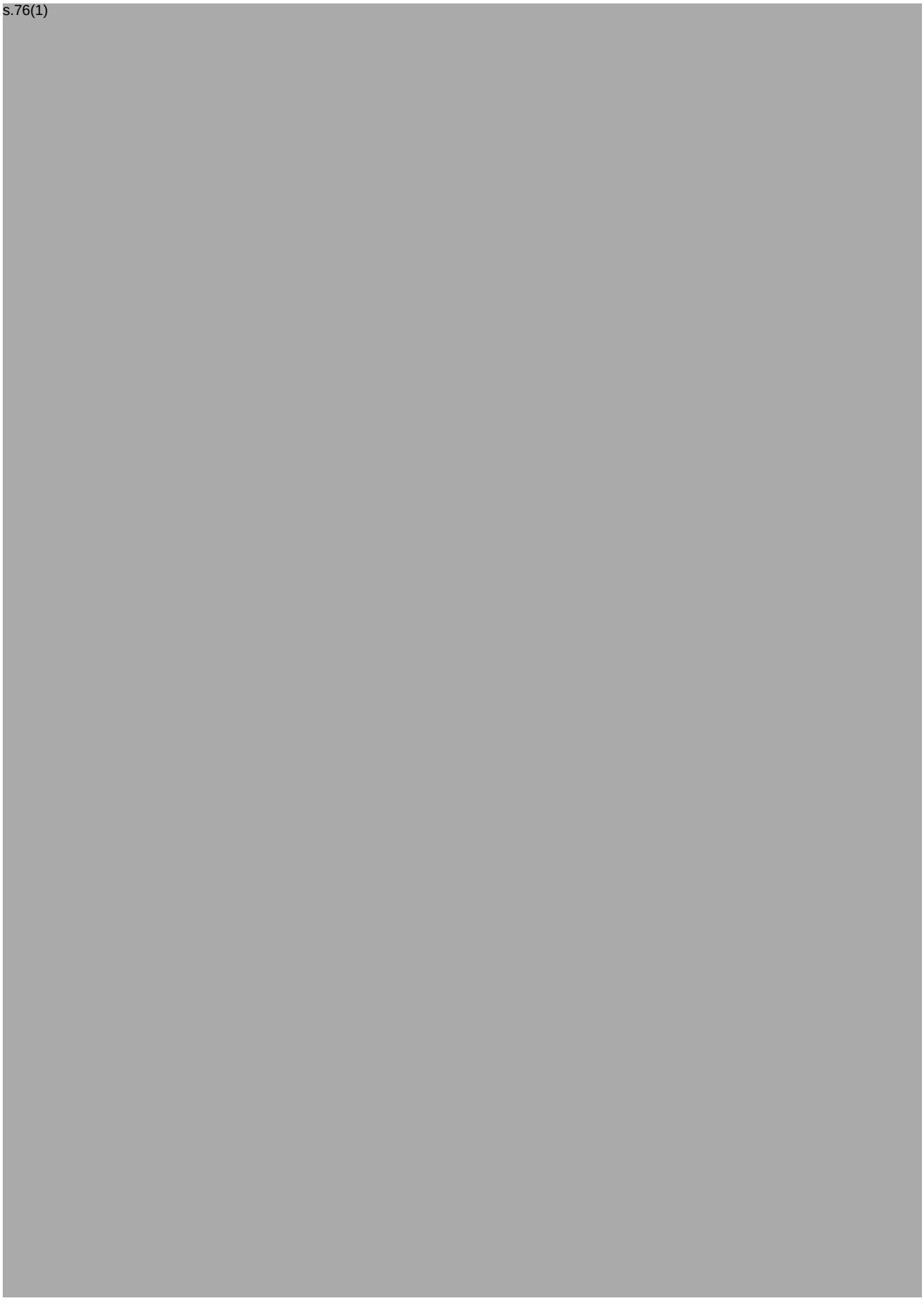
Michelle Boudreau (She/elle)
Associate Assistant Deputy Minister/Sous-ministre adjointe déléguée
Health Policy Branch | Direction générale des politiques de santé
Health Canada/Santé Canada
613-710-7663 / michelle.boudreau@hc-sc.gc.ca

M/L	T/M	W/M	T/J	F/V
BC Building	BC Building	BC Building	BC Building	

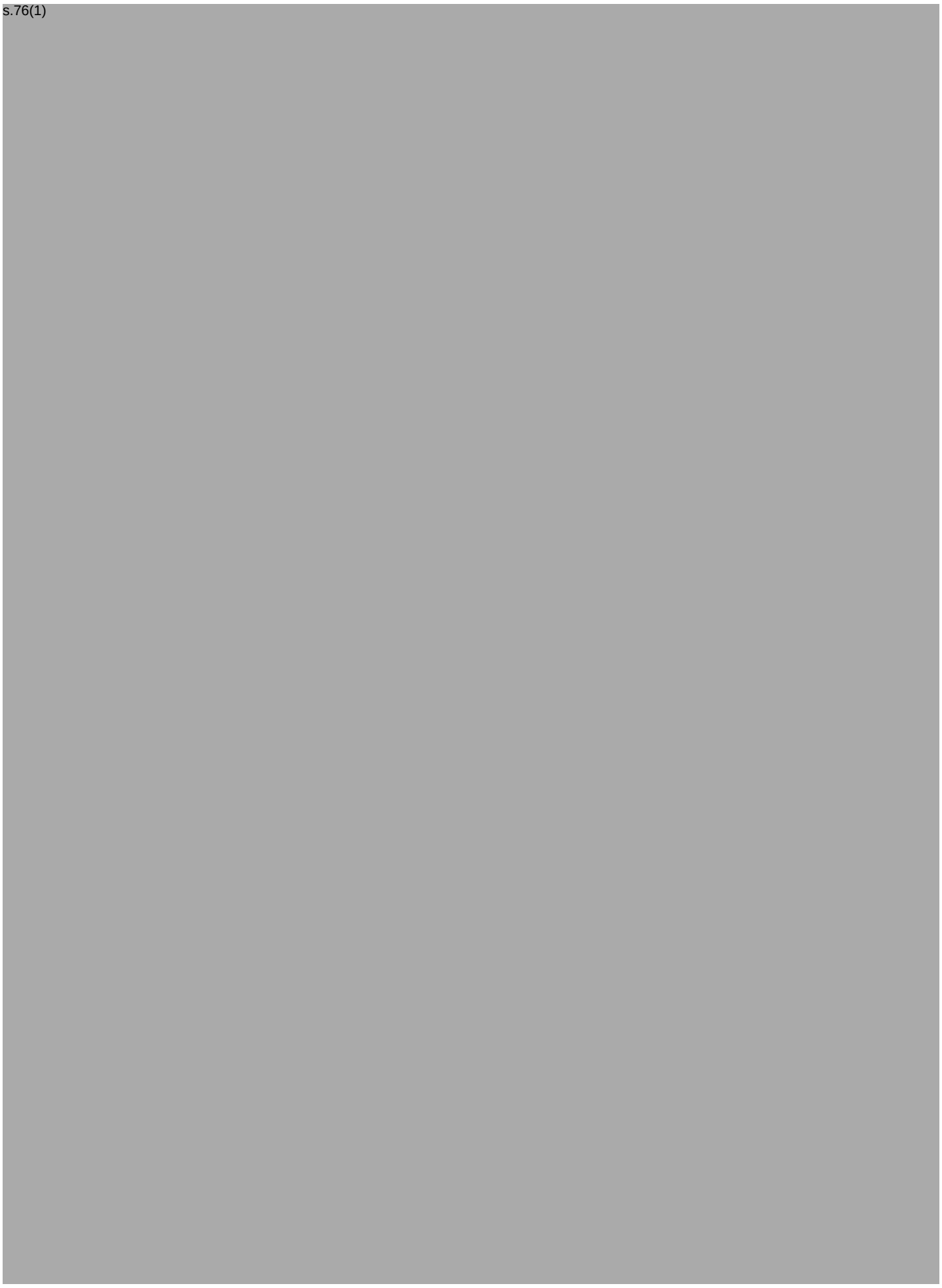
s.76(1)



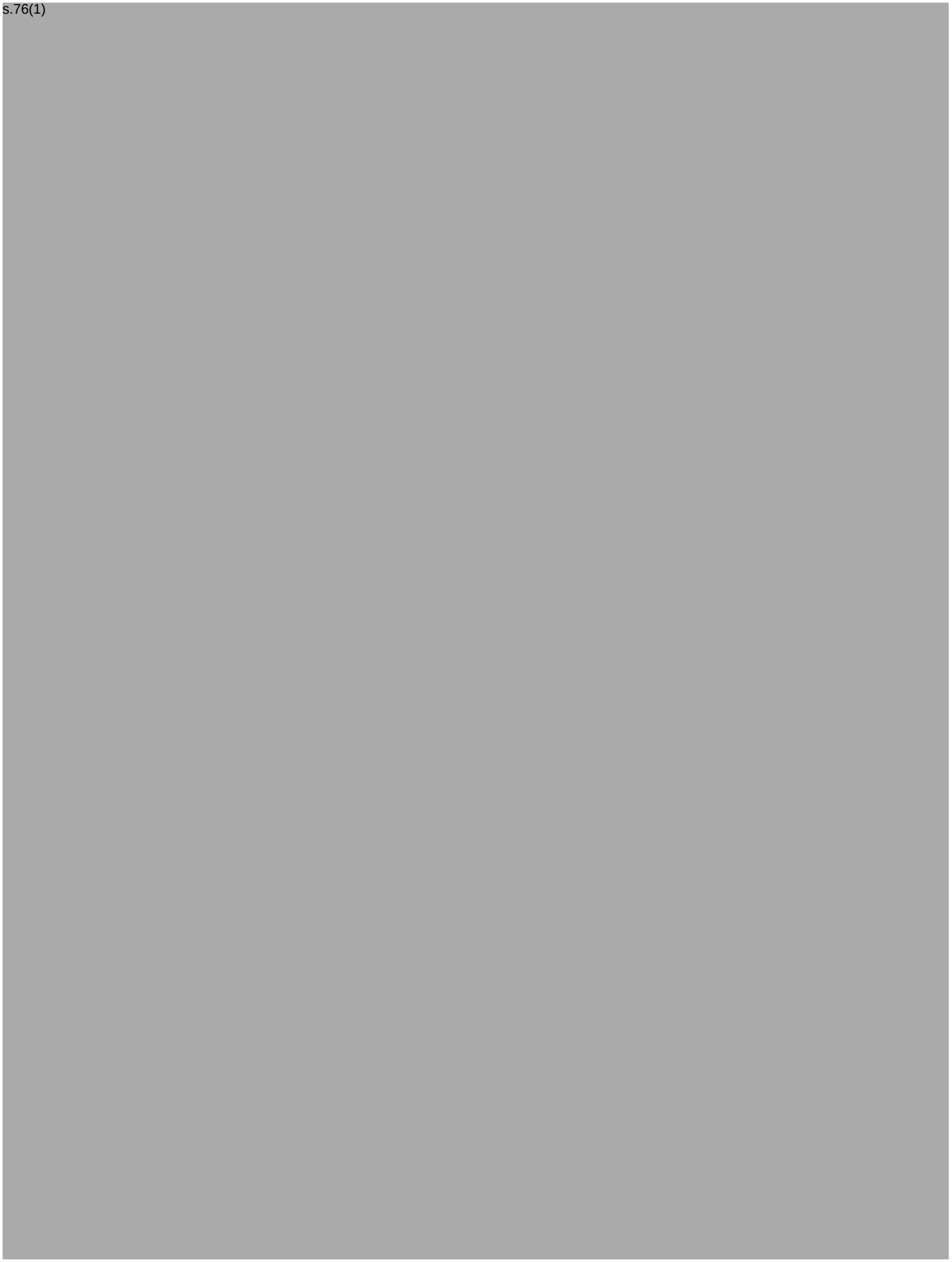
s.76(1)



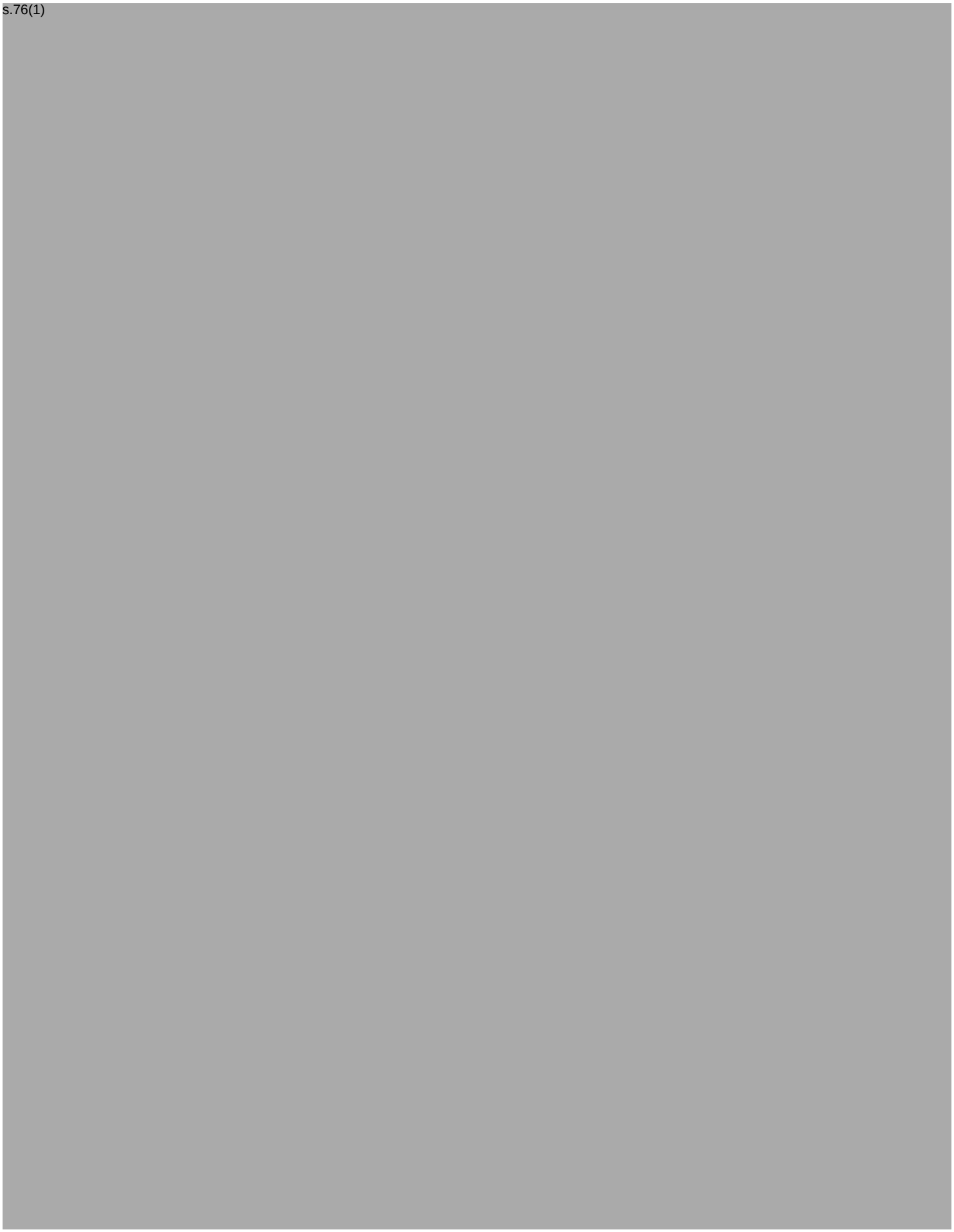
s.76(1)



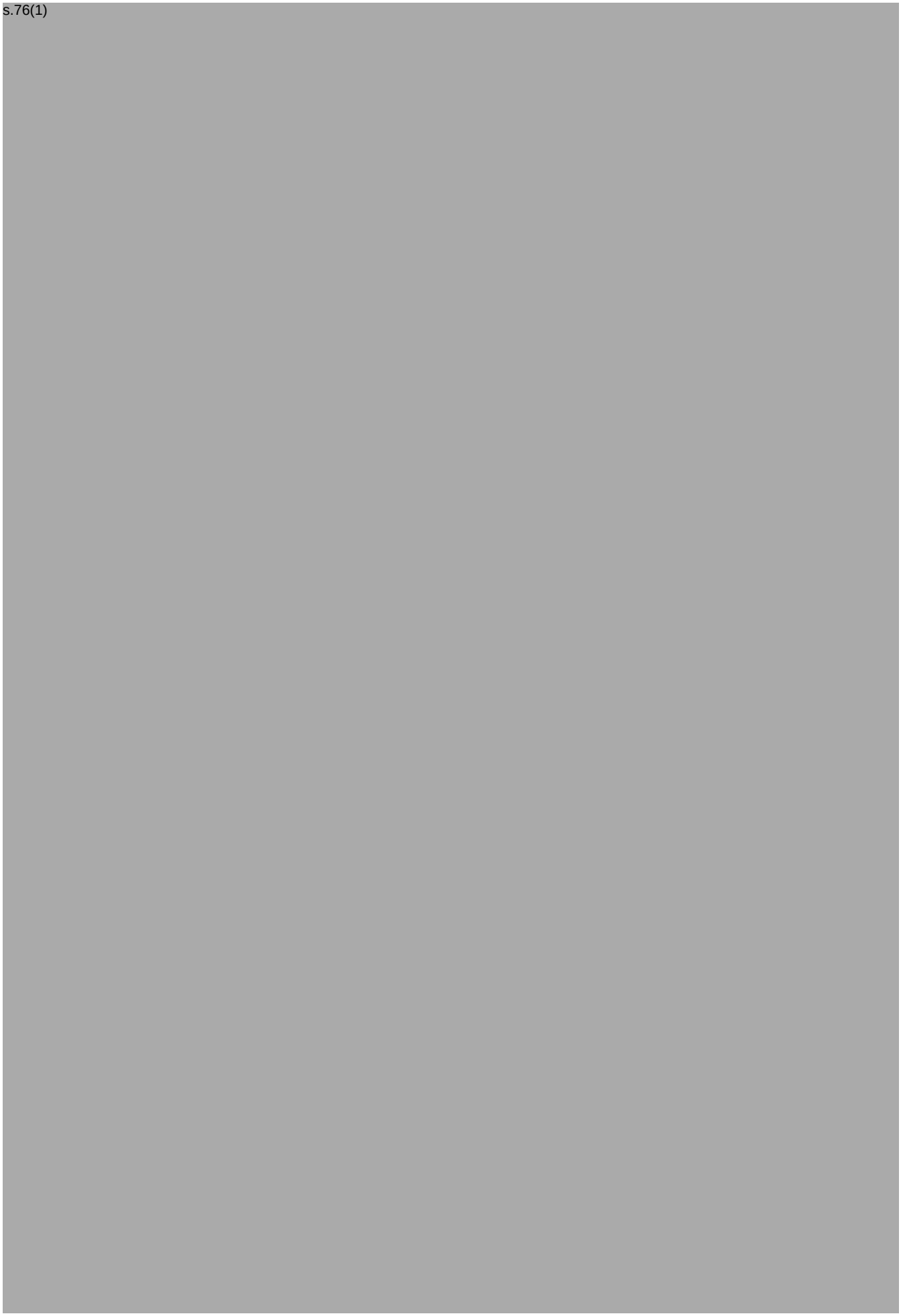
s.76(1)



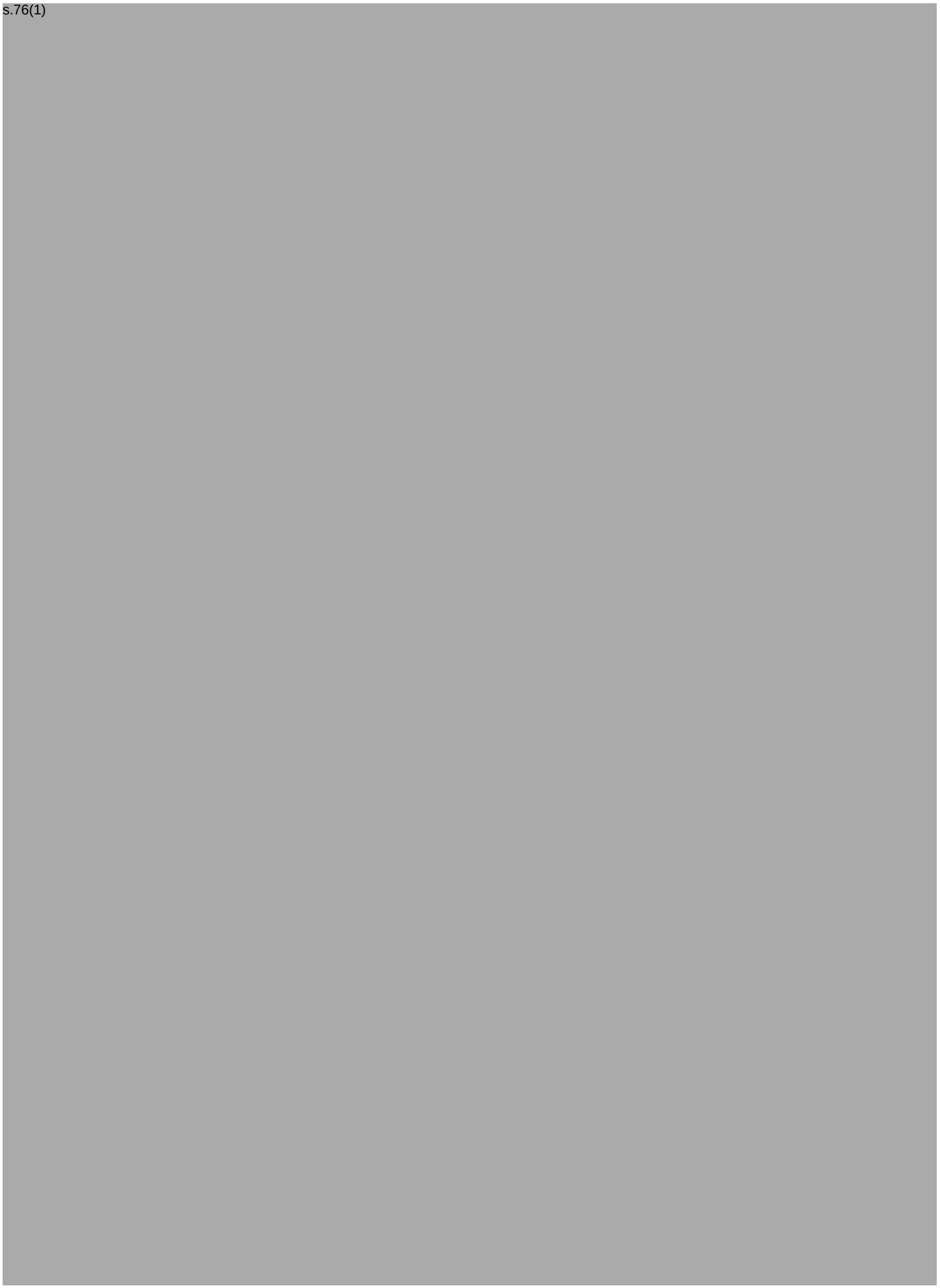
s.76(1)



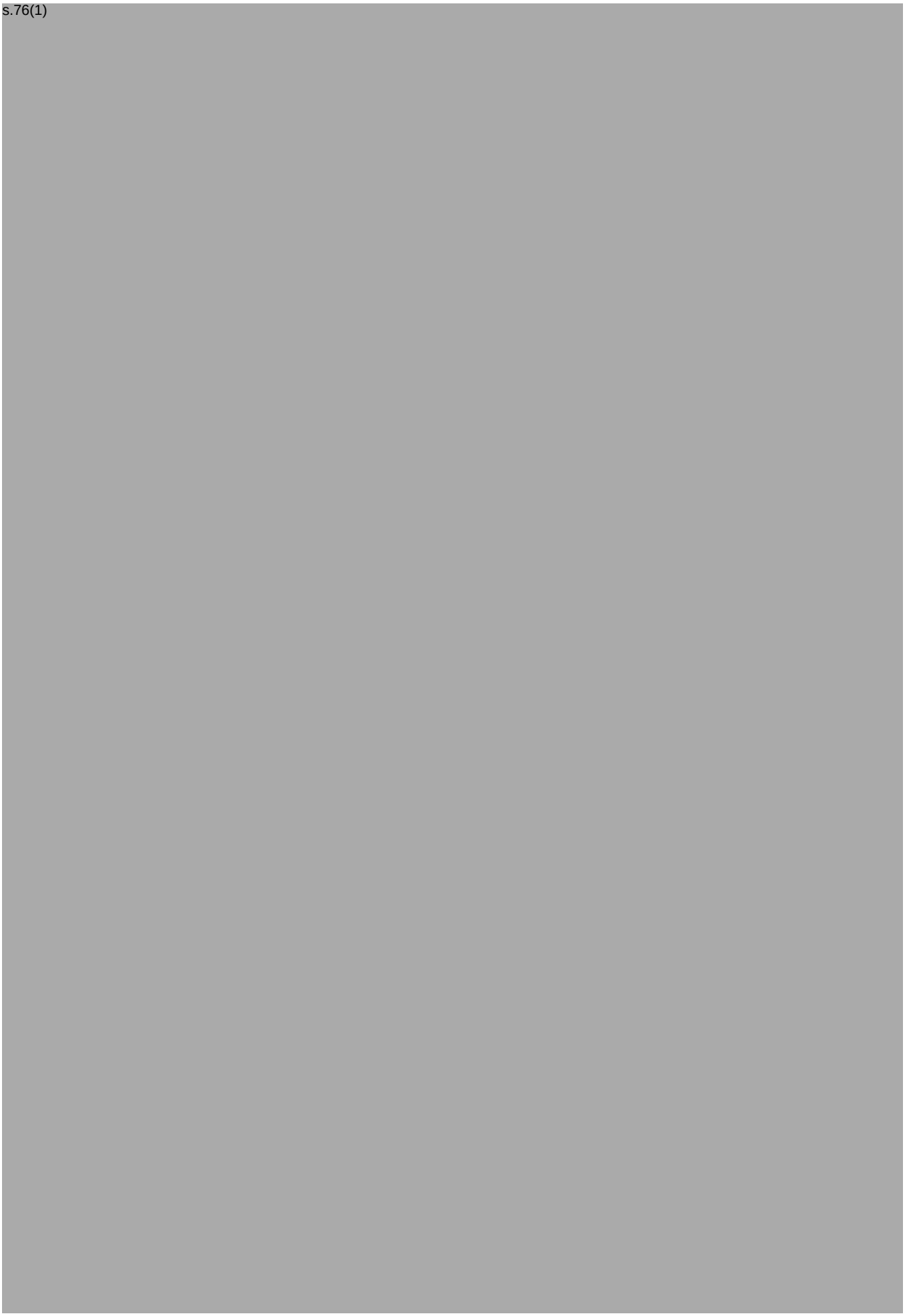
s.76(1)



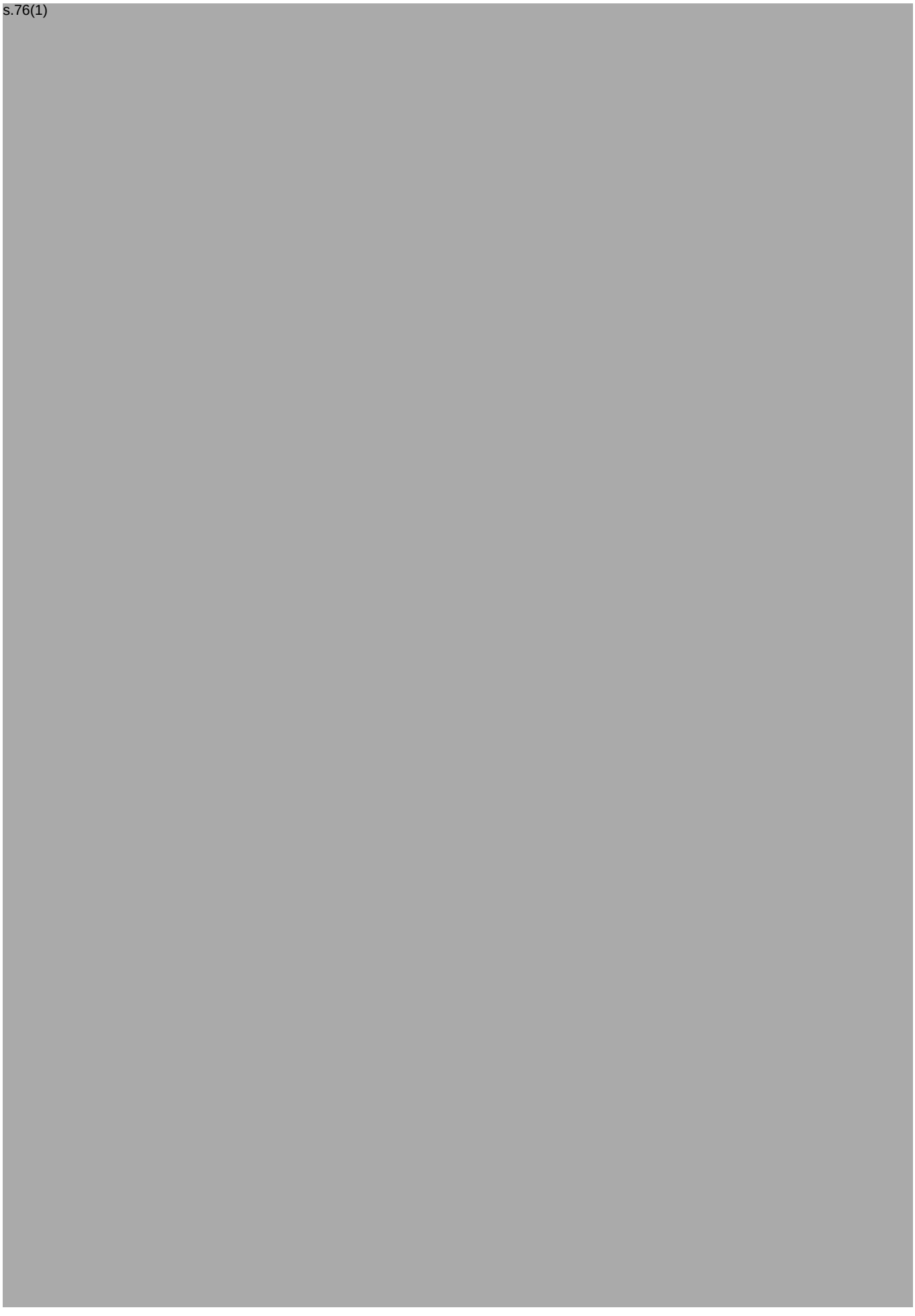
s.76(1)



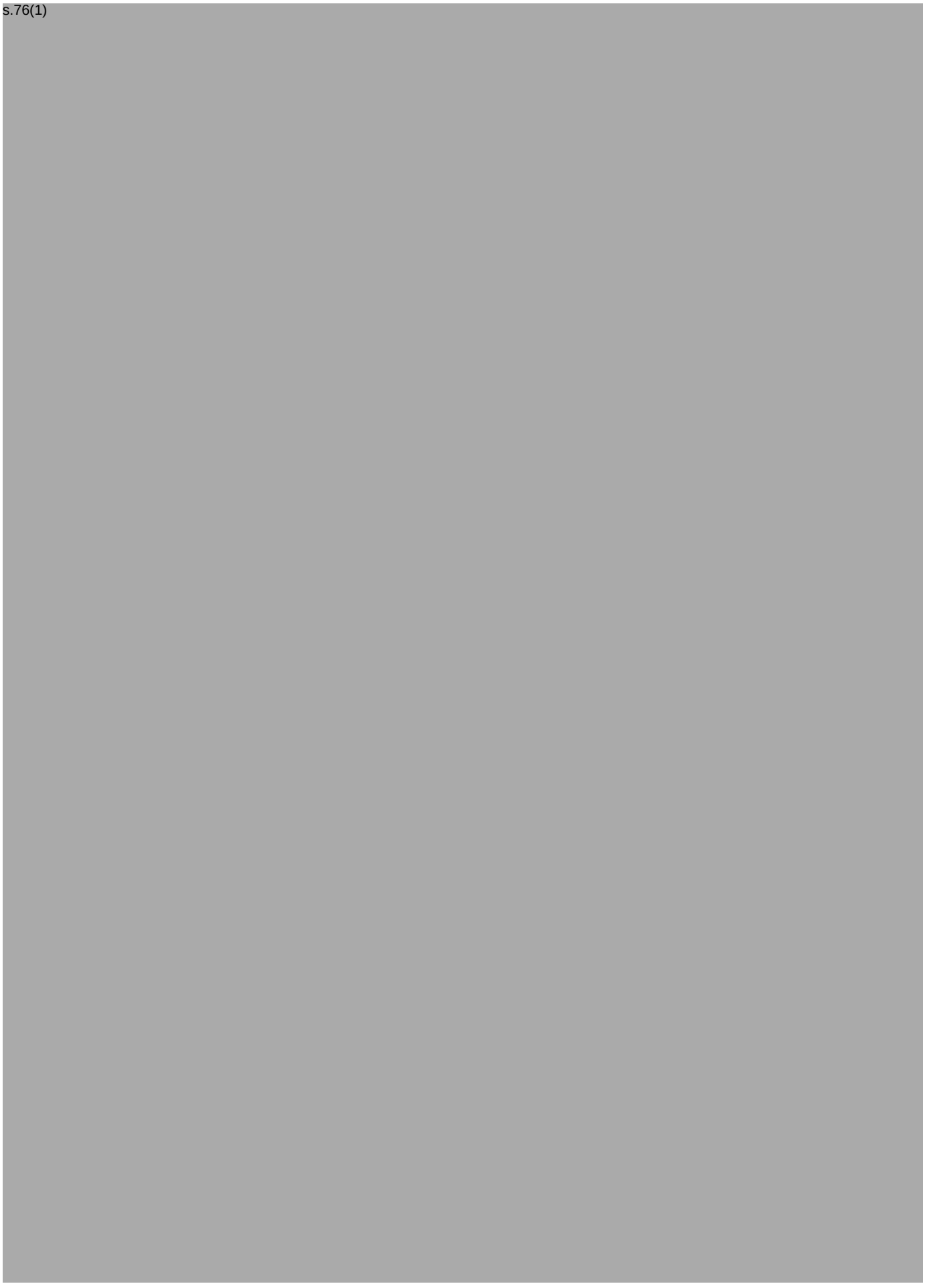
s.76(1)



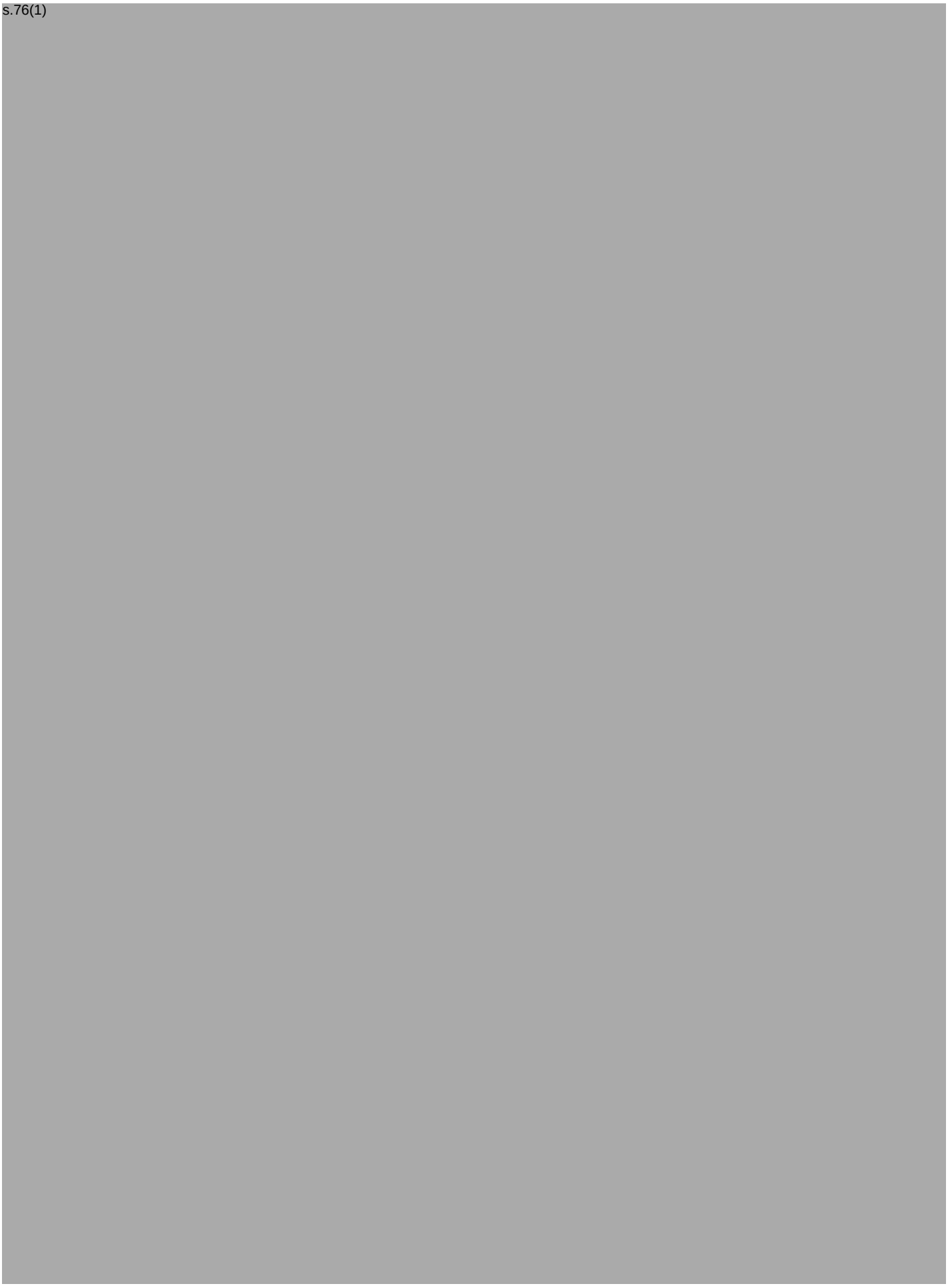
s.76(1)



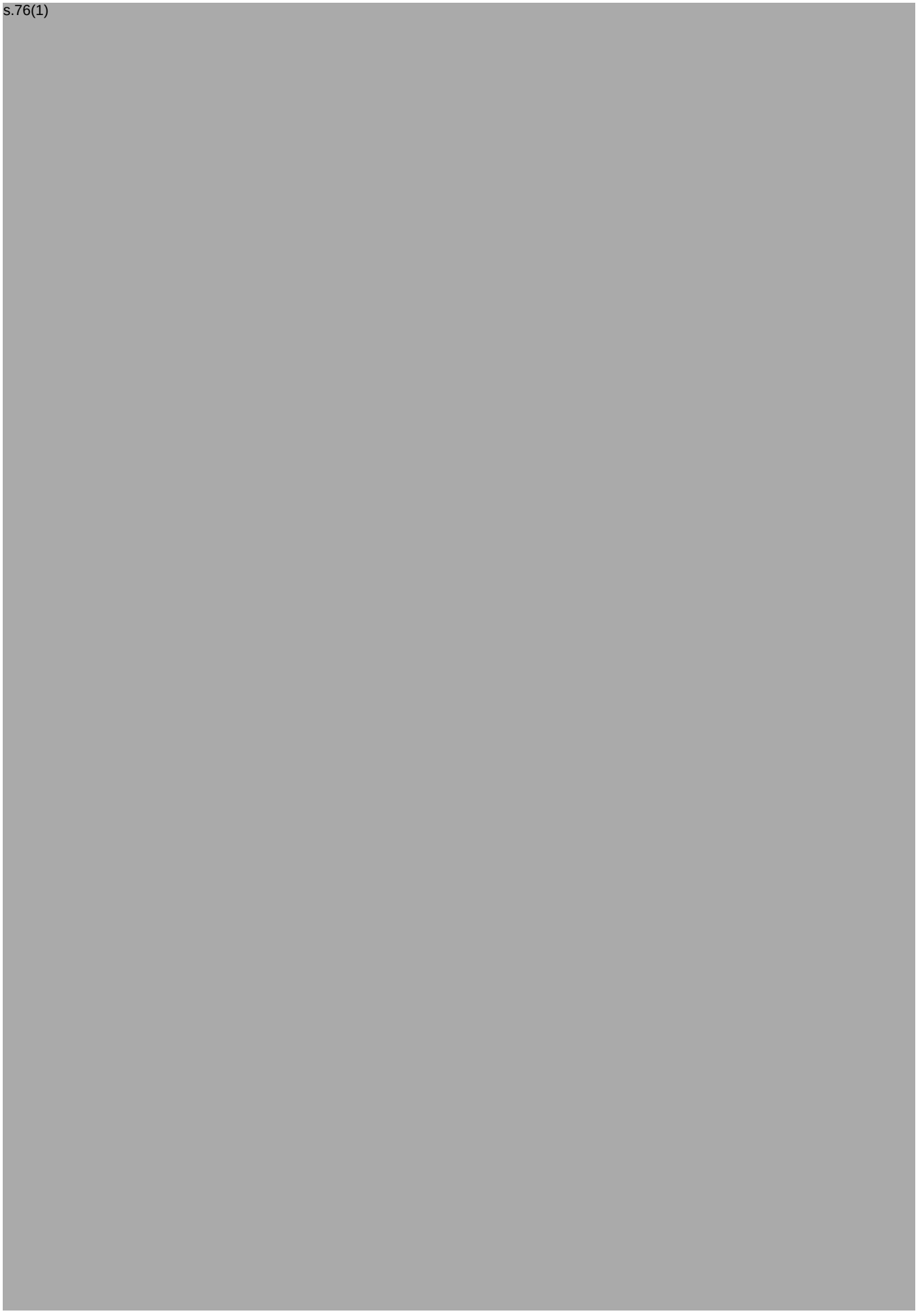
s.76(1)



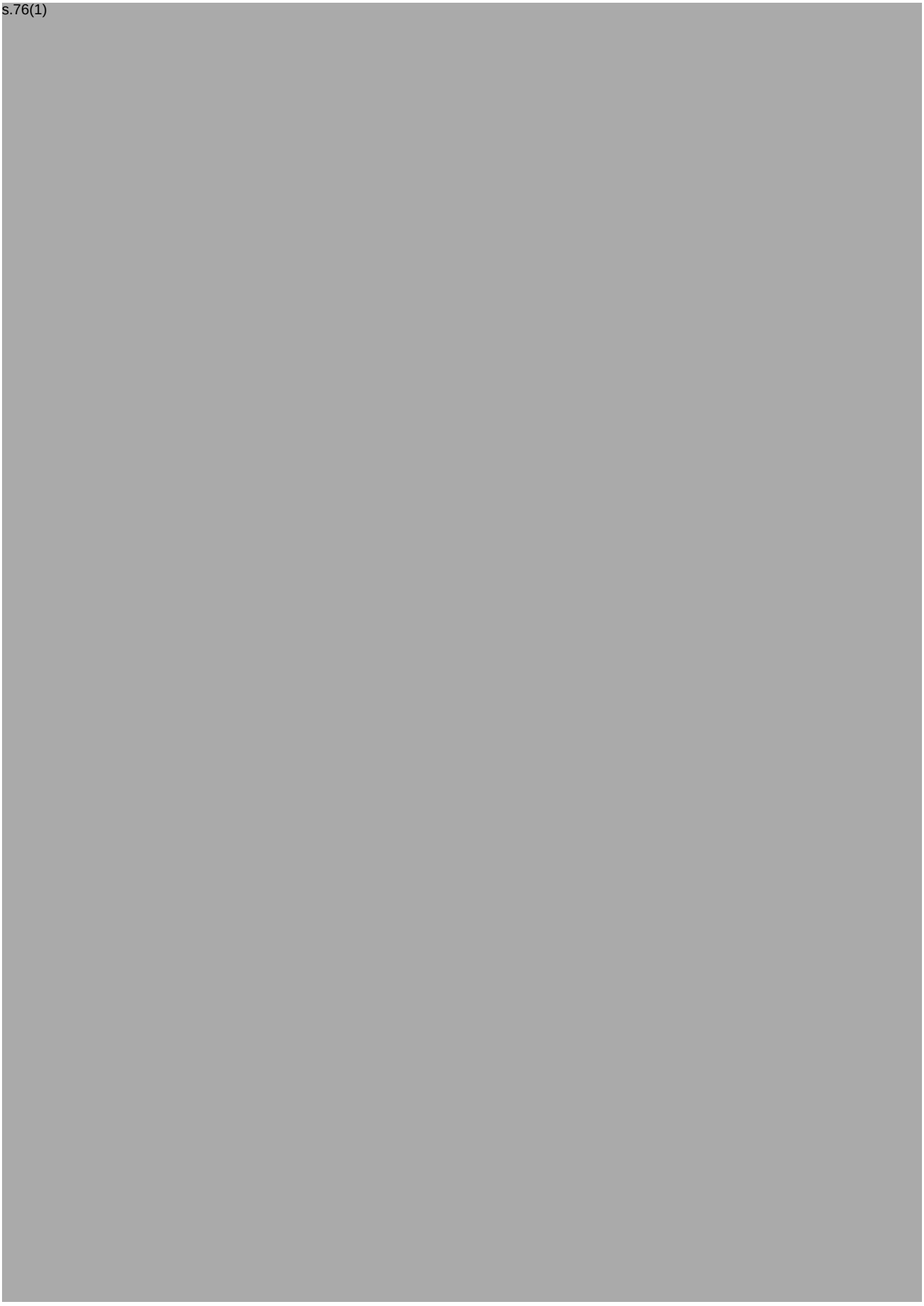
s.76(1)



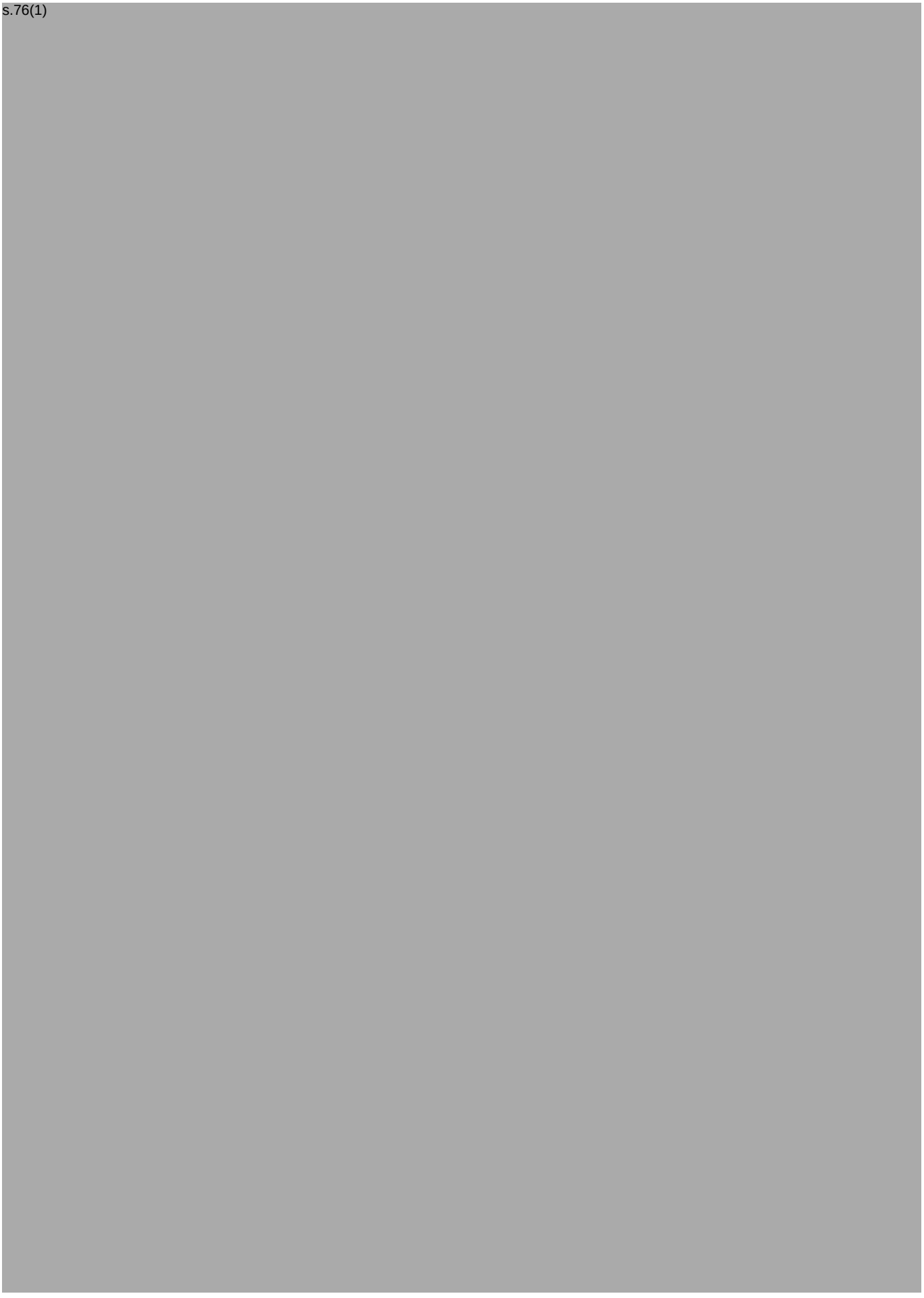
s.76(1)



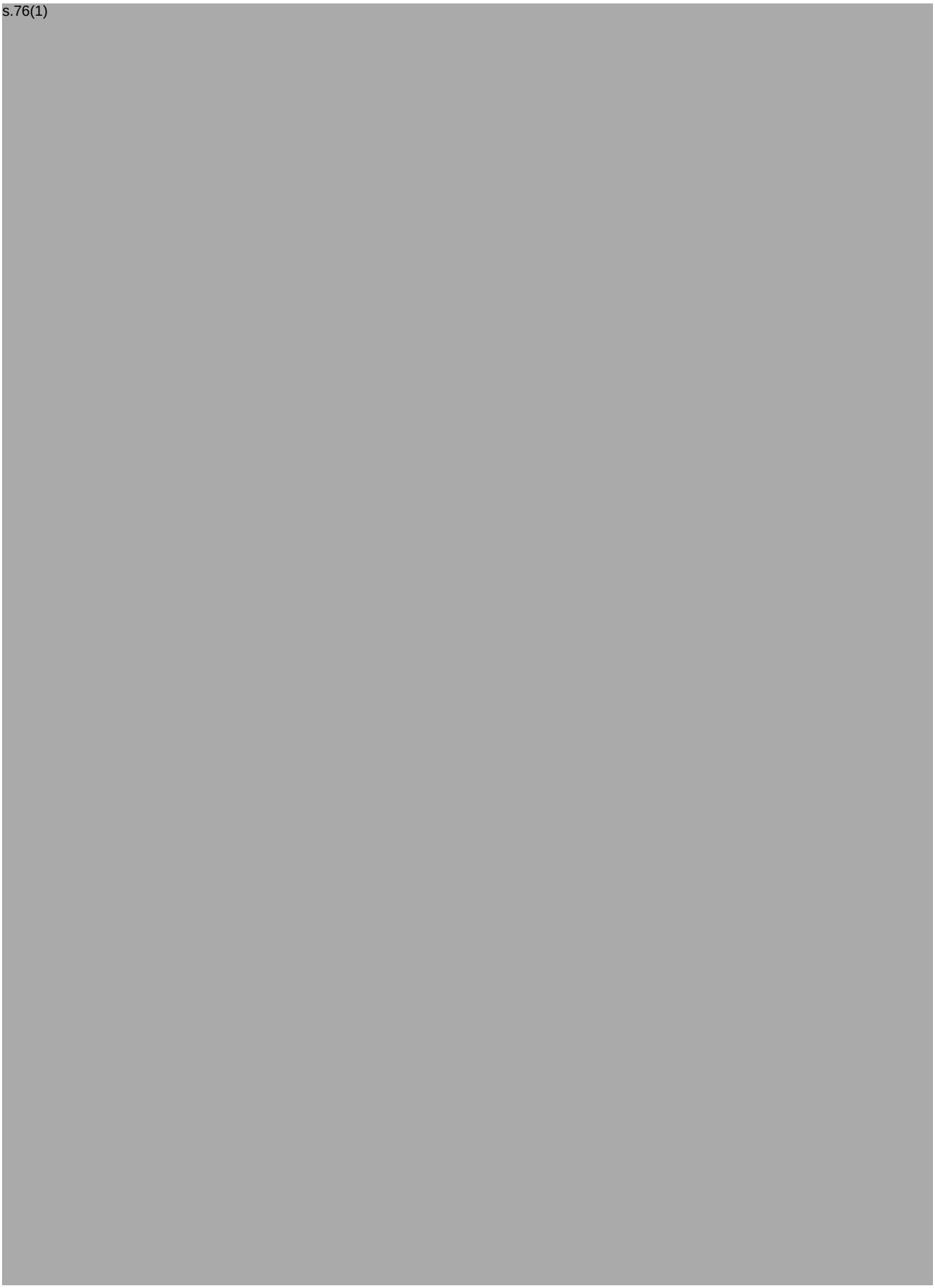
s.76(1)



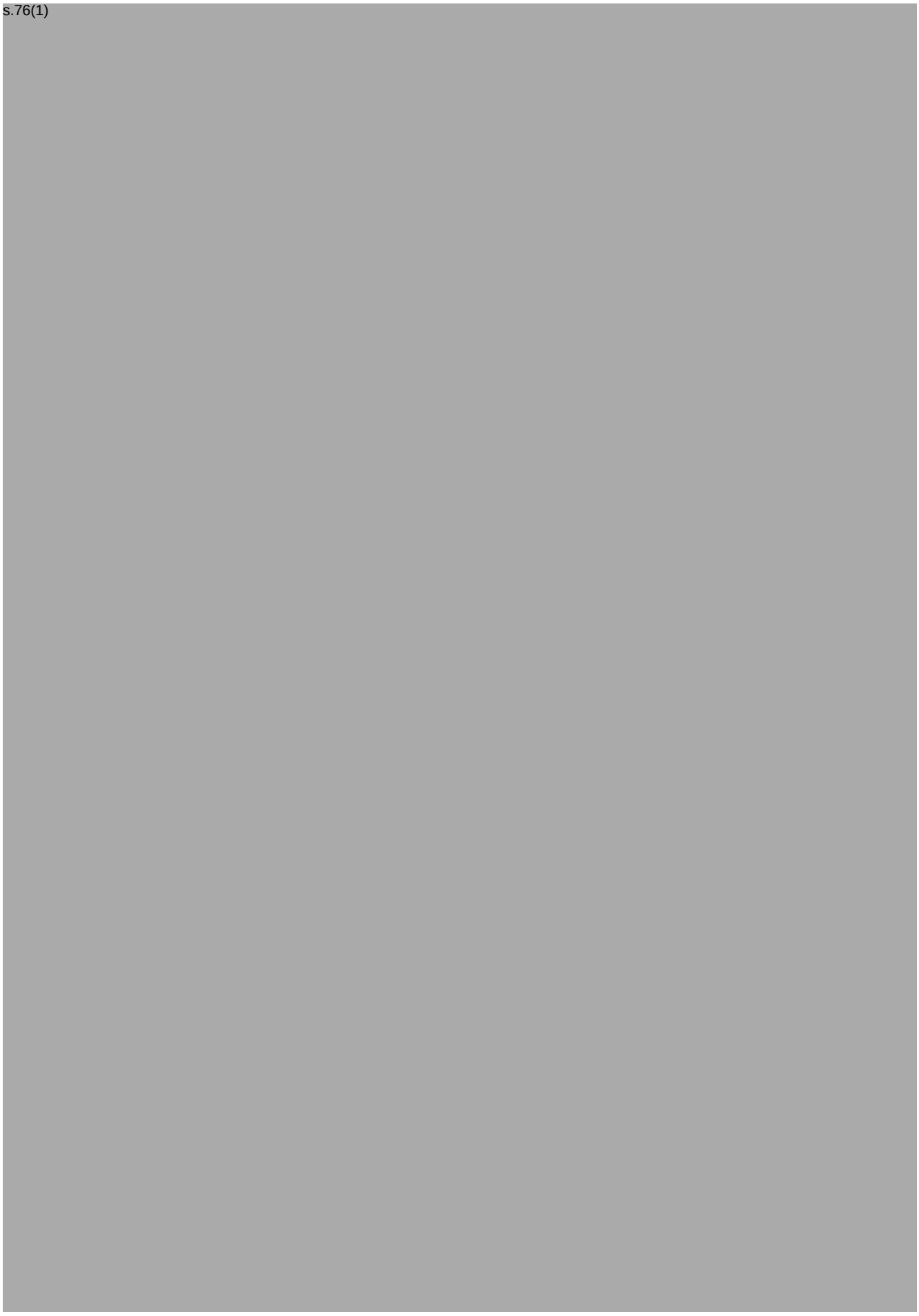
s.76(1)



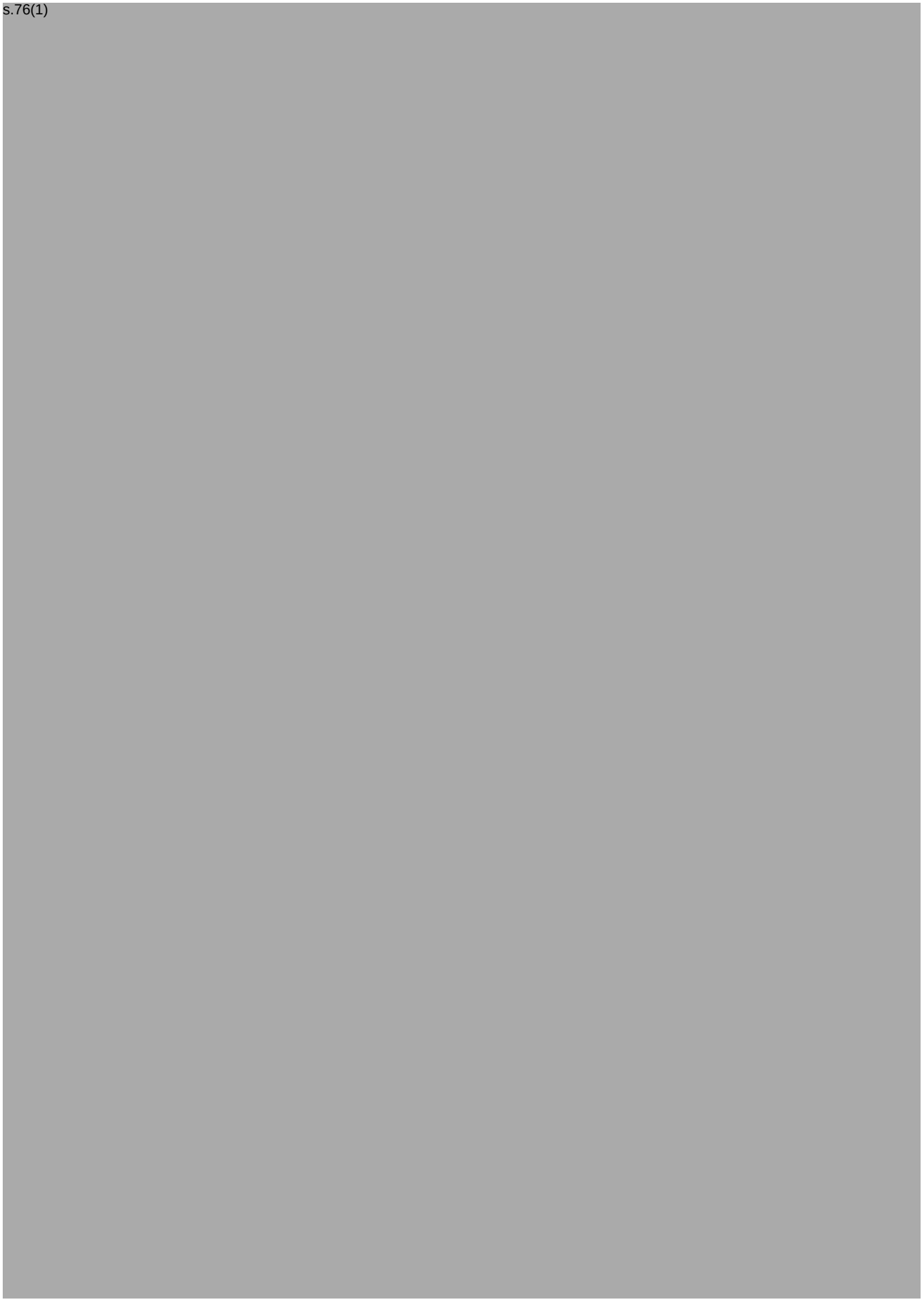
s.76(1)



s.76(1)



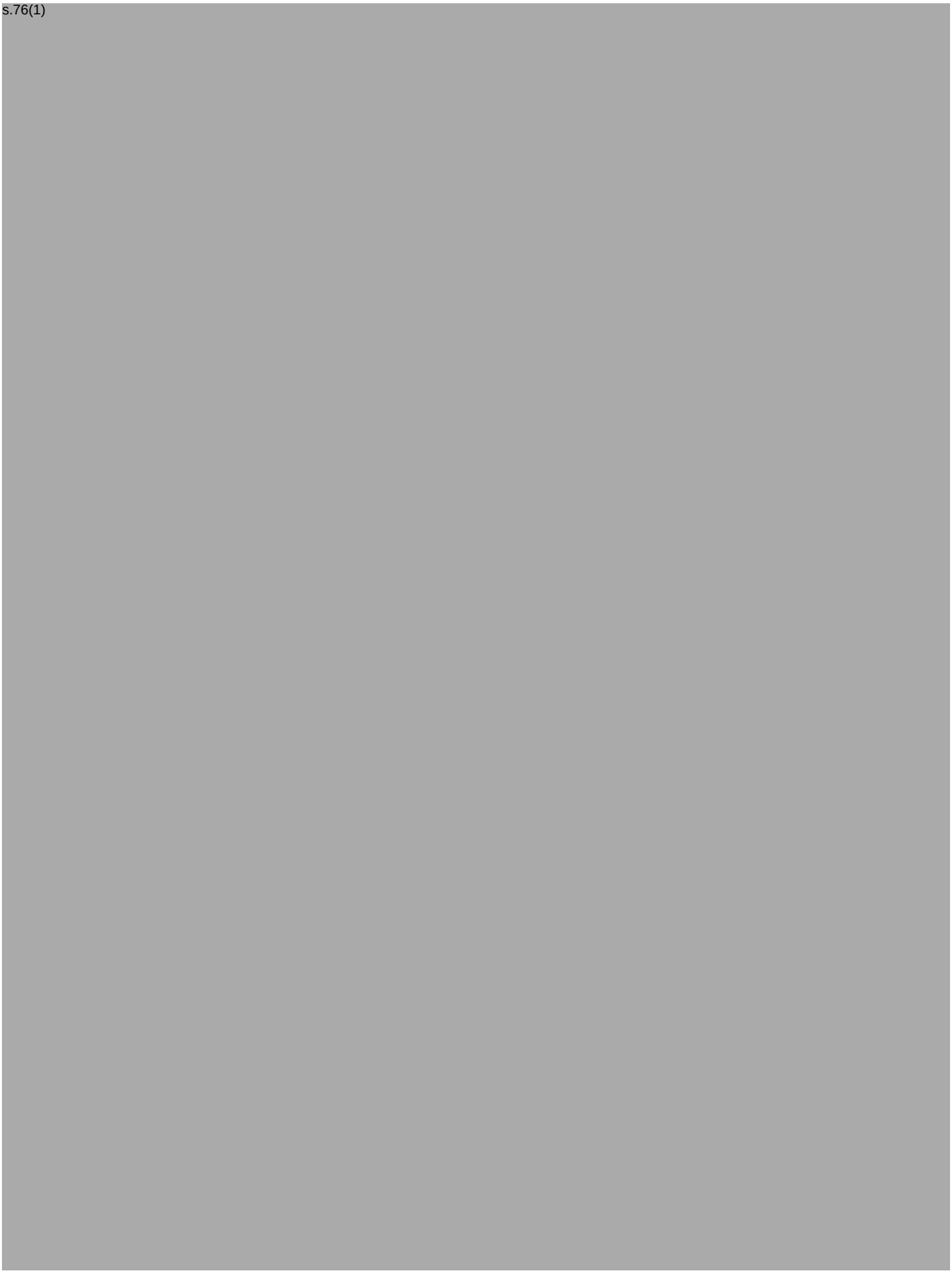
s.76(1)



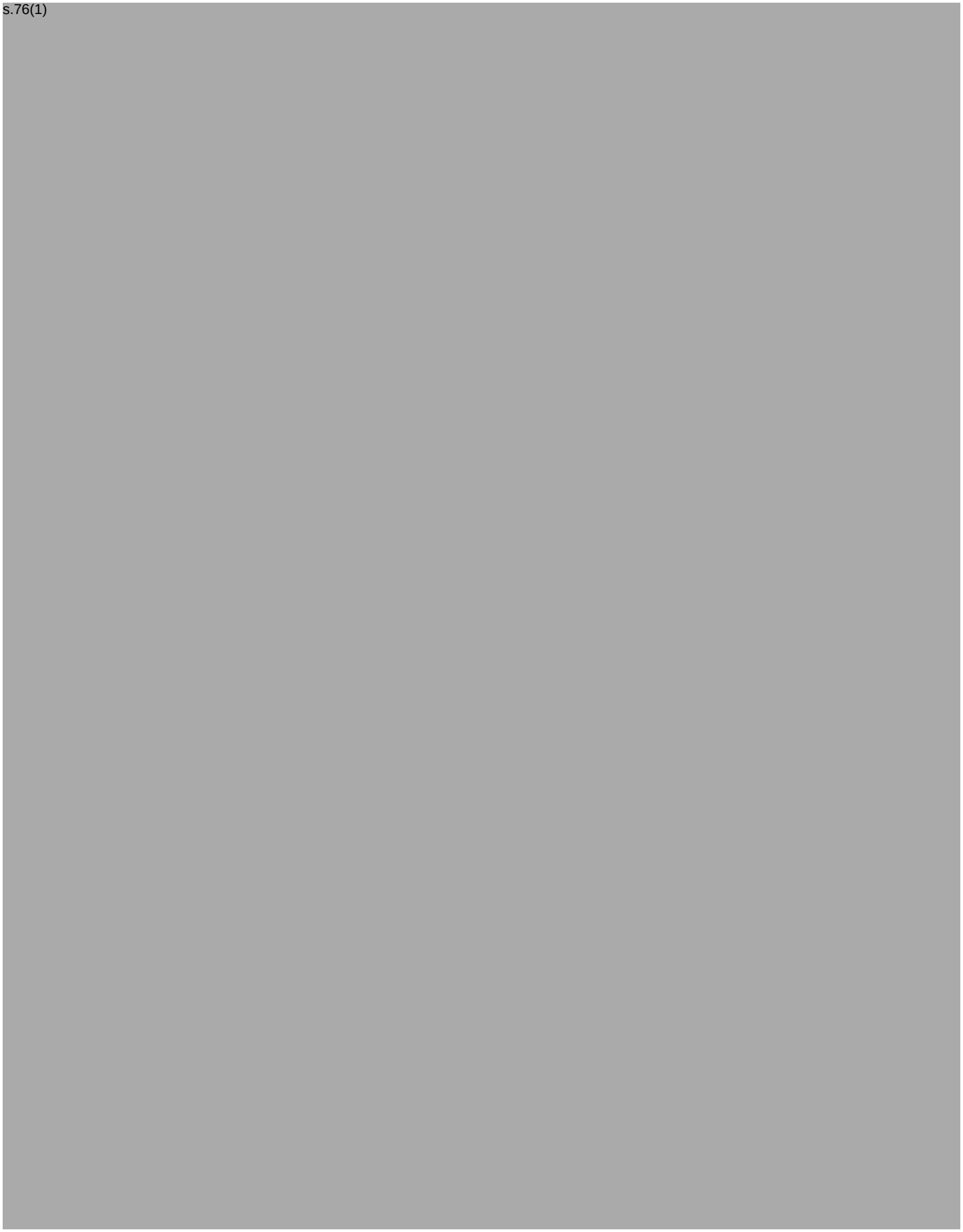
s.76(1)

[redacted]

s.76(1)



s.76(1)



From: Grandy, Jennifer (HC/SC) on behalf of DRD Secretariat / Secrétariat des MTMR (HC/SC)
To: Boudreau, Michelle (HC/SC); "Ian.Rongve@gov.bc.ca"; "Tijana.Fazlagic@gov.bc.ca"; "natalie.mcmurtry@gov.ab.ca"; "Chad.Ryan@health.gov.sk.ca"; "Robert.shaffer@gov.mb.ca"; "patrick.dicerni@ontario.ca"; "eric.levesque2@gnb.ca"; "Sheila.MacLeod@novascotia.ca"; "Kathleen.Coleman@novascotia.ca"; "alicialmccallum@GOV.PE.CA"; "PatrickMorrissey@gov.nl.ca"; Cathy.Mcneil; "Jeannie_Mathison@gov.nt.ca"; "cnieuwstraten@gov.nu.ca"; "karen.fortin@sac-isc.gc.ca"; "dominic.belanger@msss.gouv.qc.ca"
Cc: "Leah.Fuder@gov.bc.ca"; "Lauren.Bresee@gov.bc.ca"; "andrea.nagle@gov.ab.ca"; "Rachel.Cheruvallath@gov.ab.ca"; "Sherry.Holland@gov.ab.ca"; "Marina.Facci@health.gov.sk.ca"; "michelle.pashovitz@health.gov.sk.ca"; "Jillian.Farrow@health.gov.sk.ca"; "Alan.Lawless@gov.mb.ca"; "carey.lai@gov.mb.ca"; "Angie.wong@ontario.ca"; "Michelle.Falone@ontario.ca"; "Evan.Sotiropoulos@ontario.ca"; "Dan.Coulombe@gnb.ca"; "rachel.comeau@gnb.ca"; "mxdemone@gov.pe.ca"; "tjpaynter@ihis.org"; "BDBERTELSEN@gov.pe.ca"; "pbarnes@gov.nl.ca"; Jason.Durand; Prev.Naidoo; Robert.Furlong; "luke_spooner@gov.nt.ca"; "ATaylor1@gov.nu.ca"; "valerie.fontaine@msss.gouv.qc.ca"; "michelle.mujoomdar@sac-isc.gc.ca"; Carter, Luke (HC/SC); Conly, Meghan (HC/SC); Boutin, Jennifer (HC/SC); Lawlor, Brent (HC/SC); MacDonald, Daniel (HC/SC); DRD Secretariat / Secrétariat des MTMR (HC/SC); HC.F DRD / MTMR F.SC; Wilson, Clara (HC/SC); Harris, Natasha (HC/SC)
Subject: Announcement of Ontario DRD bilateral agreement and common set DRD – Annonce d'accord bilatéral avec l'Ontario sur les MTMR et de MTMR de l'ensemble commun
Date: January 24, 2025 6:23:37 AM

Unclassified / Non classifié

(le français suit)

Dear colleagues,

We are pleased to announce that an agreement has been signed with Ontario under the *National Strategy for Drugs for Rare Diseases (Drugs for rare diseases bilateral agreements - Canada.ca)*.

Ontario has elected five drugs on the common list already made public (Drugs for rare diseases: Common list of drugs - Canada.ca):

- **Poteligeo** (Mycosis fungoides or Sézary syndrome);
- **Oxlumo** (Primary hyperoxaluria type 1);
- **Epkinly** (Relapsed or refractory diffuse large B-cell lymphoma);
- **Welireg** (Von Hippel-Lindau disease); and
- **Yescarta** (Follicular lymphoma; 2nd line treatment of diffuse large B-cell lymphoma or high-grade large B-cell lymphoma).

Should you have any questions, please do not hesitate to contact the DRD Secretariat.

Thank you

Chers collègues,

Nous sommes heureux d'annoncer qu'un accord a été signé avec l'Ontario dans le cadre de

la *Stratégie nationale visant les médicaments pour le traitement des maladies rares* (Accords bilatéraux pour les médicaments pour le traitement des maladies rares - Canada.ca). Ontario a désigné cinq médicaments sur la liste commune déjà rendus publics (Médicaments pour le traitement des maladies rares: Liste commune de médicaments - Canada.ca) :

- **Poteligeo** (mycosis fongoïde ou syndrome de Sézary) ;
- **Oxlumo** (hyperoxalurie primaire de type 1) ;
- **Epkinly** (lymphome diffus à grandes cellules B (DLBCL) récidivant ou réfractaire);
- **Welireg** (maladie de von Hippel-Lindau); et
- **Yescarta** (lymphome folliculaire; traitement de deuxième intention de lymphome B diffus à grandes cellules ou lymphome B à grandes cellules de haut grade)

Si vous avez des questions, n'hésitez pas à contacter le Secrétariat des MTMR.

Merci

The DRD Secretariat | Le secrétariat des MTMR
Drugs for Rare Diseases Directorate | Bureau des médicaments pour le traitement des maladies rares
Health Policy Branch | Direction générale des politiques de la santé
Health Canada|Santé Canada
drd-secretariat-mtmr@hc-sc.gc.ca

From:	Leblanc, Josee (HC/SC) on behalf of DRD Secretariat / Secrétariat des MTMR (HC/SC)
To:	Boudreau, Michelle (HC/SC); Mitch.Moneo@gov.bc.ca; Tijana.Fazlagic@gov.bc.ca; natalie.mcmurtry@gov.ab.ca; Chad.Ryan@health.gov.sk.ca; Robert.shaffer@gov.mb.ca; patrick.dicerni@ontario.ca; eric.levesque2@gnb.ca; Sheila.MacLeod@novascotia.ca; Kathleen.Coleman@novascotia.ca; alicialmccallum@GOV.PE.CA; pbarnes@gov.nl.ca; Cathy.Mcneil; Jeannie_Mathison@gov.nt.ca; cnieuwstraten@gov.nu.ca; scott.doidge@sac-isc.gc.ca; dominic.belanger@msss.gouv.qc.ca
Cc:	Leah.Fuder@gov.bc.ca; Lauren.Bresee@gov.bc.ca; andrea.nagle@gov.ab.ca; Rachel.Cheruvallath@gov.ab.ca; Sherry.Holland@gov.ab.ca; Marina.Facci@health.gov.sk.ca; michelle.pashovitz@health.gov.sk.ca; Jillian.Farrow@health.gov.sk.ca; Alan.Lawless@gov.mb.ca; carey.lai@gov.mb.ca; Angie.wong@ontario.ca; Michelle.Falone@ontario.ca; Evan.Sotiropoulos@ontario.ca; Dan.Coulombe@gnb.ca; rachel.comeau@gnb.ca; mxdemone@gov.pe.ca; tjpaynter@ihis.org; BDBERTELSEN@gov.pe.ca; Jason.Durand; Prev.Naidoo; Robert.Furlong; luke_spooner@gov.nt.ca; ATaylor1@gov.nu.ca; valerie.fontaine@msss.gouv.qc.ca; karen.fortin@sac-isc.gc.ca; michelle.mujoomdar@sac-isc.gc.ca; Carter, Luke (HC/SC); Conly, Meghan (HC/SC); Boutin, Jennifer (HC/SC); Lawlor, Brent (HC/SC); MacDonald, Daniel (HC/SC); DRD Secretariat / Secrétariat des MTMR (HC/SC); HC.F DRD / MTMR F.SC; Wilson, Clara (HC/SC); Harris, Natasha (HC/SC)
Subject:	PEG – announcement of common set DRD with LOIs/GEPP - annonce des MTMR avec lettre d'intention
Date:	November 29, 2024 11:12:46 AM
Attachments:	Proposed Key Messages - Yescarta.docx Proposed Key Messages - Welireg.docx Key Messages - Epkinly (final).docx

---

Unclassified / Non classifié

(sent on behalf of/envoyé de la part de Michelle Boudreau)

(le français suit)

Dear colleagues,

In advance of our next PEG meeting on December 12, we wanted to inform you that **effective December 2**, British Columbia will be electing **Epkinly**, **Welireg**, and **Yescarta** in relation to their DRD bilateral agreement. All three drugs received their pCPA LOIs more than 60 days ago.

There is currently no news release planned related to that election, but Health Canada's web page on the common set will be updated on December 4.

We have also developed **proposed key messages** on Welireg and Yescarta, which you will find attached. Those key messages could be used to answer stakeholder questions or for potential future news releases related to bilateral agreements and election of those drugs. If you have any **red lines**, please let us know as soon as possible. For your reference, we are also reattaching the final key messages on Epkinly (which incorporate PT comments and were circulated last week).

Thank you,
Michelle

Chers collègues,

Avant notre prochaine réunion du GEPP le 12 décembre, nous voulions vous informer que la Colombie-Britannique va choisir **Epkinly**, **Welireg** et **Yescarta** en date du **2 décembre** en relation à leur accord bilatéral sur les MTMR. La lettre d'intention de l'AFPC pour tous ces MTMR a eu lieu il y a plus de 60 jours.

Il n'y a présentement pas de communiqué de presse en relation à ce choix, mais la page web de Santé Canada sur la liste commune sera mise à jour le 4 décembre.

Nous avons développé des **messages clés proposés** sur Welireg et Yescarta, que vous trouverez en pièce jointe. Ces messages pourraient être utilisés pour répondre aux questions des intervenant ou pour des communiqués de presse futurs reliés aux accords bilatéraux et des choix par rapport à ces médicaments. Si vous avez des **commentaires critiques**, veuillez nous en informer dans les plus brefs délais. Pour votre référence, vous trouverez aussi en pièce jointe les messages clés (version finale) sur Epkinly (qui incorporent les commentaires des PTs et ont été circulés la semaine dernière).

Merci,
Michelle
Attachments/pièces jointes:
Proposed Key Messages - Welireg
Proposed Key Messages - Yescarta
Key Messages - Epkinly

Key Points - Yescarta

- Yescarta is a drug used to treat several forms of relapsed or refractory B-cell lymphomas in adults: follicular lymphoma, large B-cell lymphoma (LBCL), diffuse large B-cell lymphoma (DLBCL), and high-grade B-cell lymphoma (HGBL).

- B-cell lymphomas are cancers that start in white blood cells called B-cells, which are part of the immune system.

- Yescarta is a CAR-T cell therapy which uses a patient's own immune cells to fight cancer.

- The incidence rate of DLBCL in Canada is approximately 34 cases per million individuals per year, meaning that there could be approximately 1,400 new cases per year. Approximately 30% to 50% of patients will experience disease relapse within 2 years of initial treatment.

- The incidence rate of follicular lymphoma in Canada is approximately 38.3 per million individuals per year, meaning that there could be approximately 1,600 new cases per year.

- According to analyses by Canada's Drug Agency, treatment with Yescarta is expected to cost $485,021 per patient (single infusion).

- Health Canada has authorized Yescarta for adult patients with:

    - diffuse large B-cell lymphoma (DLBCL) or high-grade B-cell lymphoma (HGBL) that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy, or

    - relapsed or refractory large B-cell lymphoma (LBCL) after two or more lines of systemic therapy, including DLBCL nor otherwise specified, primary mediastinal large B-cell lymphoma (PMBCL), HGBL, and DLBCL arising from follicular lymphoma.

- Health Canada has also authorized Yescarta with conditions for adult patients with relapsed or refractory grade 1, 2 or 3a follicular lymphoma after two or more lines of systemic therapy.

Key Points - Welireg

- Welireg is a drug used to treat adults with von Hippel-Lindau (VHL) disease, an inherited genetic condition associated with tumours developing in multiple organs.
- The prevalence of VHL disease is estimated to be 1 in 53,000 individuals.
- According to analyses by Canada's Drug Agency, treatment with Welireg is expected to cost $17,920 per 28 days.
- Health Canada has authorized Welireg for adult patients with von Hippel-Lindau (VHL) disease who require therapy for associated non-metastatic renal cell carcinoma, central nervous system hemangioblastomas, or non-metastatic pancreatic neuroendocrine tumors, not requiring immediate surgery.

Key Points - Epkinly

- Epkinly is a drug used in adults to treat relapsed or refractory diffuse large B-cell lymphoma (DLBCL), a form of cancer.

- DLBCL is a blood cancer that occurs when a type of white blood cell, called a B-cell, grows or divides abnormally, which causes tumours in the lymph nodes or other organs, including the spleen, liver, or bone marrow. Relapsed or refractory DLBCL is cancer that has come back after treatment or has not responded to certain treatments respectively.

- The incidence rate of DLBCL in Canada is approximately 34 cases per million individuals per year, meaning that there could be approximately 1,400 new cases per year. Approximately 30% to 50% of patients will experience disease relapse within 2 years of initial treatment.

- Treatment with Epkinly is expected to cost $14,320 per patient at list price for an initial 28-day cycle. Subsequent 28-day cycles will vary in cost.

- Epkinly is the first drug to receive a time-limited reimbursement recommendation from Canada's Drug Agency (CDA-AMC), which is a recommendation to publicly fund a drug for a certain period of time on the condition that the manufacturer will conduct ongoing clinical studies that address uncertainty in the evidence and that CDA-AMC will conduct a future reassessment of that additional evidence. The future reassessment will lead to a final reimbursement recommendation. More information can be found on the CDA-AMC website.

- Epkinly is also the first drug to go through the pan-Canadian Pharmaceutical Alliance's (pCPA) Temporary Access Process (pTAP), a new negotiation pathway developed by the pCPA to establish temporary access to drugs that have received a time-limited reimbursement recommendation from CDA-AMC. The temporary pCPA price will be in effect until a final long-term pCPA agreement is negotiated after the manufacturer submits additional data to CDA-AMC that addresses uncertainty in the evidence. More information can be found on the pCPA website.

From: Grandy, Jennifer (HC/SC) on behalf of DRD Secretariat / Secrétariat des MTMR (HC/SC)
To: Fazlagic, Tijana HLTH:EX; "kathleen.coleman@novascotia.ca"; "michelle.pashovitz@health.gov.sk.ca"; Prev.Naidoo; "jillian.farrow@health.gov.sk.ca"; "rachel.cheruvallath@gov.ab.ca"; pbarnes@gov.nl.ca; "andrea.nagle@gov.ab.ca"; Luke Spooner; "michelle.falone@ontario.ca"; Wong, Angie H (MOH); "nmacphee@gov.pe.ca"; Carey Ilchuk; alan.lawless@gov.mb.ca; "chris.schrader@gov.mb.ca"; Facci, Marina HE0; Fortin, Karen; "Lara.Grant@novascotia.ca"; Nieuwstraten, Carmine; Mujoomdar, Michelle; "Bernita.Rebeiro@ontario.ca"; natasa.ceranic@ontario.ca; Weston, Megan D HLTH:EX; Marsha Cusack
Cc: Mark DeMone; MacDonald, Daniel (HC/SC); Hunt, Amanda; Carole Chambers; Rance, Laureen (MOH); "amanda.davy@ontario.ca"; "lilly.whitham@ontario.ca"
Subject: DRD Framework: NIHB coverage of the common set
Date: June 10, 2024 4:45:53 PM

(Sent on behalf of Daniel MacDonald)

Dear colleagues,

We wanted to share information provided by ISC about NIHB coverage of the common set.

As you know, the NIHB Program provides eligible First Nations and Inuit clients with coverage for a range of health benefits that are not covered through other:

1. social programs
2. private insurance plans
3. provincial or territorial health insurance

s.76(1)

[redacted]

s.76(1)

Thank you,

The DRD Secretariat | Le secrétariat des MTMR
Drugs for Rare Diseases Directorate | Bureau des médicaments pour le traitement des maladies rares
Strategic Policy Branch | Direction générale de la politique stratégique
Health Canada|Santé Canada
drd-secretariat-mtmr@hc-sc.gc.ca

From: Fazlagic, Tijana HLTH:EX
To: Wong, Angie H (She/Her) (MOH); "kathleen.coleman@novascotia.ca"; "michelle.pashovitz@health.gov.sk.ca"; Prev.Naidoo; "jillian.farrow@health.gov.sk.ca"; "rachel.cheruvallath@gov.ab.ca"; "pbarnes@gov.nl.ca"; "andrea.nagle@gov.ab.ca"; "luke_spooner@gov.nt.ca"; Falone, Michelle (MOH); nmacphee@gov.pe.ca; "Carey Ilchuk"; "alan.lawless@gov.mb.ca"; "chris.schrader@gov.mb.ca"; "Facci, Marina HE0"; Fortin, Karen; Lara.Grant@novascotia.ca; Mujoomdar, Michelle; Rebeiro, Bernita (MOH); Ceranic, Natasa (MOH); Weston, Megan D HLTH:EX
Cc: Hunt, Amanda; Carole Chambers; Rance, Laureen (MOH); Langille, Shawna (MOH); Davy, Amanda (She/Her) (MOH); Sgrignuoli, Gabriella (MOH)
Subject: [EXT] RE: National Strategy for DRD PT Directors Working Group
Date: March 8, 2024 12:45:08 PM

You don't often get email from tijana.fazlagic@gov.bc.ca. Learn why this is important

Thank you Angie for sharing and to your team and Marina for putting the summary and questions together.

I have now forwarded those questions related to NSDRD to Michelle and Daniel for responses.

Couple of updates:

1. Draft CBN is expected to be shared today
2. Meeting with CADTH and CIHI to hear about their work is being scheduled during our WG time on Tuesday, March 19th
3. PEG is scheduled for March 16th

Daniel also shared that HC is interested and happy to help with supporting whatever is needed as we go forward (e.g. engagement in the work around evidence development, engaging in determining drugs that would fall under NSDRD beyond the initial list, etc)

Have a great weekend.
Tijana

From: Wong, Angie H (She/Her) (MOH) <Angie.Wong@ontario.ca>
Sent: Thursday, March 7, 2024 3:37 PM
To: Fazlagic, Tijana HLTH:EX <Tijana.Fazlagic@gov.bc.ca>; 'kathleen.coleman@novascotia.ca' <kathleen.coleman@novascotia.ca>; 'michelle.pashovitz@health.gov.sk.ca' <michelle.pashovitz@health.gov.sk.ca>; 'Prev.Naidoo' <Prev.Naidoo@yukon.ca>; 'jillian.farrow@health.gov.sk.ca' <jillian.farrow@health.gov.sk.ca>; 'rachel.cheruvallath@gov.ab.ca' <rachel.cheruvallath@gov.ab.ca>; 'pbarnes@gov.nl.ca' <pbarnes@gov.nl.ca>; 'andrea.nagle@gov.ab.ca' <andrea.nagle@gov.ab.ca>; 'luke_spooner@gov.nt.ca' <luke_spooner@gov.nt.ca>; Falone, Michelle (MOH) <Michelle.Falone@ontario.ca>; nmacphee@gov.pe.ca; 'Carey Ilchuk' <Carey.Ilchuk@gov.ab.ca>; 'alan.lawless@gov.mb.ca' <alan.lawless@gov.mb.ca>; 'chris.schrader@gov.mb.ca' <chris.schrader@gov.mb.ca>; 'Facci, Marina HE0' <Marina.Facci@health.gov.sk.ca>; Fortin, Karen <karen.fortin@sac-isc.gc.ca>; Lara.Grant@novascotia.ca; Mujoomdar, Michelle <michelle.mujoomdar@sac-isc.gc.ca>; Rebeiro, Bernita (MOH) <Bernita.Rebeiro@ontario.ca>; Ceranic, Natasa (MOH)

<NATASA.CERANIC@ontario.ca>; Weston, Megan D HLTH:EX <Megan.D.Weston@gov.bc.ca>
Cc: Hunt, Amanda <AmandaHunt@gov.nl.ca>; Carole Chambers <Carole.Chambers@albertahealthservices.ca>; Rance, Laureen (MOH) <Laureen.Rance@ontario.ca>; Langille, Shawna (MOH) <Shawna.Langille@ontario.ca>; Davy, Amanda (She/Her) (MOH) <Amanda.Davy@ontario.ca>; Sgrignuoli, Gabriella (MOH) <Gabriella.Sgrignuoli@ontario.ca>
Subject: RE: National Strategy for DRD PT Directors Working Group

[EXTERNAL] This email came from an external source. Only open attachments or links that you are expecting from a known sender.

Hi all,
Thanks to my team for pulling together some notes from the call on Tuesday (below). Some of the questions may have been answered in the response from HC yesterday. Tijana, happy to connect on action items below and thanks to Marina for collating questions/comments on the National Pharmacare legislation.
Best,
Angie

National Strategy for DRD PT Directors' Working Group
March 5, 2024

s.76(1), s.74(1)(a)

Additional questions:

s.76(1), s.74(1)(a) [redacted]

- Clarify what is publicly reported and what is reported to HC?

Further Discussion

s.76(1), s.74(1)(a) [redacted] or will it fall to each PT to have their own individual discussion?

Action Items:

- IGR – what is needed for PT CDM? (Tijana/Angie)
- Send additional questions to HC (Tijana)

National Pharmacare:

s.76(1), s.74(1)(a) [redacted]

s.76(1), s.74(1)(a)

[redacted]

Action Items:

s.76(1), s.74(1)(a)

[redacted]

-----Original Appointment-----
From: Fazlagic, Tijana HLTH:EX <Tijana.Fazlagic@gov.bc.ca>
Sent: August 30, 2023 10:59 AM
To: Fazlagic, Tijana HLTH:EX; 'kathleen.coleman@novascotia.ca'; 'michelle.pashovitz@health.gov.sk.ca'; 'Prev.Naidoo'; 'jillian.farrow@health.gov.sk.ca'; 'rachel.cheruvallath@gov.ab.ca'; 'pbarnes@gov.nl.ca'; 'andrea.nagle@gov.ab.ca'; 'luke_spooner@gov.nt.ca'; Falone, Michelle (MOH); Wong, Angie H (She/Her) (MOH); nmacphee@gov.pe.ca; 'Carey Ilchuk'; 'alan.lawless@gov.mb.ca'; 'chris.schrader@gov.mb.ca'; 'Facci, Marina HE0'; Fortin, Karen; Lara.Grant@novascotia.ca; Mujoomdar, Michelle; Rebeiro, Bernita (MOH); Ceranic, Natasa (MOH); Weston, Megan D HLTH:EX
Cc: Hunt, Amanda; Carole Chambers; Rance, Laureen (MOH); Langille, Shawna (MOH); Davy, Amanda (She/Her) (MOH)
Subject: National Strategy for DRD PT Directors Working Group
When: March 5, 2024 9:35 AM-10:30 AM (UTC-08:00) Pacific Time (US & Canada).
Where: Microsoft Teams Meeting

CAUTION -- EXTERNAL E-MAIL - Do not click links or open attachments unless you recognize the sender.

Microsoft Teams meeting

Join on your computer, mobile app or room device
Click here to join the meeting
Meeting ID: s.72(1)(b)(vi) [redacted]

Passcode: s.72(1)(b)(vi)
Download Join on the web
Or call in (audio only)
s.72(1)(b)(vi) Canada, Victoria
Phone Conference ID: s.72(1)(b)(vi)
Find a local number | R
Toll-free (audio only): 1-888-600-3289
Learn More | Meeting options

From: Marsha Cusack
To: Prev.Naidoo; Marie Claire.Savoie; Jason.Durand; luke_spooner@gov.nt.ca
Subject: [EXT] RE: Drugs for Rare Diseases briefing
Date: March 1, 2024 9:20:46 AM
Attachments: National Strategy Drugs for Rare Disease March 2024_1.pptx

---

Confidential – please consider these slides a working draft for internal briefing.

Thanks
Marsha

Marsha Cusack BSPharm, RPh, MHS (she/her)
Senior Manager
Pharmaceutical Services
mdcusack@ihis.org
Cell: 902-314-5205

Department of Health and Wellness
Government of Prince Edward Island
3rd floor, Sullivan Building
Charlottetown, PE C1A 7N8
www.PrinceEdwardIsland.ca

This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential and exempt from disclosure under applicable law. If the reader of this message is not the intended recipient, or the employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please delete it immediately and notify us by telephone. Thank you.

-----Original Appointment-----
From: Prev.Naidoo <Prev.Naidoo@yukon.ca>
Sent: Tuesday, February 27, 2024 6:09 PM
To: Prev.Naidoo; Marsha Cusack; Marie Claire.Savoie; Jason.Durand; luke_spooner@gov.nt.ca
Subject: Drugs for Rare Diseases briefing
When: Friday, March 1, 2024 8:30 AM-9:00 AM (UTC-07:00) Yukon.
Where: Microsoft Teams Meeting

Microsoft Teams meeting

Join on your computer, mobile app or room device
Click here to join the meeting

Meeting ID: s.72(1)(b)(vi)
Passcode:
Download on the web

Or call in (audio only)
s.72(1)(b)(vi) Canada, Whitehorse
Phone Conference ID: s.72(1)(b)(vi)
Find a local number | R

Learn More | Meeting options

Prince Edward Island
CANADA

National Strategy Drugs for Rare Disease – March 2024

Rare Disease background

- One in 12 Canadians has a rare disorder. Approximately, 3 million Canadians and their families face a debilitating disease that severely impacts their lives.

- Right now, only 60% of treatments for rare disorders make it into Canada and most get approved up to six years later than in the USA and Europe.

Rare Disease background

- As of 2019, there were 93 drugs for rare diseases approved in Canada that cost over $100,000 per patient per year, over half of which cost more than $200,000

- Innovative treatments for rare disease can cost anywhere from $100,000 to more than $2 million per year.

Rare Disease background

- **Less than 1% of the Canadian population accounts for 42% of patented medicine sales**
- Orphan medicines are increasingly dominating the market, accounting for nearly half of new launches
- Public spending on DRDs grew from $14.8 million in 2010 (11 DRDs) to $380.9 million in 2020, then a projected $527.6 million in 2021 (59 potential DRDs) and $1.6 billion in 2025 (164 potential DRDs).
- Projected DRD spending increased from 3.2% of $16.5 billion public drug spending in 2021 to 8.3% of $19.4 billion in 2025.

Federal Commitments

- $1 billion over 2 years was originally announced in **Budget 2019**, to start in 2022-2023, with up to $500 million per year ongoing, to help Canadians with rare diseases access the drugs they need.
- $35 million over four years, starting in 2019-2020 to Health Canada to establish a Canadian Drug Transition Office.

Federal Commitments

- March 22, 2023Government of Canada improves access to affordable and effective drugs for rare diseasesCanada.ca
- *Today, the Honourable Jean-Yves Duclos, Minister of Health, announced measures in support of the first-ever National Strategy for Drugs for Rare Diseases, with an investment of up to $1.5 billion over three years. Through this, we will help increase access to, and affordability of, effective drugs for rare diseases to improve the health of patients across Canada, including children.*

Governance Model

- **Pharmaceutical Executives Group (PEG)** – ADM level group who meet with Health Canada.
  - *PEI representation Kelley and Marsha*
- **PT ADM NSDRD** – table for PT ADMs to discuss what is occurring at PEG
  - *PEI representation Kelley and Marsha*
  - *Subgroup: PT ADM ON, BC, AB, NS*
- **National Strategy for Rare Disease Directors Working Group** – PT Directors who meet to discuss principles and impacts.
  - *PEI representation Marsha*
- **Implementation Advisory Group – expert group established by Health Canada to provide strategy and guidance.**
  - *PEI observer: Marsha*

Objective (Federal)

- The objective of the National Strategy for Drugs for Rare Diseases is to help increase access to, and affordability of, promising and effective drugs for rare diseases to improve the health of patients across Canada.

- As part of the Strategy, up to $1.4B is available to provinces and territories for three-year bilateral agreements to:
  - Improve access to **new and emerging drugs**
  - Improve **screening and diagnostics**
  - Improve coverage for **existing drugs for rare diseases (DRD)**

DRD Defined (Health Canada – May 2023)

s.76(1)

Funding Allocation - PEI

- Formula: Base + per capita amount (with NIHB clients excluded)
- Base for all PTs: $1.5 million
- Population used for PEI: 175,853 - NIHB client estimate of 4661 = 171,192
- PEI portion of the population 171,192/39,592,397 = 0.00432386
- Total PT funding per year: $468,774,452 - total base funding= $449,274,452
- $ 449,274,452 X 0.00432386 = $1,942,599.83 + base = **$3,442,599.83**

Funding Allocation- PEI

- **New and Emerging Drugs:** **A minimum of 50%** of total federal funding allocated to a PT through bilateral agreements in each year will be to enhance access to new and emerging drugs for rare diseases. Flexibility in year 1 and 2 only
- **Screening and Diagnostics: Up to 10%** of federal funding, per year, will be allocated to eligible expenditures toward improving screening and diagnostics, including striving for national consistency in newborn screening. Variation in this target in the first two years of the agreements (e.g., ramp up period) is anticipated and will be addressed in bilateral agreement negotiations.

Funding Allocation - PEI

- **Supporting Governance: Up to 2%** of federal funding, per year, will be allocated to eligible expenditures for supporting national governance and infrastructure, including data and evidence projects led by CADTH and CIHI under the National Strategy.
- Remaining Funds: Remaining funds must go to enabling PTs to improve coverage for other available drugs for rare diseases.

Cost Sharing

s.76(1)

Continuity of Funding

- **A note on the funding commitment** The 2019 Government of Canada Budget committed to providing up to $1 billion over two years to help Canadians with rare diseases access the drugs they need, with up to $500 million per year ongoing. In Budget 2021, this Government further confirmed that, "To maintain momentum, the government will proceed with its announced plan to provide ongoing funding of $500 million for the program for high-cost drugs for rare diseases."

Funding Breakdown PEI

- Annual Federal Funding :$3,442,599.83
- New and Emerging Drugs: minimum $1,721,299.92
- Screening and Diagnostics: up to 10% $344,259.98
- Supporting Governance: up to 2% $68,852.00
- Remainder for existing DRD: up to $1,308,187.93

Work to Date on Drug Categories

s.76(1)

s.76(1)

Next Steps

- Bilateral agreement target April 1 (funding will be retroactive to then)
- No carry over allowed. Variation in model for years 1 and 2
- Existing Public Drug Program funding mechanism is acceptable for implementation

Potential Risks

- Financial risk to province is unknown.
  - For example, if PEI had 1 patient/year for each of the 12 new and emerging drugs identified, the potential spend **$10,292,474. At a 50:50 split, the $3,029,487.85 federal contribution for drugs would only represent a 30% share of the expense. Province would be responsible for the remainder.**
- Expectation that the list of drugs will grow.
- NIHB calculation is uncertain- many of the drugs would be given in CTC or OOP.
- Earlier circulated principles from federal government indicated a **requirement to list – final listing decisions are with the Minister of Health and Wellness.** Need to incorporate something into to bilateral to account for drugs that are added to the list after signing.

Potential Risks

- While PEI is small, the same number of drug files exists in the space, regardless of population. If data/reporting/administration support is required at the PT level, at 2% **($68,852.00)** of the total funding allotted to supporting governance, PEI would be unable to hire any resources.
- Bilateral agreements expected to be for 3 years- uncertainly will then exist at end of agreement.

Potential Risks

- No escalator on funding allotment by Federal Government despite DRD being a known area of expansion and known factors that increase cost (population growth, CPI).

- Confidentiality of net pricing. If the number of drugs is very low, it will be challenging to maintain the confidentiality of the pricing when reporting to Health Canada.

Contact Information

Marsha Cusack

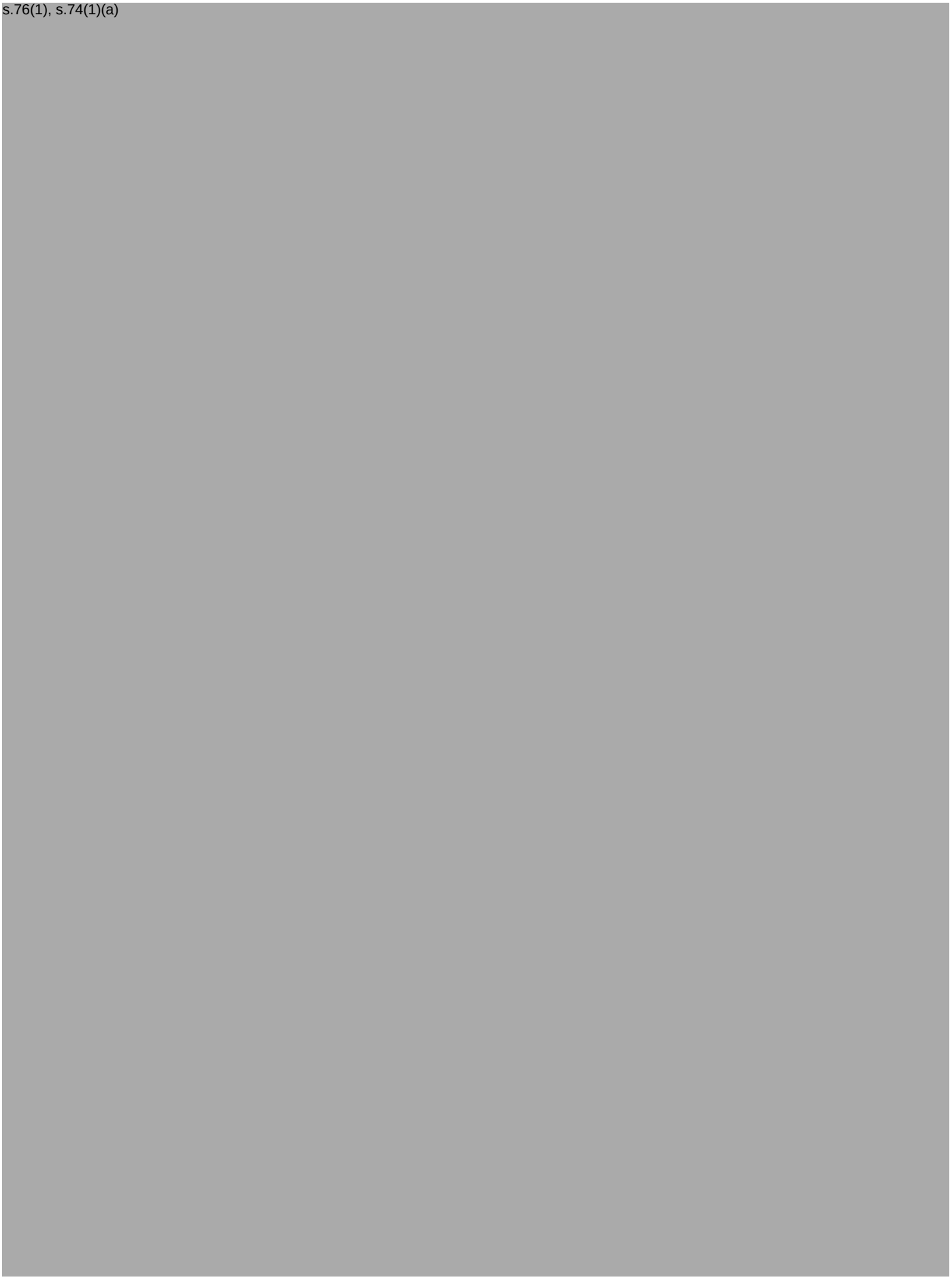
Senior Manager, Pharmaceutical Services

Department of Health and Wellness

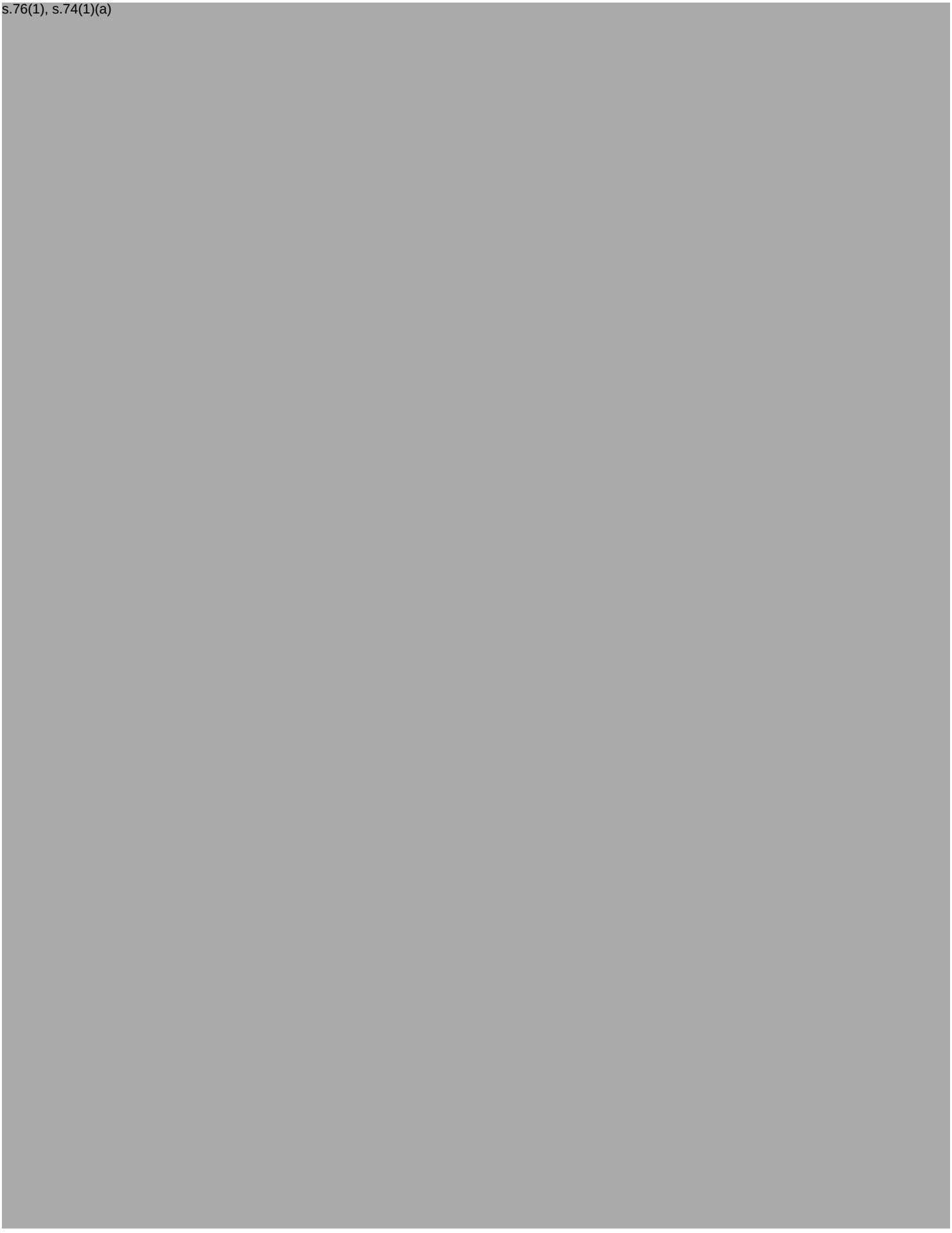
mdcusack@ihis.org

902 314-5205

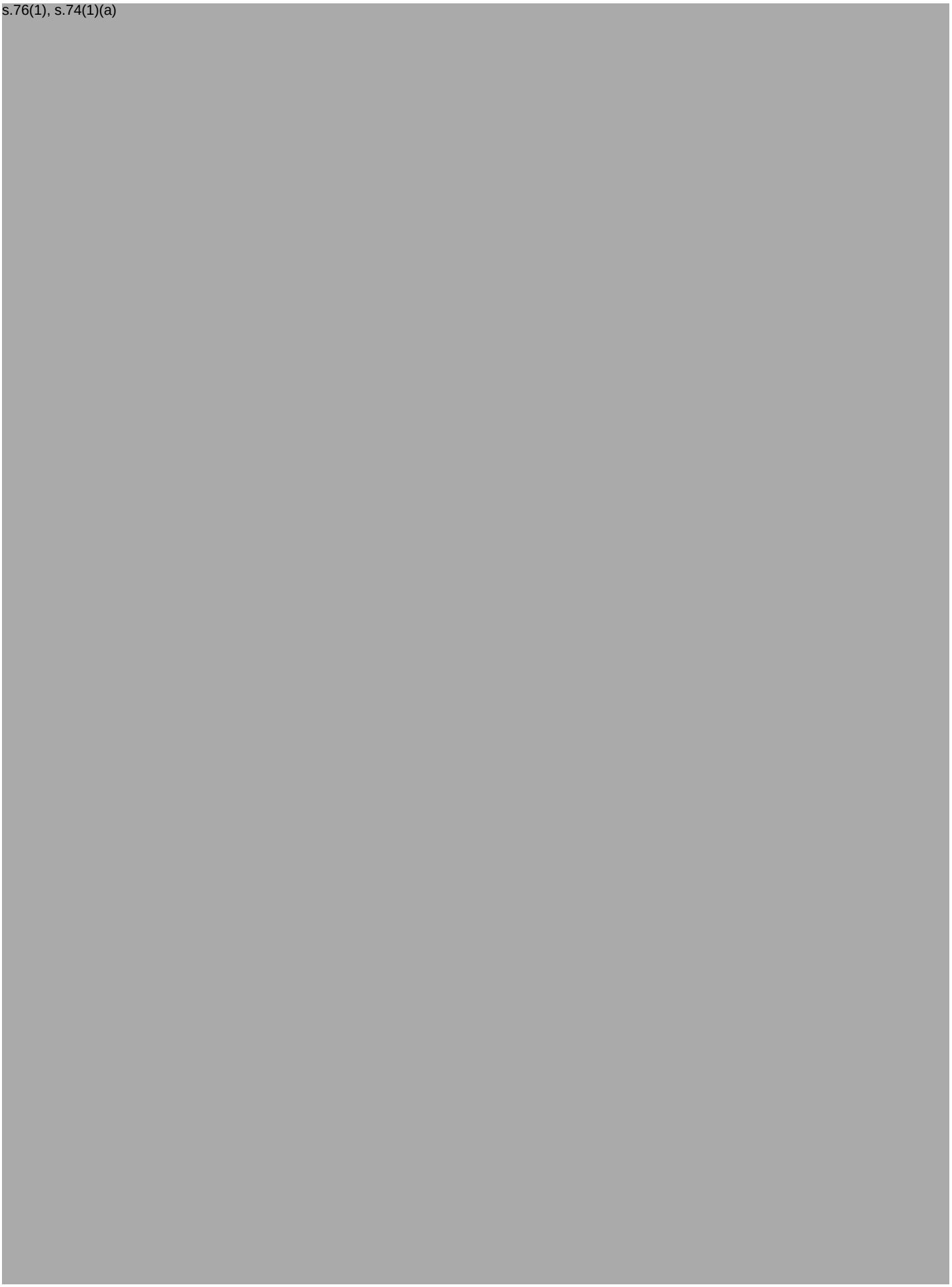
s.76(1), s.74(1)(a)



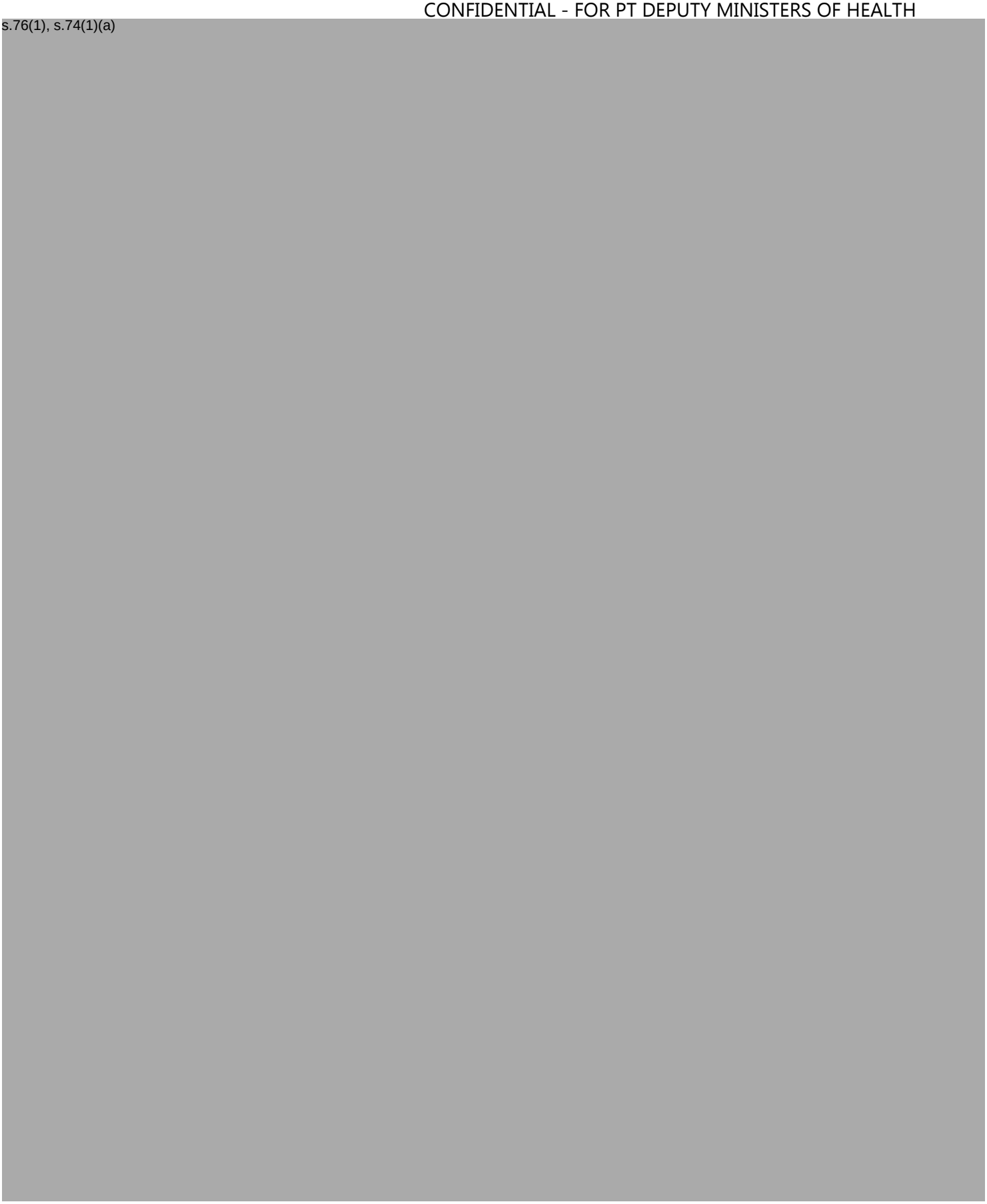
s.76(1), s.74(1)(a)



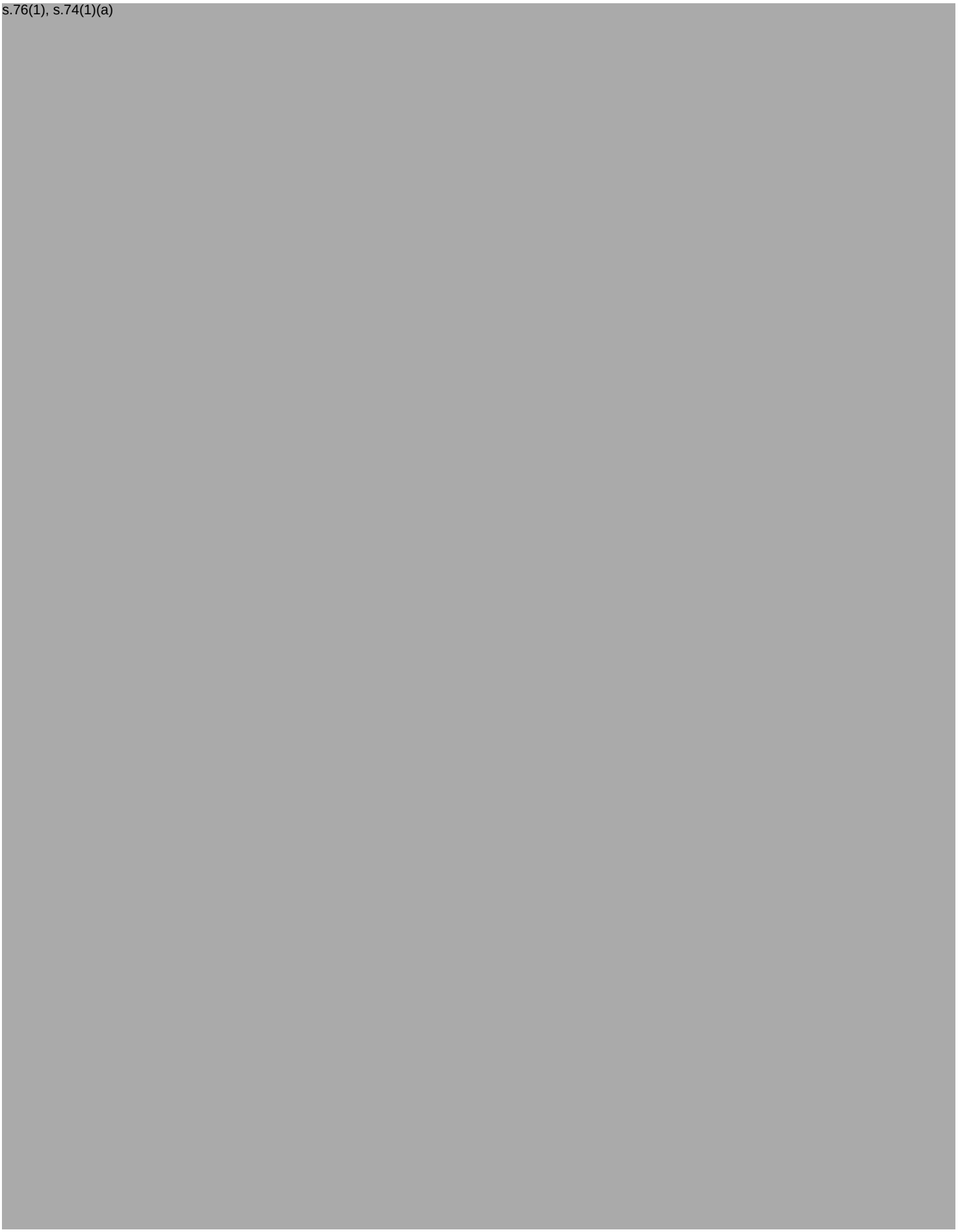
s.76(1), s.74(1)(a)



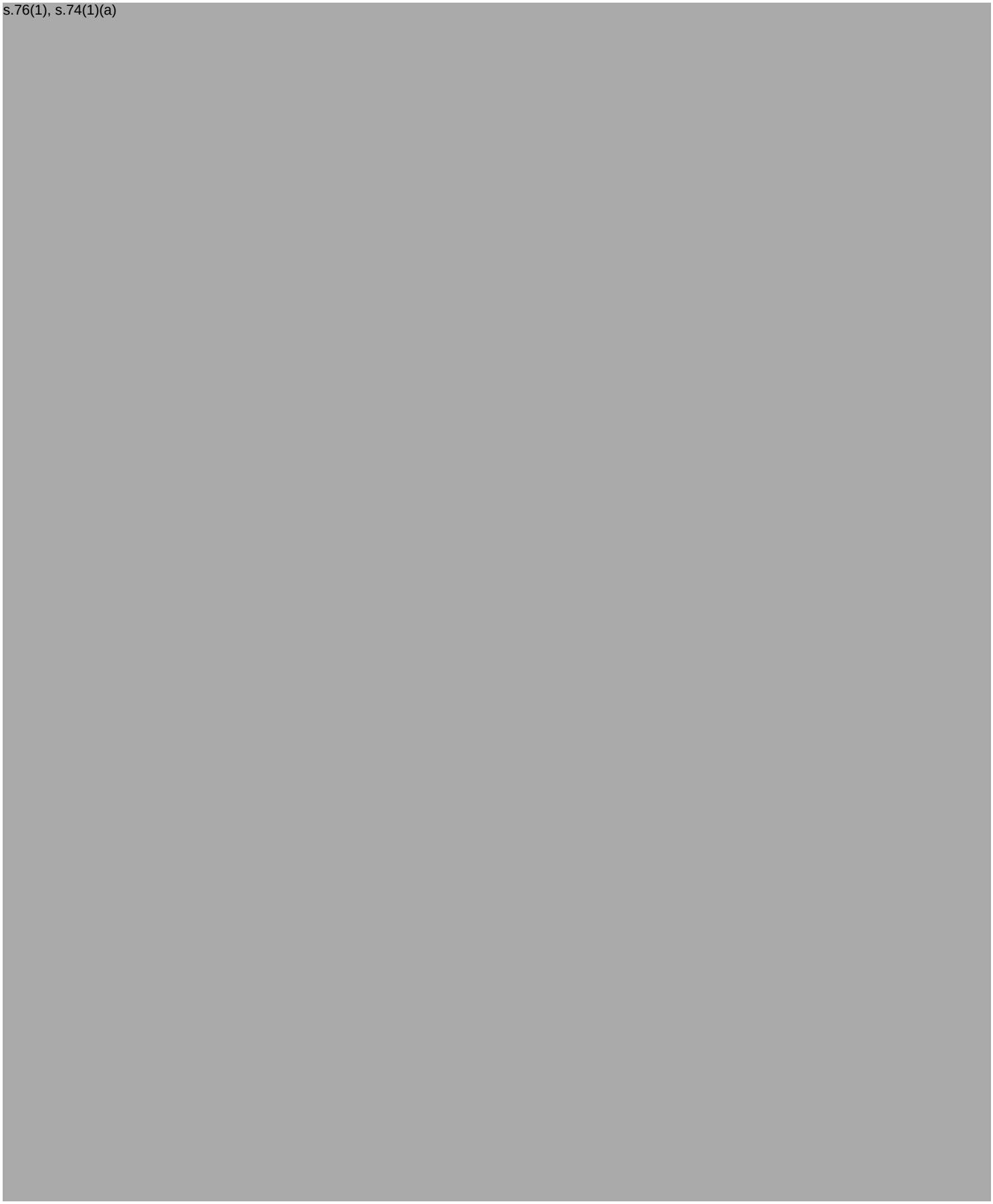
s.76(1), s.74(1)(a)



s.76(1), s.74(1)(a)



s.76(1), s.74(1)(a)



s.76(1), s.74(1)(a)

s.76(1), s.74(1)(a)

s.76(1), s.74(1)(a)

s.76(1), s.74(1)(a)

s.76(1), s.74(1)(a)

2022-02-25
DRAFT FOR DISCUSSION

NATIONAL STRATEGY FOR DRUGS FOR RARE DISEASES

FPT DISCUSSION GUIDE ON DRAFT STRATEGY ELEMENTS AND CONSIDERATIONS

Purpose

Building on the work of the FPT Pharmaceuticals Executive Group and additional research and consultation activities carried out since January 2021, the purpose of this document is to support the discussion on potential parameters of the national strategy for drugs for rare diseases and components associated with the federal government's funding commitment announced in Budget 2019. The FPT Pharmaceuticals Executive Group is scheduled to meet on March 1, 2022 to have a preliminary discussion of the draft thinking contained in this guide. Following that meeting, Health Canada will meet with each Province and Territory to have more in-depth bilateral discussions on individual feedback, concerns, and ideas related to the draft strategy materials. This document is therefore considered evergreen and will be further refined as discussions progresses and a draft strategy is finalized.

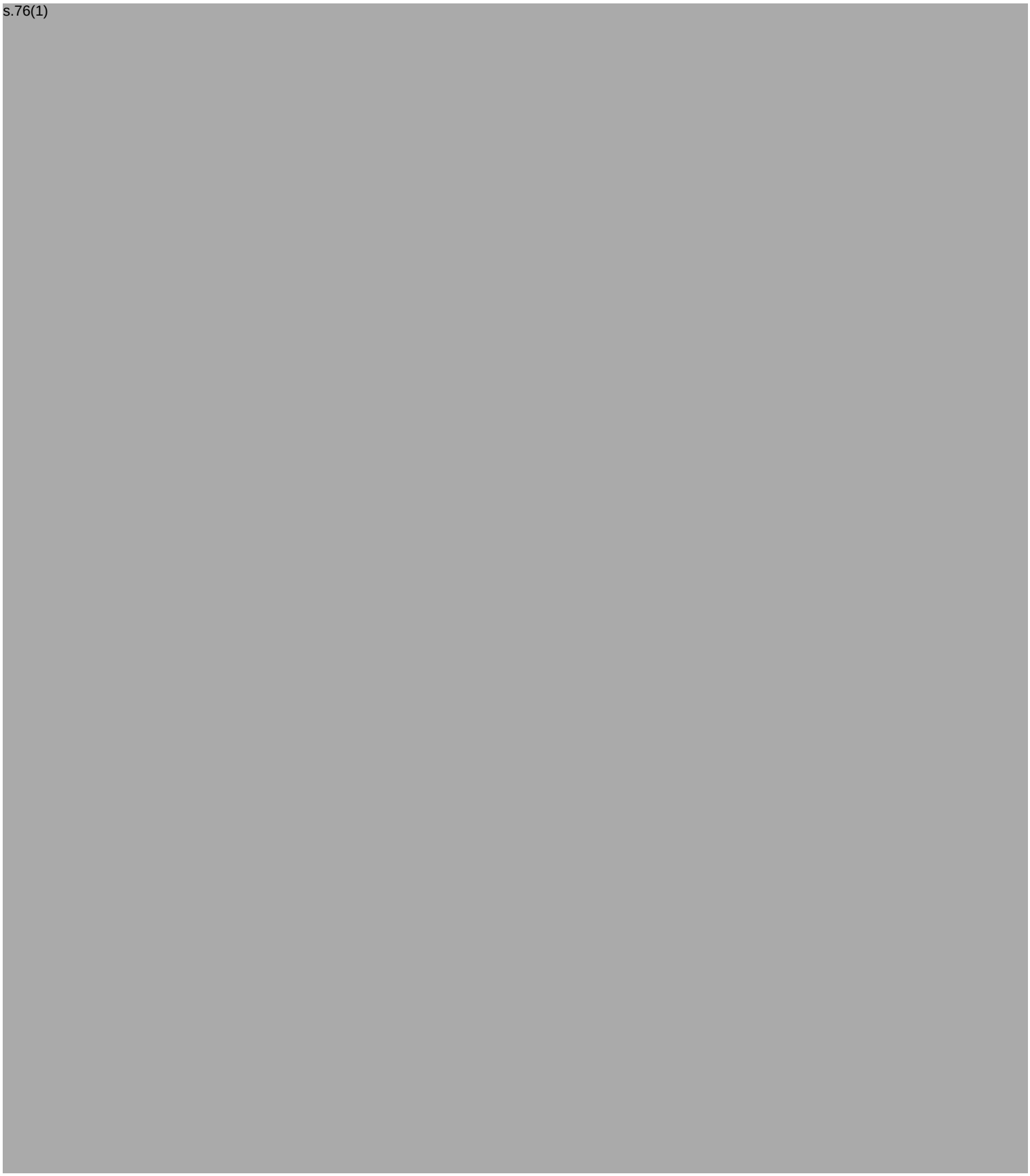
Context

To help Canadians with rare diseases access the drugs they need, Budget 2019 proposed to invest up to $1 billion over two years, starting in 2022-23, with up to $500 million per year ongoing. This commitment was re-affirmed in the current mandate letter for the Minister of Health and it includes working with provinces, territories, partners and stakeholders to establish a national strategy for drugs for rare diseases.

From January to March 2021, Health Canada launched an extensive public and stakeholder engagement and spoke with patients and caregivers with lived experience, clinicians, pharmaceutical companies, insurance carriers, benefit advisors and associations representing businesses and employers, researchers, Indigenous partners, and more. The *What We Heard* Report, released in July 2021, is available here. Following the publication of the *What We Heard* Report, Health Canada has continued follow up meetings with stakeholders from multiple perspectives to have more in-depth discussion on potential elements for the draft strategy. Concurrently, Health Canada has also had ongoing dialogue with health system partners, including federal, provincial, and territorial drug plans.

s.76(1)

s.76(1)



s.76(1)

Potential Strategy Elements and Implementation Considerations

s.76(1)

Governance

The potential core governance mechanism would leverage and inform existing common decision-making structures in the pharmaceutical management system in Canada, including those related to regulatory approval and health technology assessment.

The role and function of the governance mechanism in the foundational phase would be to develop and maintain a comprehensive suite of infrastructure that would serve as the foundation for a national leadership and coordination. The responsibilities could include:

s.76(1)

An informal governance structure, such as a committee and secretariat that leverages the current FPT Pharmaceuticals Executive Group, could be established for the initial phase. With evolution over time,
s.76(1)

Access and Affordability

s.76(1)

After discussions with multiple stakeholders and partners and preliminary analyses, a number of options have emerged to initially scope drug coverage for the launch of the strategy, including:

s.76(1)

Evidence generation infrastructure

s.76(1)

s.76(1)