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NATIONAL HEALTH SERVICE, SCOTLAND HEALTH AND PERSONAL SOCIAL SERVICES, NORTHERN IRELAND

The Health Service Medicines (Price Control Appeals) Regulations 2000

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ARRANGEMENT OF REGULATIONS REGULATIONS CONCERNING THE CONDUCT OF APPEALS

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The Secretary of State, in exercise of the powers conferred by sections 37(5) and (6) of the Health Act 1999(a) and having consulted the industry body, hereby makes the following Regulations:—

PARTI

INTRODUCTION

Citation and commencement

1. These Regulations may be cited as the Health Service Medicines (Price Control Appeals) Regulations 2000 and shall come into force on 14th February 2000.

Interpretation

- 2. In these Regulations, unless the context otherwise requires—
 - "the chairman" means the person assigned to be chairman of the tribunal in relation to an appeal under these Regulations;
 - "costs", in relation to Scottish proceedings, means "expenses";
 - "document" includes information recorded in writing or any other form;
 - "Scottish proceedings" means proceedings in relation to an appeal which relates to matters arising in Scotland;
 - "the tribunal" means-
 - (a) in relation to an appeal under these Regulations in respect of which the chairman and members have been assigned or appointed under regulation 7(4) and (5), the tribunal consisting of that chairman and those members;
 - (b) in relation to the appointment of staff under regulation 3(2), the senior chairman appointed under regulation 7(1);
 - (c) in relation to any other matter, a member of that panel of tribunal chairmen or a member of staff appointed under regulation 3(2).

The name and address of the tribunal

- **3.**—(1) The Secretary of State must as soon as practicable after these Regulations come into effect publish in such manner as he thinks appropriate the name and the address of the tribunal or if there is more than one address, indicate which address applies in which cases.
- (2) The tribunal may, with the approval of the Secretary of State, appoint such staff as it may determine, and may determine the terms and conditions on which they are appointed.

PART II

MAKING AN APPEAL

Time for and manner of making an appeal

- **4.**—(1) An appeal to the tribunal must be made by sending a notice of appeal to the tribunal so that it is received not later than the end of the period of 28 days beginning with the date on which the enforcement decision is taken.
- (2) The tribunal may extend the time limit imposed by paragraph (1), whether or not it has already expired, but must not do so unless it is satisfied—
 - (a) that the circumstances are such that it would not be reasonable to expect the appellant to comply (or, as the case may be, to have complied) with the time limit, and
 - (b) that not to extend the time limit would result in substantial injustice.
- (3) Where the appellant considers it likely that a notice of appeal will be received outside the time limit, he may include with the notice of appeal a statement of the reasons on which he relies to justify the delay, and the tribunal must consider any such statement in deciding whether or not to extend the time limit.

Notice of appeal

- **5.**—(1) The notice of appeal must state the name and address of the appellant and must contain sufficient information to identify the enforcement decision(a).
 - (2) The notice of appeal must set out the grounds of appeal in sufficient detail to indicate—

⁽a) The words "enforcement decision" are defined in section 37(7) of the Health Act 1999.

- (a) to what extent (if any) the appellant contends that the enforcement decision was based on an error of fact,
- (b) to what extent (if any) he contends that the disputed action was wrong in law, and
- (c) to what extent (if any) he is appealing against the Secretary of State's exercise of discretion in relation to the decision.
- (3) The appellant or his representative must sign the notice of appeal.
- (4) The tribunal must make available on request a form which may be used for making an appeal, but a notice of appeal need not be made using such a form.

Additional material

- **6.**—(1) The appellant must send the material required by paragraphs (2) and (3) (the "additional material") to the tribunal either—
 - (a) with his notice of appeal, or
 - (b) so that it is received not later than the end of the period of 28 days beginning with the date on which he sent the notice of appeal to the tribunal.
 - (2) The appellant must send to the tribunal—
 - (a) a copy of any document he has received from the Secretary of State notifying him of the enforcement decision,
 - (b) a copy of any notice he has received from the Secretary of State, either before or after the Secretary of State took the enforcement decision, explaining as the case may be his reasons for considering or taking the enforcement decision, and
 - (c) two copies of every other document on which he relies for the purposes of the appeal.
 - (3) The appellant must send to the tribunal a document stating—
 - (a) the name and address and the profession of the person (if any) representing the appellant, and whether the tribunal should send documents concerning the appeal to the representative instead of to the appellant,
 - (b) whether the appellant requests that the appeal should be decided at an oral hearing, and
 - (c) if in the opinion of the appellant any other person has a direct interest in the subject matter of the appeal, the name and address of such other person.
- (4) Where the tribunal is satisfied that it would not be reasonable to expect the appellant to send any document, or documents of any description, within the time limit mentioned in paragraph (1), it may extend the time limit in relation to that document or documents of that description.

Appointment of tribunal

- 7.—(1) There shall be appointed by the Lord Chancellor–
- (a) a panel of tribunal chairmen,
- (b) a senior tribunal chairman.
- (2) Appointments shall be made-
- (a) from persons in England and Wales who have a seven year general qualification within the meaning of section 71 of the Courts And Legal Services Act 1990(a), and
- (b) from solicitors or advocates of at least seven years standing in Scotland or Northern Ireland.
- (3) A person appointed under this regulation—
- (a) must be appointed (or re-appointed) for a period not exceeding five years, but
- (b) may be removed from office by the Lord Chancellor on the ground of incapacity or misbehaviour;

and subject to that, shall hold and vacate office in accordance with the terms of his appointment.

- (4) On receiving a notice of appeal under regulation 4, the senior chairman shall assign a chairman of the tribunal and appoint two other members of the tribunal to decide the appeal.
- (5) The senior chairman must assign the chairman of the tribunal within 21 days and the other members of the tribunal within 28 days of receiving the notice of appeal.
 - (6) Of the other members of the tribunal-
 - (a) one must be a person whom the senior chairman considers by reason, of experience or otherwise, to have special knowledge of matters likely to be considered by the tribunal, and

⁽a) The Courts and Legal Services Act 1990 c. 41.

- (b) the other must be a person whom the senior chairman considers representative of the interests of persons in relation to whom the Secretary of State has the power to take the enforcement decision in question.
- (7) The senior chairman shall have regard to whether the appeal relates to matters arising in England and Wales, Scotland or Northern Ireland when determining whom to assign as the chairman under paragraph (5) and the other members of a tribunal under paragraph (6).
- (8) The Secretary of State may determine the fees and expenses to be paid to the members of the tribunal, and any other expenses of the tribunal which are to be defrayed.
- (9) The Council on Tribunals may make to the Lord Chancellor general recommendations as to the arrangements for the making of appointments—
 - (a) to membership of the panel constituted under paragraph (1)(a), or
 - (b) to the tribunal,

and, without prejudice to the preceding provisions of this paragraph, the Lord Chancellor must have regard to any such recommendations.

(10) Subject to the terms of his appointment, the senior chairman may appoint another member of the panel of tribunal chairmen to exercise functions conferred on him by these Regulations.

Amendment of grounds of appeal

- **8.**—(1) The appellant may at any time before the date by which he must send the additional material under regulation 6–
 - (a) amend the grounds of appeal identified in the notice of appeal, or
 - (b) withdraw or amend any of the additional material.
- (2) After that date, the appellant may amend the notice of appeal or withdraw or amend any of the additional material, or supply any further additional material, only with the permission of the chairman.
 - (3) The chairman must not give permission under paragraph (2) unless he is satisfied—
 - (a) that the circumstances are such that it would not be reasonable to expect the appellant to have made the amendment or withdrawal or supplied the material within the time allowed under paragraph (1), and
 - (b) that the amendment or withdrawal (if made), or the material (if supplied), is capable of significantly affecting the outcome of the appeal.
- (4) Where the chairman grants permission under paragraph (2), he may do so on such terms as he thinks fit.
- (5) The appellant must send two copies of every amendment or every item of additional material to the tribunal.
 - (6) On receiving the copies required under paragraph (5), the tribunal must without delay-
 - (a) send one of the copies to the Secretary of State, and
 - (b) where the copy is sent after the Secretary of State has sent his reply to the tribunal, invite the Secretary of State to send a revised reply to the tribunal so that it is received before the end of the period of 7 days beginning with the date of the invitation.
- (7) The tribunal must not decide the appeal before the end of any period allowed under paragraph (6)(b).

Withdrawal of appeal

- **9.**—(1) The appellant may withdraw his appeal at any time before the date by which he must send the additional material under regulation 6.
 - (2) After that date the appellant may withdraw his appeal only with the chairman's permission.
- (3) Where an appeal is withdrawn, any interim order made or direction given under regulation 16 shall immediately cease to have effect.
- (4) Where an appeal is withdrawn, a fresh appeal may not be brought in relation to the enforcement decision.

PART III

RESPONSE TO THE APPEAL

Acknowledgement and notification

- **10.**—(1) On receiving the notice of appeal and the additional material, the tribunal must in each case without delay–
 - (a) send an acknowledgement of its receipt to the appellant, and
 - (b) send a copy of it to the Secretary of State.
 - (2) This regulation is subject to regulation 11.

Costs warning

- 11.—(1) Where a notice of an appeal has been received by the tribunal, and at the end of the period within which the appellant is required to send the additional material under regulation 6, the tribunal is of the opinion—
 - (a) that it is so unlikely that the appeal will succeed on the basis of the notice and any additional material supplied that to proceed with it would be unfair to the Secretary of State, or
 - (b) that the notice and any additional material supplied reveal no valid grounds of appeal, or that the appeal is otherwise misconceived,

it may, before sending the additional material to the Secretary of State, serve a notice to that effect on the appellant.

- (2) A notice under this regulation must state the reasons for the opinion and inform the appellant—
 - (a) that the appeal will not proceed unless the appellant informs the tribunal in writing within 14 days of the date of the notice that he wishes it to proceed, and
 - (b) that if he makes such a statement, and the appeal is subsequently withdrawn or decided against him, he may be liable, subject to the limitations imposed by regulation 33, to pay the costs incurred by the Secretary of State in connection with the appeal.
- (3) Where a notice is given under this regulation in relation to an appeal, unless the appellant informs the tribunal in writing before the end of the period of 14 days starting with the date of the notice, that he wishes to proceed with the appeal—
 - (a) no further proceedings shall be taken in relation to the appeal, and
 - (b) at the end of the period, any interim order made or direction given under regulation 16 immediately ceases to have effect.

Incomplete appeals

- 12.—(1) Where notice of an appeal and additional material have been received by the tribunal, and it considers that the appeal could be decided more fairly and efficiently if the appellant provided further additional material, the tribunal may serve on the appellant a notice to that effect, inviting him to supply that material to the tribunal within 14 days of the date of the notice.
- (2) Where the tribunal serves a notice under paragraph (1), it must at the same time inform the Secretary of State that it has done so.
- (3) Where the tribunal has served a notice under paragraph (1) on the appellant, the time limit imposed by regulation 13 shall not begin until the expiry of the period within which the further additional material may be supplied.
- (4) The tribunal must without delay send to the Secretary of State a copy of any material it receives under this regulation.

Reply by the Secretary of State

- 13.—(1) The Secretary of State must send to the tribunal the documents required under this regulation and regulation 14 ("the reply") so that they are received not later than the end of the period of 28 days beginning with the first date on which it has received the copies of the notice of appeal and of the additional material.
 - (2) The reply must-
 - (a) acknowledge that the Secretary of State has received the notice of appeal and the additional material,

- (b) indicate whether the Secretary of State seeks to uphold the enforcement decision, and
- (c) give the information required under paragraph (3).
- (3) The following information is required under this paragraph—
- (a) the Secretary of State's address;
- (b) the name, address and profession of the person (if any) representing the Secretary of State and whether the tribunal should send documents concerning the appeal to the representative rather than to the Secretary of State;
- (c) if in the opinion of the Secretary of State any other person has a direct interest in the subject matter of the appeal, the name and address of such other person.
- (4) The tribunal may extend the time limit imposed by paragraph (1), but must not do so unless it is satisfied—
 - (a) that the circumstances are such that it would not be reasonable to expect the Secretary of State to comply with the time limit, and
 - (b) that it is necessary to extend the time limit in order to avoid a significant risk of harm to any person.
 - (5) On receiving the reply, the tribunal must without delay send a copy to the appellant.

Further documents

- **14.** Where the Secretary of State seeks to uphold the disputed action, he must send to the tribunal—
 - (a) a statement summarising his answer to each ground of appeal supplied by the appellant,
 - (b) two copies of every document on which he relies for the purposes of opposing the appeal,
 - (c) where the appellant has not sent to the tribunal a copy of a notice giving the Secretary of State's reasons as mentioned in regulation 6(2)(b), a statement explaining why he made the enforcement decision, and
 - (d) a statement indicating whether or not the Secretary of State requests an oral hearing.

Withdrawal of opposition

15. Where the Secretary of State states in the reply or at any time in writing that he does not seek to uphold the enforcement decision, the tribunal must without delay allow the appeal.

PART IV

PREPARATION FOR DECIDING THE APPEAL

Power to make interim orders and directions

- **16.**—(1) The chairman may make an order granting on an interim basis any remedy which the tribunal would have the power to grant in its final decision, or otherwise give an interim direction in relation to the enforcement decision in question.
- (2) An order may be made or a direction given under this regulation on the chairman's own motion or on the application of—
 - (a) the appellant, or
 - (b) any interested person whom the tribunal is required to invite to make representations under regulation 17.
- (3) Where an application is made for an order or direction under this regulation before the appointment of the chairman, the order or direction may be made or given by the tribunal on a temporary basis.
- (4) An order made or direction given by the tribunal under paragraph (3) is subject to the decision of the chairman, and when the chairman has been appointed, he must without delay either affirm the order or direction (with or without variation) or discharge it.
- (5) Before making, giving or affirming an order or direction under this regulation, the tribunal must give the Secretary of State an opportunity to object, and, subject to paragraph (6), must consider any such objection.
- (6) In an urgent case, the tribunal may make an order or give a direction under this regulation before considering any objection made by the Secretary of State, but it must consider whether to revoke or vary the order or direction in the light of any such objection.

- (7) The chairman may exercise his power to make, give or affirm an order or direction under this regulation only if he is satisfied that—
 - (a) failure to do so will deprive the appellant of the substance of the remedy which may be available if the appeal is successful, and
 - (b) such an order or direction, if made, given or affirmed, will not cause significant risk of harm to any person.
- (8) Any order or direction under this regulation is subject to the tribunal's final decision under regulation 31.

Representations by interested persons

- 17.—(1) The tribunal must as soon as practicable send to—
- (a) any person named by the appellant or the Secretary of State as having a direct interest in the subject matter of the appeal, and
- (b) any other person whom the chairman is satisfied has such a direct interest, copies of the documents supplied by each party in relation to the appeal, together with an invitation to send written representations to the tribunal so that they are received before the end of a period of 21 days beginning with the date of that invitation.
- (2) The tribunal must as soon as practicable send to each of the parties a copy of any representations received under this regulation, together with an invitation to send written comments on them to the tribunal so that they are received before the end of the period of 7 days beginning with the date of that invitation.
 - (3) The tribunal must not decide the appeal before—
 - (a) the end of the period allowed for making representations under paragraph (1), or
- (b) the end of any period allowed for making comments under paragraph (2), whichever is the later.

Experts

- **18.**—(1) The chairman may, if he thinks that any technical question arises in relation to the appeal on which it would be desirable for the tribunal to have the assistance of an expert, appoint a person having appropriate qualifications to enquire into and report on the matter and, if either party requests, to attend the hearing and give evidence.
- (2) The tribunal must supply the Secretary of State and the appellant with a copy of any report received under paragraph (1) in advance of the hearing.
- (3) The tribunal shall pay such fees as it may determine to any person appointed under this regulation.

Legal assessor

- 19.—(1) The chairman may, if he thinks that a question of law arises in relation to the appeal on which it would be desirable to have the advice of a lawyer, appoint a solicitor or barrister (or, in relation to Scottish proceedings, an advocate) to give such advice.
- (2) The tribunal shall pay such fees as it may determine to any person appointed under this regulation.

PART V

DECISIONS OF THE TRIBUNAL WITHOUT A HEARING

Power to decide the appeal without a hearing

- **20.**—(1) Where, at the end of the period within which the Secretary of State is required to send his reply—
 - (a) the Secretary of State has not done so, or
- (b) neither the appellant nor the Secretary of State has requested an oral hearing, and the chairman does not consider that a hearing is necessary in the public interest or for the just disposal of the matter, the tribunal may decide the appeal without a hearing.
- (2) Subject to paragraph (3) and regulations 8 and 17, where the tribunal determines to decide the appeal under this regulation, it must do so as soon as practicable after the end of the period mentioned in paragraph (1).

- (3) Before deciding the appeal the tribunal must consider—
- (a) the notice of appeal and the appellant's additional material;
- (b) any reply sent by the Secretary of State;
- (c) any representations or written comments received under regulation 17;

and may if it thinks fit direct the appellant or the Secretary of State to provide in writing further information about any matter relevant to the appeal.

- (4) A direction under paragraph (3) must include a statement of the time allowed for complying with it, and where the appellant or the Secretary of State has not complied with such a direction within the time allowed, the tribunal may—
 - (a) decide the appeal on the basis of the material available, or
 - (b) apply to the county court or, in relation to Scottish proceedings, make a summary application to the sheriff, for an order requiring a party to comply with the tribunal's direction.
- (5) The court's permission is required for any appeal from a decision of a court under this regulation.
- (6) Where the tribunal delays its decision so that it can consider information provided under paragraph (3) or representations received under regulation 17, it must send to the appellant and the Secretary of State a notice giving the reasons for the delay, and stating when it expects to decide the appeal.

PART VI

THE HEARING

Arrangements for the hearing

- **21.**—(1) The regulations in this Part apply where the appeal is to be decided following an oral hearing.
- (2) When the tribunal has received the notice of appeal, the additional material and the reply, the tribunal must without delay fix a date for the hearing, bearing in mind—
 - (a) the seriousness and complexity of the case;
 - (b) the convenience of the parties;
 - (c) whether there is to be a pre-hearing review under regulation 25;
 - (d) whether representations are to be (or have been) invited under regulation 17.
 - (3) The tribunal must serve on the parties a notice informing each of them—
 - (a) of the time and place of the hearing of the appeal;
 - (b) where there is to be a pre-hearing review, of the time and place of the review and the powers of the chairman in relation to the review.
- (4) The date fixed for the hearing must be no less than 21 days and no more than 6 weeks after the date of the notice under paragraph (3).
- (5) The notice must include guidance in a form approved by the chairman, regarding the procedure which will apply to the hearing, including in particular information about—
 - (a) attending the hearing and bringing documents and evidence,
 - (b) calling witnesses and the power of the tribunal to summon or cite witnesses,
 - (c) the right to be represented or assisted at the hearing,
 - (d) the right to receive reasons in writing for the determination made by the tribunal,
 - (e) the limitation imposed by regulation 33 on any award of costs which the tribunal is able to make, and
 - (f) the right to appeal on a question of law arising from the decision of the tribunal.

Action by appellant and the Secretary of State on receiving notice of hearing

- **22.**—(1) Not less than 14 days before the date fixed for the hearing, the appellant and the Secretary of State–
 - (a) must each inform the tribunal whether or not he intends to appear or be represented at the hearing, and which, if any, witnesses he intends to call, and

- (b) may each, if he does not intend to appear or be represented at the hearing, send to the tribunal further written representations in support of material already sent to the tribunal.
- (2) The tribunal must as soon as practicable send to each of the parties a copy of any representations received under this regulation.

Alteration of place or time of the hearing

- 23.—(1) The tribunal may alter the time and place of the hearing—
- (a) where both the appellant and the Secretary of State agree, or
- (b) in exceptional circumstances, provided that the altered date of the hearing is not earlier than the original date.
- (2) Where the tribunal alters the time or place of the hearing under paragraph (1)(b), it must without delay inform the appellant and the Secretary of State in writing of the alteration and the reasons for it.

Publication of notice of hearings

- **24.**—(1) The tribunal must publish in such manner as the chairman may direct, taking into account the need for transparency, the importance of each appeal and the degree of public interest in each appeal, a list of all appeals for which an oral hearing is to be held and of the time and place fixed for each hearing.
- (2) The tribunal must, subject to paragraph (3), make available on request the material supplied by each party in relation to each appeal for which an oral hearing is to be held.
- (3) Where any material supplied by either party contains any matter which is confidential, the party may request that for that reason it is not made available under this regulation, or is made available in an amended form, and in such a case the material must be made available to such extent and in such form as the chairman thinks appropriate, and the chairman may make such deletions from any material as may be necessary for the purposes of complying with this paragraph.
 - (4) For the purposes of this regulation, a matter is confidential if—
 - (a) it relates to intimate personal or financial circumstances, is commercially sensitive, or consists of information communicated or obtained in confidence, or
 - (b) its disclosure would be contrary to the interests of national security.
- (5) This regulation does not affect any duty of confidentiality imposed by or under any other enactment or by any rule of law.

Pre-hearing review

- **25.**—(1) Where the tribunal has received the notice of appeal, the additional material and the reply, the chairman must without delay decide whether it is appropriate to conduct a pre-hearing review with a view to—
 - (a) identifying the issues which are likely to be material to the tribunal's decision,
 - (b) expediting the proceedings at the hearing, and
 - (c) assisting his management of the appeal.
- (2) The chairman may, if he is satisfied that to do so will produce a substantial saving in the cost of the appeal, determine at the pre-hearing review any question of law arising in relation to the appeal which he is satisfied will significantly affect its outcome.
- (3) The tribunal must as soon as practicable send to each of the parties a copy of any determination made under paragraph (2).
- (4) A determination under paragraph (2) may be varied or reversed by the tribunal at the hearing of the appeal, but otherwise it shall have effect throughout the hearing.

Hearing to be in public

- **26.**—(1) The hearing must be in public except where the tribunal is satisfied that, because the subject matter to be considered by the tribunal–
 - (a) relates to intimate personal or financial circumstances, is commercially sensitive, or consists of information communicated or obtained in confidence; or
- (b) is a matter whose disclosure would be contrary to the interests of national security or for any other reason, it is fair and reasonable for the hearing, or any part of the hearing, to be conducted in private.

(2) Whether or not the hearing is held in public, a member of the Council on Tribunals or its Scottish Committee is entitled to attend the hearing and may remain present during the deliberations of the tribunal, but must not take part in the deliberations.

Procedure at the hearing

- **27.**—(1) At the beginning of the hearing the chairman must explain the order of proceedings which the tribunal proposes to adopt.
- (2) The tribunal must conduct the hearing in the manner which it considers most suitable to clarification of the issues before it and generally to fair handling of the proceedings; it shall so far as appears appropriate seek to avoid formality in its proceedings.
- (3) The appellant and the Secretary of State may appear at the hearing and may be represented or assisted by any person.
- (4) If the appellant or the Secretary of State fails to attend or be represented at the hearing, the tribunal may hear and, provided they have considered any representations made by the party under regulation 21(1)(b), determine the appeal in that party's absence.
- (5) The tribunal must consider any representations made by an interested person under regulation 17.
- (6) Subject to paragraph (7), the appellant and the Secretary of State are entitled to give evidence, to call witnesses, to question any witnesses and to address the tribunal both on the evidence and generally on the subject matter of the appeal.
- (7) The tribunal may at any point in the hearing limit the rights of either party under paragraph (6), provided that it is satisfied that to do so will not prevent the appeal from being decided fairly.
- (8) The tribunal may adjourn the hearing, but must not do so unless it is satisfied that it is necessary to do so in order for the appeal to be decided fairly.
 - (9) The time and place fixed for an adjourned hearing must be-
 - (a) announced before the adjournment, or
 - (b) published in accordance with regulation 24.

Absence of a member of the tribunal

28. The tribunal may continue to hear the appeal in the absence of one member of the tribunal other than the chairman, and the tribunal shall be taken to be properly constituted in those circumstances.

Evidence

- **29.**—(1) Evidence before the tribunal may be given orally or, if the tribunal so orders, by sworn or written statement, but the tribunal may at any stage of the proceedings require the personal attendance of any deponent or maker of a written statement.
- (2) The tribunal may receive evidence of any fact which appears to the tribunal to be relevant, whether or not the evidence—
 - (a) would be admissible in a court of law, or
 - (b) was available to the Secretary of State when the disputed action was taken.
- (3) The tribunal may require any witness to give evidence on oath or affirmation which may be administered for the purpose by the chairman.

Summoning or citing of witnesses

- **30.**—(1) Subject to paragraphs (2) and (3), the tribunal may on the application of either party issue a summons, or in relation to Scottish proceedings a citation, requiring any person—
 - (a) to attend as a witness at the hearing, at the time and place set out in the summons or citation, and
 - (b) to answer any questions or produce any documents or other material in his possession or under his control which relate to any matter in question in the appeal.

- (2) No person may be required to attend in compliance with a summons or citation under this regulation unless—
 - (a) he has been given at least 7 days' notice of the hearing, and
 - (b) he is paid the necessary expenses of his attendance.
- (3) No person may be required in compliance with a summons or citation under this regulation to give any evidence or produce any document or other material that he could not be required to produce in legal proceedings.
 - (4) Where a person summoned under paragraph (1)–
 - (a) refuses or neglects, without sufficient cause, to appear or to produce any documents required by the summons to be produced, or
 - (b) having been so summoned, refuses to be sworn or to give evidence, a judge may, on the application of the chairman, exercise his powers under section 55 of the County Courts Act 1984(a) or, in relation to matters arising in Northern Ireland, Article 54 of the County Courts (Northern Ireland) Order 1980(b) in relation to that person as though the person had been summoned in pursuance of county court regulations as a witness in a county court.
 - (5) Where a person cited in paragraph (1)–
 - (a) refuses or neglects, without sufficient cause, to appear or to produce any documents required by the citation to be produced, or
 - (b) having been so cited, refuses to be sworn or to give evidence,
- a sheriff may, on the application of the chairman, exercise in relation to that person any power which is for the time being conferred on the sheriff in the Ordinary Cause Rules set out in the First Schedule to the Sheriff Courts (Scotland) Act 1907(c) to ordain a witness to forfeit and pay a penalty and to grant decree for that penalty in favour of the party on whose behalf the witness was cited, as though the person had been duly cited and had demanded and been paid his travelling expenses and had failed to attend a Proof in a cause to which the said Ordinary Cause Rules apply.
 - (6) In this regulation, "legal proceedings" means—
 - (a) in the case of proceedings relating to an appeal which relates to matters arising in England or Wales or Northern Ireland, proceedings in a county court, and
 - (b) in the case of Scottish proceedings, proceedings in an ordinary cause before the sheriff.

PART VII

DECISION OF THE TRIBUNAL

The decision

- **31.**—(1) The tribunal must decide, taking into account in particular the appellant's grounds of appeal—
 - (a) whether the enforcement decision is justified on its merits, and
 - (b) what (if any) enforcement action should be taken in relation to the matter, and what (if any) other action should be taken by either party in relation to the matter;

and it is the duty of the parties to give effect to its decision.

- (2) A decision of the tribunal may be taken by a majority, and the decision must record whether it was unanimous or taken by a majority; provided that where the tribunal is constituted by two members the chairman shall have a second or casting vote.
- (3) The decision of the tribunal may be made and announced at the end of the hearing, but in any event, whether there has been a hearing or not, must be recorded immediately it is made in a document which must also contain a statement of the reasons for the decision and must be signed and dated by the chairman.
 - (4) Where the decision is not announced at the end of the hearing, the tribunal must-
 - (a) within 7 days of the end of the hearing, inform each party of its decision under paragraph (1)(a), and
 - (b) as soon as reasonably possible, send to each party a copy of the document mentioned in paragraph (3).

⁽a) 1984 c. 28.

⁽b) S.I. 1980/397 (N.I. 3).

⁽c) 1907 c. 51; the First Schedule was substituted by S.I. 1993/1956.

- (5) Except where the decision is announced at the end of a hearing, it shall be treated as having been made on the day on which a copy of the document mentioned in paragraph (3) is sent to the appellant.
 - (6) Where either party is required to pay any sum in consequence of the decision—
 - (a) in the case of proceedings of a tribunal in relation to matters arising in England and Wales or Northern Ireland, either party or the tribunal may, after the end of the period during which an appeal may be brought under regulation 34, apply to a county court for an order requiring the party to pay the sum;
 - (b) in the case of Scottish proceedings, the party entitled to payment may, as soon as practicable after the expiry of the period during which an appeal may be brought under regulation 34, register an extract of the decision containing a requirement to pay the sum for preservation and execution in the Books of Council and Session, and an extract of a document so registered shall be enforceable accordingly.

Publication

- **32.**—(1) The Secretary of State must make such arrangements for the publication of the tribunal's decisions as he considers appropriate, but in doing so must have regard to the need to preserve the confidentiality of any evidence heard in private or of any confidential material supplied to the tribunal.
- (2) For the purposes of any arrangements made under paragraph (1), the tribunal may make any necessary deletions from the text of a decision.

Costs and expenses

- **33.**—(1) The tribunal may make an order awarding costs to or against the appellant or the Secretary of State.
- (2) The tribunal must, unless it is satisfied that it would not be just to do so, make an order under paragraph (1) against the appellant where the appeal has been decided against him and a notice was issued to him under regulation 11.
- (3) An order under paragraph (1) may require the party against whom it is made to pay to the other party either—
 - (a) a specified sum not exceeding the relevant costs incurred by that other party, or
- (b) the whole or part of those costs as taxed (if not otherwise agreed); and, in determining how much the party is required to pay, the tribunal must take account of the conduct of both parties in relation to the appeal.
 - (4) The relevant costs of a party are the costs incurred by the party in-
 - (a) attending the hearing, including loss of income,
 - (b) reimbursing the expenses of witnesses attending the hearing on his behalf, or
 - (c) being represented at the hearing.
 - (5) Any costs required by an order under this regulation to be taxed are to be taxed—
 - (a) in the case of proceedings of a tribunal in relation to matters arising in England, Wales and Northern Ireland, in the county court according to such of the scales prescribed by the county court rules for proceedings in the county court as shall be directed in the order;
 - (b) in the case of Scottish proceedings, by the Auditor of the Sheriff Court according to such mode and such scale as shall be directed in the order.

PART VIII

SUPPLEMENTARY

Further appeals

- **34.**—(1) The appellant or the Secretary of State may, at any time during the period of 3 months beginning with the day on which the decision is made, bring a further appeal on any question of law arising from the decision of the appeal by the tribunal.
- (2) Where the decision relates to an appeal concerning matters arising in England or Wales, any further appeal under this regulation must be made to the High Court.
- (3) Where the decision relates to an appeal concerning matters arising in Scotland, any further appeal under this regulation must be made to the sheriff or, where the Scottish Ministers have so determined in relation to all appeals under these Regulations, to the Court of Session.

- (4) Where the decision relates to an appeal concerning matters arising in Northern Ireland, any further appeal under this regulation must be made to the High Court of Justice in Northern Ireland.
- (5) The High Court, the sheriff or the Court of Session or the High Court of Northern Ireland (as the case may be) may confirm, vary, set aside, revoke or remit the decision of the tribunal, and may make any order the tribunal could have made.
- (6) No appeal to the Court of Appeal may be brought from a decision of the High Court under this regulation except with the permission of the High Court or the Court of Appeal.
- (7) No appeal to the sheriff principal or the Court of Session may be brought from a decision of the sheriff under this regulation except with the leave of the sheriff.
- (8) No appeal to the Court of Appeal of Northern Ireland may be brought from a decision of the High Court of Justice in Northern Ireland under this regulation except with the permission of the High Court of Justice in Northern Ireland or the Court of Appeal of Northern Ireland.

Irregularities

- **35.**—(1) Any irregularity resulting from failure to comply with any provision of these Regulations before the tribunal has reached its decision shall not of itself render the proceedings void.
- (2) Where any such irregularity comes to the attention of the tribunal, the tribunal may, and must if it considers any person may have been prejudiced by the irregularity, give such directions as it thinks just, before reaching its decision, to cure or waive the irregularity.
- (3) Clerical mistakes in any document recording a direction, order or decision of the chairman or tribunal, or errors arising in such a document from an accidental slip or omission, may be corrected by the chairman by certificate under his hand.

Documents etc.

- **36.**—(1) Anything required to be sent to or served on any person for the purposes of the appeal may be—
 - (a) delivered to the person personally,
 - (b) sent to him at his appropriate address by post or by recorded delivery, or
 - (c) sent to him by fax or E-mail (electronic mail), or other similar means which are capable of producing a document containing the text of the communication, in which case the document shall be regarded as sent when it is received in a legible form.
 - (2) A person's appropriate address for the purposes of paragraph (1) is-
 - (a) in the case of a document directed to the tribunal, the address published under regulation 3:
 - (b) in the case of a document directed to the appellant or his representative, the address stated in the notice of appeal in accordance with regulation 5 or such other address as may be subsequently notified to the tribunal;
 - (c) in the case of a document addressed to the Secretary of State, the address stated in the reply in accordance with regulation 13 or such other address as may be subsequently notified to the tribunal.
- (3) Anything required to be sent to or served on a company is duly sent or served if it is sent to or served on the secretary of the company at its principal or registered address for the time being.
- (4) Anything required to be sent or delivered to or served on a partnership is duly sent or served if it is sent to or served on any one of the partners for the time being.
- (5) Where anything is sent to any person by registered post or recorded delivery, it shall be treated as if it had been received by that person on the next working day.

Time

37. Where the time prescribed by these Regulations for doing any act expires on a Sunday or public holiday, the act is in time if done on the next following day which is not a Sunday or public holiday.

Supervision by the Council on Tribunals

38. The constitution and working of tribunals established under these Regulations shall be kept under review and reported on by the Council on Tribunals as if they were tribunals specified in Schedule 1 to the Tribunals and Inquiries Act 1992(a).

General power of the tribunal

39. Subject to the provisions of these Regulations, the tribunal may regulate its own procedure.

22nd January 2000

Alan Milburn
One of Her Majesty's Principal Secretaries of State

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision in relation to appeals against determinations made under the National Health Service price control scheme set out in the Health Service Medicines (Control of Prices of Branded Medicines) Regulations 2000 (No. 123). They extend to England, Wales, Scotland and Northern Ireland.

The Regulations provide for-

- (a) the manner in which, and the time within which, such an appeal may be made; and
- (b) the procedure to be followed where such an appeal is made.

They impose no costs on business.