Regulation 7

#### Exemptions

- 1.—(1) The kinds of single use carrier bags to which regulation 6 does not apply are—
  - (a) bags used solely to contain one or more items of the following kinds-
    - (i) unpackaged food for human or animal consumption;
    - (ii) unpackaged loose seeds, bulbs, corms or rhizomes;
    - (iii) any unpackaged axe, knife, knife blade or razor blade;
    - (iv) unpackaged goods contaminated by soil;
    - (v) items from the categories specified in sub-paragraph (2);
  - (b) bags used solely to contain packaged—
    - (i) uncooked fish or fish products;
    - (ii) uncooked meat or meat products;
    - (iii) uncooked poultry or poultry products,

and in respect of which the maximum dimensions are 205 millimetres ("mm") (width) x 125 mm (gusset width) x 458 mm (height inclusive of handles);

- (c) bags used to contain hot foods or hot drinks intended for consumption away from the premises on which they are sold;
- (d) bags used to contain purchases made on board ships, trains, aircraft, coaches or buses;
- (e) bags used to contain purchases made in an area designated by the Secretary of State as a security restricted area under section 11A of the Aviation Security Act 1982(1);
- (f) mail order dispatch and courier bags;
- (g) bags which-
  - (i) are made wholly from paper;
  - (ii) have maximum dimensions of 175 mm (width) x 260 mm (height);
  - (iii) do not have a gusset; and do
  - (iv) not have a handle;
- (h) bags which-
  - (i) are made wholly or mainly from plastic;
  - (ii) have maximum dimensions of 125 mm (width) x 125 mm (height);
  - (iii) do not have a gusset; and
  - (iv) do not have a handle;
- (i) bags which-
  - (i) are made wholly from paper;
  - (ii) have maximum dimensions of 80 mm (width) x 50 mm (gusset width) x 155 mm (height); and
  - (iii) do not have a handle;
- (j) gusseted liners used to line or cover boxes, crates or other containers of a similar nature;
- (k) bags used solely to contain live aquatic creatures in water;

<sup>(1) 1982</sup> c. 36; section 11A was inserted by the Aviation and Maritime Security Act 1990 (c. 31), Schedule 1, paragraph 3; and amended by S.I. 2010/902, regulations 3 and 9(b).

- (2) The specified categories are—
  - (a) medicinal products or listed appliances sold in accordance with a prescription issued by a registered medical practitioner, a dentist, a supplementary prescriber, a nurse independent prescriber, an independent nurse prescriber, an optometrist independent prescriber, a pharmacist independent prescriber or an EEA health professional;
  - (b) where sold otherwise than in accordance with paragraph (a), pharmacy medicine.
- (3) In this paragraph—

"dentist" means a person registered in the dentists register kept under section 14 of the Dentists Act 1984(2);

"EEA health professional" has the meaning given in regulation 1(2) of the Medicines for Human Use (Prescribing by EEA Practitioners) Regulations 2008(3);

"independent nurse prescriber" has the meaning given in the Pharmaceutical Services Regulations (Northern Ireland) 1997(4);

"listed appliances" means listed appliances within the meaning of article 63 of the Health and Personal Social Services (Northern Ireland) Order 1972(5);

"medicinal product" has the meaning given in section 130 of the Medicines Act 1968(6);

"pharmacy medicine" means a medicinal product which is not a prescription only medicine and which-

- in accordance with section 52(7) of the Medicines Act 1968, can only be sold or supplied (a) under the conditions specified in sub-section (1)(a) to (c) of that section; or
- (b) but for the fact that it is sold or supplied in accordance with section 55(8) of that Act, could only lawfully be sold or supplied under those conditions;

"prescription only medicine" means a medicinal product-

- of a description or falling within a class specified in an order made under section 58(9) of the Medicines Act 1968;
- to which section 58 of that Act applies by virtue of an order made under section 104(10) (b) of that Act:

"supplementary prescriber", "nurse independent prescriber", "optometrist independent prescriber" and "pharmacist independent prescriber" each have the meanings respectively ascribed to them in article 1(2) of the Prescription Only Medicines (Human Use) Order 1997(11);

"unpackaged" means wholly or partly unwrapped.

<sup>(2) 1984</sup> c. 24; section 14 was substituted by S.I. 2005/2011, articles 2(1) and 6; and amended by S.I. 2007/3101, regulations 109 and 111.

<sup>(3)</sup> S.I. 2008/1692, to which there are amendments not relevant to these Regulations.

 <sup>(4)</sup> S.I. 1997/381 as amended by 2003/447
(5) S.I. 1972/1265 (N.I. 14), amended by 1978/1907 (N.I. 26); there are other amendments but none is relevant.

<sup>(6) 1968</sup> c. 67; section 130 was amended by S.I. 1994/3119, regulation 2(b); and S.I. 2005/50, regulation 25(1)(c) and (d); there are other amendments but none is relevant.

<sup>(7)</sup> Section 52 was amended by the Health Act 2006 (c. 28); there are other amendments but none is relevant.

<sup>(8)</sup> Section 55 was amended by S.I. 2004/1771, article 3 and paragraph 10(b) of the Schedule; by S.I. 2006/2407, paragraphs 1 and 26 of Schedule 8.

<sup>(9)</sup> There are amendments to section 58 which are not relevant to these Regulations.

<sup>(10)</sup> Section 104 was amended by S.I. 2004/1031, regulation 54 and paragraph 17 of Schedule 10; and by S.I. 2006/2407, paragraphs 1 and 54 of Schedule 8.

<sup>(11)</sup> S.I. 1997/1830; relevant amending instruments are S.I. 2003/696, S.I. 2004/1771, S.I. 2005/765, S.I. 2006/915, S.I. 2010/1621.

Regulation 12

## Fixed monetary penalties

# PART 1

## Imposition of fixed monetary penalties and procedure

## Power to impose fixed monetary penalty

**1.**—(1) The Administrator may by notice impose a fixed monetary penalty on a seller who breaches these Regulations in the circumstances specified in regulation 11(1).

(2) The Administrator may exercise the power conferred by sub-paragraph (1) in relation to a case if it is satisfied on the balance of probabilities that a breach has occurred.

## **Fixed monetary penalties**

**2.** The amount of penalty that can be imposed by the Administrator as a fixed monetary penalty in any case is the amount listed in the second column of the table in Part 2 by reference to the kind of breach concerned.

#### Notice of intent

**3.**—(1) Where the Administrator proposes to impose a fixed monetary penalty on a seller, the Administrator shall serve by post a notice of intent on that seller.

- (2) A notice of intent shall—
  - (a) state the amount of the penalty;
  - (b) offer the seller the opportunity to discharge its liability to the penalty by paying the specified sum within 28 days beginning with the day on which the notice is served;
  - (c) include information as to-
    - (i) the grounds for the proposal to impose the fixed monetary penalty;
    - (ii) the effect of payment of the specified sum;
    - (iii) the right to make representations and objections conferred by paragraph 5;
    - (iv) the circumstances in which the Administrator may not impose the fixed monetary penalty;
    - (v) the 28 day period within which liability to the fixed monetary penalty may be discharged by virtue of paragraph 4;
    - (vi) the 28 day period within which representations and objections may be made;
    - (vii) how payment may be made.

## Discharge of liability following notice of intent

**4.**—(1) A seller's liability to a fixed monetary penalty is discharged if the specified sum is paid within 28 days beginning with the date of service of the notice of intent.

(2) The specified sum is the amount specified in the third column of the table in Part 2 by reference to the kind of breach concerned.

#### Making representations and objections

**5.**—(1) This paragraph applies if a seller does not discharge liability to a fixed monetary penalty by payment of the specified sum.

(2) Within 28 days of the date of the service of the notice of intent, the seller may make written representations and objections to the Administrator in relation to the proposed imposition of the fixed monetary penalty.

#### Decision whether to impose a fixed monetary penalty

**6.**—(1) At the end of the 28 day period for making representations and objections under paragraph 5, the Administrator shall decide whether to impose the fixed monetary penalty.

(2) In making a decision under this paragraph the Administrator shall take into consideration any representations or objections made by the seller in accordance with paragraph 5.

(3) The Administrator may not decide to impose a fixed monetary penalty in any of the following circumstances—

- (a) if liability to a fixed monetary penalty in respect of the same breach has been discharged by payment of the specified sum;
- (b) if a fixed penalty has previously been imposed in respect of the same breach;
- (c) if a discretionary requirement has been imposed in respect of the same act or omission.

(4) Without restricting the power under sub-paragraph (1), the Administrator may decide not to impose a fixed penalty if the Administrator considers that in all the circumstances of the case it would be inexpedient to do so.

(5) Where the Administrator decides to impose the fixed monetary penalty it shall do so by serving by post a final notice on the seller.

(6) The final notice shall comply with paragraph 7.

#### **Contents of final notice**

7. The final notice shall include information as to-

- (a) the grounds for imposing the fixed monetary penalty;
- (b) the Administrator's response to any representation and objections made by the seller;
- (c) the amount of the penalty;
- (d) how payment may be made;
- (e) the period of 56 days within which payment shall be made;
- (f) the effect of paragraph 9 (early payment discount);
- (g) the effect of paragraph 10 (late payment penalty);
- (h) rights of appeal; and
- (i) the consequences of non-payment.

## Payment

**8.**—(1) Subject to regulation 20(4) (suspension of requirements and notices pending appeal) and sub-paragraph (2), a fixed monetary penalty shall be paid by a seller within 56 days beginning with the date of service of the final notice.

(2) If a decision to impose a fixed monetary penalty is the subject of an appeal which upholds the imposition of a penalty, that penalty shall be paid by the seller within 28 days beginning with the date upon which the appeal is determined.

## Early payment discount

**9.** A seller may discharge liability to a fixed monetary penalty by paying 50% of the amount of the penalty within 28 days beginning with the date of service of the final notice.

## Late payment penalty

**10.** If a fixed monetary penalty is not paid within the period allowed in paragraph 8 the amount of the penalty shall be increased by 50%.

## Grounds of appeal

**11.**—(1) A seller may appeal against the Administrator's decision to impose a fixed monetary penalty.

- (2) The grounds of appeal are—
  - (a) that the decision was based on a error of fact;
  - (b) that the decision was wrong in law;
  - (c) that the decision was unreasonable;
  - (d) any other reason.

# PART 2

## Fixed monetary penalty amounts and specified sums

Breach	Amount of penalty which can be imposed as a fixed monetary penalty	Specified sums
Failure to comply with the requirement to charge in accordance with regulation 6 (regulation 11(1) and (2))	£200	£100
Failure to comply with the requirement to pay the net proceeds of the charge to the Department in accordance with regulation 8	£200	£100
(regulation 11(1) and (2))		
Failure to keep records in accordance with regulation 9 (regulation 11(1) and (2))	£100	£50
Failure to retain records in accordance with regulation 9 (regulation 11(1) and (2))	£100	£50

Breach	Amount of penalty which can be imposed as a fixed monetary penalty	Specified sums
Failure to supply records in accordance with regulation 10	£100	£50
(regulation 11(1) and (2))		

Regulation 12

Discretionary requirements

# PART 1

# Imposition of discretionary requirements and procedure

#### Power to impose discretionary requirements

**1.**—(1) The Administrator may by notice impose one or more discretionary requirements on a seller who breaches these Regulations.

(2) The Administrator may exercise the power conferred by sub-paragraph (1) in relation to a case if it is satisfied on the balance of probabilities that the breach occurred.

## Variable monetary penalties: maximum amounts

**2.** The maximum penalty which may be imposed by the Administrator as a variable monetary penalty in respect of any particular kind of breach is the amount listed in the second column of the table in Part 2 by reference to the kind of breach specified in the first column.

## Notice of intent

**3.**—(1) Where the Administrator proposes to impose one or more discretionary requirements on a seller, the Administrator shall serve by post a notice of intent on that seller.

(2) If the Administrator proposes to impose a non-monetary discretionary requirement, the notice of intent shall—

- (a) specify the steps that the Administrator requires the seller to take;
- (b) include information as to-
  - (i) the grounds for the proposal to require those steps to be taken;
  - (ii) the time period within which the Administrator requires those steps to be completed;
  - (iii) the right to make representations and objections conferred by paragraph 4;
  - (iv) the 28 day period within which representations and objections may be made.

(3) If the Administrator proposes to impose a variable monetary penalty, the notice of intent shall—

- (a) specify the amount of the penalty proposed;
- (b) include information as to-
  - (i) the grounds for the proposal to impose a variable monetary penalty;

- (ii) the right to make representations and objections conferred by paragraph 4;
- (iii) the circumstances in which the Administrator may not impose a variable monetary penalty;
- (iv) the 28 day period within which representations and objections may be made.

#### Making representations and objections

**4.** Within 28 days beginning with the date of service of the notice of intent, the seller may make written representations and objections to the Administrator in relation to the proposed imposition of the one or more discretionary requirements.

#### Decision whether to impose discretionary requirements

**5.**—(1) After the end of the 28 day period for making representations and objections under paragraph 4, the Administrator shall decide whether to—

- (a) impose the one or more discretionary requirements with or without modifications; or
- (b) impose any other discretionary requirement that the Administrator has the power to impose under these regulations.

(2) In making a decision under this paragraph the Administrator shall take into consideration any representations or objections made by the seller in accordance with paragraph 4.

- (3) The Administrator may not decide to impose a discretionary requirement if-
  - (a) a discretionary requirement has previously been imposed in relation to the same act or omission;
  - (b) liability to a fixed monetary penalty in respect of the same breach has been discharged by payment of a specified sum;
  - (c) a fixed monetary penalty has been imposed in respect of the same breach.

(4) The Administrator may not decide to impose a fixed monetary penalty in place of a discretionary requirement.

(5) Without restricting the power under sub-paragraph (1), the Administrator may decide not to impose a discretionary requirement if it considers that in all the circumstances of the case it would be expedient to do so.

(6) Where the Administrator decides to impose a discretionary requirement it shall do so by serving the final notice on the seller.

(7) The final notice shall comply with paragraph 6.

## Contents of a final notice

6. The final notice shall include information as to—

- (a) the grounds for imposing the one or more discretionary requirements;
- (b) the Administrator's response to any representations and objections made by the seller, including the effect (if any) on the amount of any variable monetary penalty imposed;
- (c) where the discretionary requirement is a non-monetary discretionary requirement—
  - (i) the steps the seller is required to take;
  - (ii) the period within which those steps shall be completed;
- (d) where the discretionary requirement is a variable monetary penalty—
  - (i) the amount of the penalty;

- (ii) how payment may be made;
- (iii) the period within which the penalty shall be made;
- (iv) the effect of paragraph 8 (early payment discount);
- (v) the effect of paragraph 9 (late payment penalty);
- (e) rights of appeal; and
- (f) the consequences of failing to comply with the notice.

## Payment

7.—(1) Subject to regulation 20(4) (suspension of requirements and notices pending appeal) and sub-paragraph (2), a variable monetary penalty shall be paid by a seller within 56 days beginning with the date of service of the final notice.

(2) If the decision to impose a variable monetary penalty is the subject of an appeal then to the extent that that decision is upheld, the penalty shall be paid by the seller within 28 days beginning with the date upon which the appeal is determined.

## Early payment discount

**8.** A seller may discharge liability to a variable monetary penalty by paying 50% of the amount of the penalty within 28 days beginning with the day on which the final notice imposing it is received.

## Late payment penalty

**9.** If a variable monetary penalty is not paid within the period specified in paragraph 7 the amount payable shall be increased by 50%.

## Grounds of appeal

**10.**—(1) A seller may appeal against the Administrator's decision to impose a discretionary requirement.

- (2) The grounds of appeal are—
  - (a) that the decision was based on an error of fact;
  - (b) that the decision was wrong in law;
  - (c) in case of a variable monetary penalty, that the amount of the penalty is unreasonable;
  - (d) in the case of a non-monetary discretionary requirement, that the nature of the requirement is unreasonable;
  - (e) that the decision was unreasonable for any other reason;
  - (f) any other reason.

# PART 2

# Variable monetary penalties: maximum amounts

Breach	Maximum amount which may be imposed as a variable monetary penalty
Failure to comply with the requirement to charge in accordance with regulation 6	£10,000

Breach	Maximum amount which may be imposed as a variable monetary penalty
(regulation 11(1) and (2))	
Failure to comply with the requirement to pay the net proceeds of the charge to the Department in accordance with regulation 8	$\pounds 20,000$ or 10% of the amount estimated to be due – whichever is the greater
(regulation 11(1) and (2))	
Failure to keep records in accordance with regulation 9 (regulation 11(1) and (2))	£5,000
Failure to retain records in accordance with regulation 9 (regulation 11(1) and (2))	£5,000
Failure to supply records in accordance with regulation 10 (regulation 11(1) and (2))	£5,000
Without reasonable cause, giving false or misleading information to the Administrator	£20,000
(regulation 11(3))	
Without reasonable cause, otherwise obstructing or failing to assist the Administrator in the conduct of its functions under these Regulations (regulation 11(3))	£20,000

Regulation 15

Non-monetary Discretionary requirements: enforcement

**1.**—(1) In this Schedule—

"specified steps" means the steps specified in a final notice under paragraph 6(c)(i) of Schedule 3;

"specified period" means the period specified in a final notice under paragraph 6(c)(ii) of Schedule 3.

(2) A reference in this Schedule to a complete failure is a reference to a seller having taken none of the specified steps within the specified period.

(3) A reference in this Schedule to a partial failure is a reference to a seller having taken at least one, but not all, of the specified steps within the specified period.

## Power to impose non-compliance penalties

**2.**—(1) If a seller fails to comply with a non-monetary discretionary requirement the Administrator may by notice impose a non-compliance penalty on the seller.

(2) A non-compliance penalty may be imposed in respect of a complete or partial failure to comply with a non-monetary discretionary requirement.

(3) A non-compliance penalty may be imposed irrespective of whether a variable monetary penalty was imposed in addition to the non-monetary discretionary requirement to which the non-compliance penalty relates.

(4) The amount of a non-compliance penalty is to be determined by the Administrator.

(5) The maximum penalty which may be imposed by the Administrator as a non-compliance penalty is the amount specified in sub-paragraph (6)by reference to the kind of failure concerned.

(6) The maximum penalties are—

- (a) £5,000 in relation to a partial failure;
- (b) £5,000 in relation to a complete failure.

## Notice of intent

**3.**—(1) Where the Administrator proposes to impose a non-compliance penalty on a seller, the Administrator shall serve by post on that seller a notice of what is proposed (a "notice of intent").

(2) A notice of intent shall include information as to-

- (a) the kind of failure in relation to which the Administrator proposes to impose the noncompliance penalty;
- (b) the specified steps which remain to be taken by the seller concerned;
- (c) the amount of the penalty proposed;
- (d) how payment may be made;
- (e) the date by which payment would be due;
- (f) the consequences of failure to make payment by the date it is due;
- (g) the right to make representations and objections conferred by paragraph 4;
- (h) the 28 day period within which representations and objections may be made;
- (i) the circumstances (if any) in which the Administrator may be inclined to reduce the amount of the penalty imposed.

## Making representations and objections

**4.** Within 28 days beginning with the date of service of the notice of intent, the seller may make written representations and objections to the Administrator in relation to the proposed imposition of a non-compliance penalty.

#### Decision whether to impose a non-compliance penalty

**5.**—(1) After the end of the 28 day period for making representations and objections under paragraph 4, the Administrator shall decide whether to impose the non-compliance penalty with or without modifications.

(2) Without restricting the power under sub-paragraph (1), the Administrator may decide not to impose a non-compliance penalty if the Administrator considers that in all the circumstances of the case it would be inexpedient to do so.

(3) In making a decision under this paragraph the Administrator shall take into consideration any representations or objections made by the seller in accordance with paragraph 4.

(4) Where the Administrator decides to impose a non-compliance penalty it shall do so by serving by post a notice on the seller.

(5) A non-compliance penalty notice shall comply with paragraph 6.

#### Contents of a non-compliance notice

6.—(1) A non-compliance penalty notice shall include information as to—

- (a) the grounds for imposing the non-compliance penalty;
- (b) the Administrator's response to any representations and objections made by the seller, including the effect (if any) on the amount of the penalty imposed;
- (c) the amount of the penalty;
- (d) how payment may be made;
- (e) the date by which payment shall be made;
- (f) the right of appeal; and
- (g) the consequences of failure to make payment by the date it is due.

(2) A non-compliance penalty shall be paid by a seller within 56 days beginning with the date of service of the non-compliance notice.

(3) But this is subject to sub-paragraph (4) and regulation 20(4) (suspension of requirements and notices pending determination of an appeal).

(4) If the requirements of the non-monetary discretionary requirement are complied with before the 56 days expire, the non-compliance penalty is not payable.

(5) A seller on whom a non-compliance penalty notice is served may appeal against it.

- (6) The grounds of appeal are—
  - (a) that the decision to serve the notice was based on an error of fact;
  - (b) that the decision was wrong in law;
  - (c) that the decision was unfair or unreasonable for any reason (including, in a case where the amount of the non-compliance penalty was determined by the Administrator, that the amount is unreasonable);
  - (d) any other reason.

#### Payment of non-compliance penalties following appeal

7. If a non-compliance penalty notice is the subject of an appeal, then to the extent that the notice is upheld, the penalty shall be paid by the seller within 28 days beginning with the day on which the appeal is determined.

## Non-compliance penalties: late payment penalty

**8.** If a non-compliance penalty is not paid within the period allowed by paragraph 6(2) or (as the case may be) by paragraph 7, the amount shall be increased by 50%.