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NBPM AT 28/11

DEPARTMENT OF HEALTH AND SOCIAL SECURITY

Alexander Fleming House, Elephant & Castle, London SE1 6BY

Telephone 01-407 5522

From the Minister for Health

The Rt Hon Peter Rees QC MP
Chief Secretary of the Treasury
Treasury Chambers
Parliament Street
LONDON
SW1

25th November 1982

Dear Mr Rees,

Norman Fowler wrote to you on 21 July outlining the measures we proposed to reduce the NHS drugs bill, and you replied on 1 August broadly endorsing our proposals. We have had extensive discussions with the pharmaceutical industry's representatives since then, and we are now ready to put final proposals to them.

You will recall that we proposed reductions under the Pharmaceutical Price Regulation Scheme in three areas. As regards the target return on capital for the industry as a whole, the industry's representatives appear to be resigned to a cut of four percentage points, one point more than suggested in his letter to you, which will bring the target down to 21 per cent ROC. We can look at this if necessary in the light of the forthcoming report of the Review Board for Government Contracts, though we would hope not to have to make further changes, up or down, for some time. Frequent changes in profit rates make the scheme difficult to administer and heighten uncertainty in the industry.

The industry sets great store by maintaining a sufficiently large area of flexibility above a company's target profit rate (the "grey area") to provide the incentive to research and develop new drugs and promote efficiency. They have suggested that the size of the grey area should, instead of being at the present flat rate of 10 per cent, be related to individual company targets, and we think this has a lot to commend it. We propose to pitch it at one third of target which will mean that companies on the new maximum target rate of 21 per cent ROC will have a grey area of seven percentage points, while those at the lowest target rate will have one of five.

The industry's representatives have also suggested a different method of controlling expenditure on sales promotion. At present the limit is 10 per cent of industry sales, but the total for the industry is invariably exceeded. The proposal is that a company which overspends its limit should in future "repay" to the Department £1 for £1 overspent. This penalises the overspenders and avoids the present difficulty that a company whose profits are below target can spend heavily on sales promotion without incurring any penalty (which in turn encourages other companies to overspend). If the scheme can be made to stick, we think it should persuade most companies to keep within the limit; and if they do not, should enable us to recover the overspending. We believe that the proposal is sufficiently promising to introduce it at the existing limit of 10 per cent of sales, but we propose to put the industry on notice that

we shall reduce the limit to nine per cent next year and review it thereafter. The change of system should enable us to recoup about £20 million extra at levels of sales promotion even before there is any reduction in the 10 per cent limit.

Although the sales promotion proposal has come from the industry's own representatives, it is by no means certain that it will prove acceptable to member companies. Norman has no statutory powers to require companies to repay excess sales promotion expenditure, or for that matter excess profits. We shall make it clear to the industry that if the new arrangement is not honoured we shall have to revert to present arrangements and a lower target, as proposed in Norman's letter.

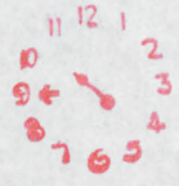
The combined effect of these measures, whichever of the sales promotions options we take, will rule out all but a very few price increases during 1984/85, thus in effect continuing the current price freeze imposed following the July restraints on public expenditure. We estimate that this will be worth some £65 million in 1984/85 (bearing in mind that prices were lowered by 2½ per cent in the summer), and perhaps as much as £120 million in later years as the measures take full effect. In addition, we are at present reviewing costs and profits in transfer prices and hope that by means of more use of accountant manpower in the scrutiny of companies' annual financial returns to the Department some further savings may be achieved. Our officials have been in touch with yours about ways in which this additional input can be funded, and we hope that an early and satisfactory result can be achieved.

There is little additional savings to be achieved from generic substitution and parallel imports, as you acknowledged in your letter of 1 August to Norman. However, we regard it as important to continue the quest for more effective means of reducing prescribing costs. We shall very shortly be issuing a consultative document on proposals to ensure that parallel imports of medicines for general dispensing are properly controlled.

I am copying this letter to the Prime Minister, and the Secretaries of State for Trade and Industry, Scotland, Wales and Northern Ireland.

Yours sincerely

for KENNETH CLARKE
(approved by the Minister and signed in his absence)



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END

NBPM AT 30/4

Treasury Chambers, Parliament Street, SW1P 3AG

Kenneth Clarke QC MP
Minister of State
Department of Health & Social Security
Alexander Fleming House
Elephant & Castle
LONDON SE1 6BY

29 November 1983

Dear Minister,

PHARMACEUTICAL INDUSTRY

Thank you for your letter of 25 November about the final proposals which you wish to put to the representatives of the pharmaceutical industry.

When I agreed in my letter of 1 August to Norman Fowler to the original package of measures, I said that I would be content if in the event your talks with the industry led to minor changes in the detail. I see from your letter that for the most part such changes as have occurred are indeed minor, with the exception of the industry's proposals on promotional expenditure. I am naturally pleased, if somewhat surprised, that these changes have enabled you to forecast savings of £120m in a full year as against the £60m Norman was expecting in July. My officials, who have not had the chance to study these figures in detail will be in touch with yours to discuss them further, but meanwhile I am quite content for you to put your proposals to the industry.

I have two comments on your letter not related to the immediate issue of your talks with the industry, but to the slightly longer term.

First, I can well understand that, having reached an understanding with you on allowed rates of return and so forth, the industry will be unwilling to change the figures frequently. But we must remember the difficulties which can be created by continuing figures agreed in one set of circumstances into later years when circumstances may have changed radically. I should be grateful therefore if you would avoid any commitment not to change the figures for a specified period, even though I can understand the industry's natural wish for a period of stability.

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Secondly, I am increasingly coming to feel that it is anomalous for the NHS to refund any of the promotional expenditure incurred by the drug companies. In the absence of direct price competition, advertising and other sales promotion offers one of the main means for drug companies to compete for NHS business. I do not think that the NHS itself should pay for that. If there is a function of disseminating within the NHS information about new drugs or other formalities, it occurs to me that that could be discharged more cheaply and less wastefully if the NHS carried out the work itself directly. This is an issue to which I shall wish to return during the full-scale review of the PPRS which, I understand, is due to take place after your current talks with the industry. Meanwhile I should be grateful for any comments you might have.

I am sending copies of this letter to the recipients of yours.

yours sincerely

PETER REES

pp (agreed by the Chief Secretary & signed in his absence).

With permission, Mr Speaker,

I would like to make a statement on the discussion that I and the Secretary of State have been having on behalf of all the UK Health Ministers with representatives of the pharmaceutical industry on the scope for savings in the NHS drugs bill and other matters of mutual concern.

2. Prescription medicines cost the NHS in England about £1,250 million in 1982/83. Drugs account for about 40 per cent of the total cost of the FPS, and about 10 per cent of the cost of the NHS as a whole. The pharmaceutical industry's profits from NHS sales are governed by the non-statutory Pharmaceutical Price Regulation Scheme which was introduced in its present form in 1978. In the words of the published Scheme, it is a key objective that "safe andeffective medicines [should be] available on reasonable terms to the NHS, but also that a strong, efficient and profitable pharmaceutical industry" should exist in the UK. The industry's present target profit level was set by the Labour Government in 1978. Like our predecessors we recognise that there is a major and successful industry providing 67,000 jobs and with a net balance of exports over imports of around £600 million a year.

3. However, the present Scheme has run unaltered for over five years. A review of the PPRS and its role in relation to the industry and the NHS was announced earlier this year. After extensive discussion with the industry's representatives and having taken account of the 10th Report of the PAC published in April, we have decided both to reduce the level of profit from NHS business and the level of sales promotion allowed as an expense under the Scheme.

4. First, under the scheme each pharmaceutical company participating in it is assigned a target rate of profit taking account of "the circumstances of the individual company, the contribution which it makes or is likely to make to the economy, including foreign earnings, investment, employment or research". We have decided that these targets should be reduced by an average of four percentage points which will represent a saving to the NHS in the UK of about £40 million a year. We have also decided that the discretion which our Department allows in certain circumstances when companies exceed their target profit rates should be tightened and related more closely to a company's particular circumstances. Companies will be told what their new targets are very shortly.

5. Second, the industry will spend about £180 million this year on sales promotion. Some, but not all, of this amount is an allowable expense under the PPRS. Such promotion is funded largely from NHS sales, and we have concluded that the allowable level should be reduced. We propose, first, that companies should be asked to repay to the Department a sum equivalent to any sales promotion expenditure which exceeds the level allowed under the scheme; and, second, that the industry limit should be reduced from the present level of 10 per cent of turnover to 9 per cent in 1985/86. We estimate that when fully implemented these measures should reduce actual expenditure on sales promotion by 25 per cent but we will review this area again to see if further reduction can be made.

through a modified licence to cover such safety matters as storage, labelling and tracing.

8. There remains the question of generic substitution which we have also been considering in the context of the PPRS review, as announced earlier this year. The Greenfield Committee proposed that a pharmacist should substitute an equivalent generic preparation for proprietary medicine unless the prescribing doctor had specifically indicated that this should not be done. The Committee acknowledged that they had not taken account of the wider implications, for example, on the pharmaceutical industry, of their recommendation. Consultation on the Greenfield report earlier this year showed professional opinion to be divided on this recommendation - which was only one of 14. It become clear that many general practitioners were concerned that their patients would be supplied with formulations of drugs that their doctors had not prescribed. General practitioners and pharmacists foresaw problems of divided responsibilities for the treatment of patients. The various procedures considered all raised serious practical problems. We have therefore decided not to proceed with generic substitution. We do, however, intend to start a new campaign to encourage generic prescribing by doctors. As to the other recommendations of the Greenfield Committee, we have already announced our acceptance of these or referred them to the appropriate educational bodies.

6. All measures I have announced will take effect from 1 April next year. In a full year they will produce savings on the NHS drug bill rising on present estimates from £65 million in 1984/85 to well over £100 million in later years. This compares with the industry's total profit from sales in the UK in 1983 of an estimated £200 million. The changes will mean that the price freeze on drugs - introduced in August as part of the £25 million savings agreed then - will continue, with few exceptions, through 1984/85 and beyond. Furthermore, the price freeze will be at the level established by the 2½ per cent cut of August.

7. We have also discussed with the industry the problem of parallel importing of medicines. This occurs when an importer takes advantage of exchange rates and low regulated prices of particular drugs in other countries to import or reimport those drugs into this country in competition with the identical or near identical products already marketed here. At present, an exemption order under the Medicines Act is being used by parallel importers, in a way not envisaged when the order was made, to bring into Britain substantial quantities of medicines without a licence. Clearly there are potential health hazards if a drug has not been properly manufactured or stored, or if labels are in a foreign language, or if there is difficulty in tracing a batch of drugs found to be faulty. We are not aware of any actual injury to patients but we propose to guard against that possibility. We are statutorily required to consult on these matters, and we will therefore shortly issue a consultative document on proposals which will ensure that medicines parallel imported for general dispensing must be licensed under the Medicines Act, either in the ordinary way, or in the case of medicines also licensed in the European Community,

9. Finally, there are a number of other matters arising from the review of the PPRS which have still to be resolved in discussion with the industry. In particular, a study of transfer prices, which are the prices charged by a foreign-based company to its UK subsidiary, is being conducted by independent consultants and our Department is undertaking a study of pharmaceutical wholesalers' profit margins.

10. In framing these proposals the Government has sought to achieve a balance between the interests of the NHS as customer and the interests of the industry. We recognise the research achievements of the industry and the contribution it makes to the UK economy and we want to see it continue to flourish. However, there is an urgent need to contain the drugs bill for the health service and this we are also determined to achieve. I very much hope that the industry will accept this position as we wish to continue with the price regulation scheme on a non-statutory basis.

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cc TF
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DEPARTMENT OF HEALTH & SOCIAL SECURITY

Alexander Fleming House, Elephant & Castle, London SE1 6BY

Telephone 01-407 5522

From the Secretary of State for Social Services

Andrew Turnbull Esq
Private Secretary
10 Downing Street
LONDON
SW1

Dear Andrew, 5 December 1983

STATEMENT ON NHS PHARMACEUTICAL PRICES AND PROFITS

I attach a draft of the statement on NHS pharmaceutical prices and profits which my Secretary of State intends to make on Thursday. Perhaps you and recipients could let me know if you have any comments as soon as possible.

Copies go to Charles Marshall (Lord Privy Seal's Office) John Gieve (Chief Secretary's Office) Johnathan Spencer (Department of Trade and Industry) Judy Roberts (Welsh Office) John Graham (Scottish Office) and Noel Cornick (Northern Ireland Office).

Yours sincerely,
Ellen Roberts

ELLEN ROBERTS
Private Secretary

DRAFT 5.12.83

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1. I would like to make a statement on the discussion that the Minister of Health and I have been having with representatives of the pharmaceutical industry on the scope for savings in the NHS drugs bill and other matters of mutual concern.

2. Prescription medicines cost the NHS in England about £1,250 million in 1982/83. Drugs account for about 40 per cent of the total cost of the FPS, and about 10 per cent of the cost of the NHS as a whole. The pharmaceutical industry's profits from NHS sales are governed by the non-statutory Pharmaceutical Price Regulation Scheme which was introduced in its present form in 1978. In the words of the published Scheme, it is a key objective that "safe and effective medicines [should be] available on reasonable terms to the NHS, but also that a strong, efficient and profitable pharmaceutical industry" should exist in the UK. The industry's present target profit level was set by the Labour Government in 1978. Like our predecessors we recognise that there is a major and successful industry providing 67,000 jobs and with a net balance of exports over imports of around £600 million a year.

3. However, the present Scheme has run unaltered for over five years, and a review of it was announced earlier this year. After extensive discussion with the industry's represenatives and having taken account of the 10th Report of the PAC published in April, I have decided both to reduce the level of profit from NHS business and the level of sales promotion allowed as an expense under the Scheme.

4. First, under the scheme each pharmaceutical company participating in it is assigned a target rate of profit taking account of "the circumstances of the individual company, the contribution which it makes or is likely to make to the economy, including foreign earnings, investment, employment or research". I have decided that these targets should be reduced by an average of four percentage points which will represent a saving to the NHS in the UK of about £40 million a year. I have also decided that the discretion which my Department allows in certain circumstances when companies exceed their target profit rates should be tightened and related more closely to a company's particular circumstances. Companies will be told what their new targets are very shortly.

5. Second, the industry spends about £180 million each year on sales promotion. Some, but not all, of this amount is an allowable expense under the PPRS. The UK industry spends proportionately less on Sales promotion than any other comparable country. Nonetheless such promotion is funded largely from NHS sales, and I have concluded that the allowable level should be reduced. I propose, first, that companies should be asked to repay to the Department a sum equivalent to any sales promotion expenditure which exceeds the level allowed under the scheme; and, second, that the industry limit should be reduced from the present level of 10 per cent to 9 per cent in 1985/86. We estimate that when fully implemented these measures should reduce actual expenditure on Sales promotion by 25 per cent but we will review this area in 1985/86 to see if further reduction can be made.

6. All measures I have announced will take effect from 1 April next year. In a full year they will produce savings on the NHS drug bill rising on present estimates from £65 million in 1984/85 to well over £100 million in later years. This compares with the industry's total profit from sales in the UK in 1983 of an estimated £200 million. The changes will mean that the price freeze on drugs - introduced in August as part of the £25 million savings agreed then - will continue, with few exceptions, through 1984/85 and beyond. Furthermore, the price freeze will be at the level established by the 2½ per cent cut.

7. Among the other issues discussed with the industry is the problem of parallel importing of medicines - that is to say medicines purchased at a relatively low price in one country for sale in another in competition with identical or virtually identical products already marketed there. At present, an exemption order under the Medicines Act is being used by parallel importers, in a way not envisaged when the order was made, to bring into Britain substantial quantities of medicines without a licence. Clearly there are potential health hazards if a drug has not been properly manufactured or stored, or if labels are in a foreign language, or if there is difficulty in tracing a batch of drugs found to be faulty. We are not aware of any actual injury to patients but I propose to guard against that possibility. I am statutorily required to consult on these matters, and my Department will therefore shortly be issuing a consultative document on proposals which will ensure that medicines parallel imported for general dispensing must be licensed under the Medicines Act, either in the ordinary way, or in the case of medicines also licensed in the European Community, through a modified licence to cover such safety matters as storage, labelling and tracing.

8. There remains the question of generic substitution which I have also been considering in the context of the PPRS review, as announced earlier this year. The Greenfield Committee proposed that a pharmacist should substitute an equivalent generic preparation for proprietary medicine unless the prescribing doctor had specifically indicated that this should not be done. The Committee acknowledged that they had not taken account of the wider implications, for example, on the pharmaceutical industry, that their recommendation might have. While consultation on the Greenfield report earlier this year showed opinion to be divided on this recommendation - which was only one of 14 - it is clear that general practitioners in particular found the procedure involved in the Greenfield recommendation unacceptable, and I do not propose to proceed with it. I do, however, intend to start a new campaign to encourage generic prescribing by doctors. As to the other recommendations of the Greenfield Committee, I have already announced my acceptance of these or referred them to the appropriate educational bodies.

9. Finally, there are a number of other matters still to be resolved in discussion with the industry. In particular, a study of transfer prices (the prices charged by a foriegn-based company to its UK subsidiary) is being conducted by independent consultants and the Department is undertaking a study of pharmaceutical wholesalers' profit margins.

10. In framing these proposals the Government has sought to achieve a balance between the interests of the NHS as customer and the interests of the industry. We recognise the research achievements of the industry and the contribution it makes to the UK economy but we want to see it continue to flourish. However, there is an urgent need to retain the drugs bill for the health service and this we are also determined to achieve. I very much hope that the industry will accept this position as we would wish to continue with the price regulation scheme on a voluntary basis.

JW

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DEPARTMENT OF HEALTH & SOCIAL SECURITY

Alexander Fleming House, Elephant & Castle, London SE1 6BY

Telephone 01-407 5522

G.T.N. 2915

From the Secretary of State for Social Services

Charles Marshall Esq
Private Secretary to
Lord Privy Seal

1 December 1983

Dear Charles,

We spoke yesterday about my Secretary of State's wish to make an oral statement next Wednesday on NHS pharmaceutical prices. You thought that, subject to any unforeseen developments, this was unlikely to present any problems.

I am copying this to Tim Flesher (Prime Minister's Office) and Peter Moore (Chief Whip's Office).

Yours sincerely,

Ellen Roberts

ELLEN ROBERTS
Private Secretary