PERSONAL

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Prime Minister - to see

DEPARTMENT OF HEALTH & SOCIAL SECURITY

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

Telephone 01-407 5522 ext 6981

From the Permanent Secretary

Sir Kenneth Stowe KCB CVO

29th June, 1983

Robin Butler Esq.,
10 Downing Street

Noted

Dear Robin

I talked to the Prime Minister last night about some of our concerns in the NHS; and was left in no doubt that she is looking for progress in reducing costs. This prompts me to alert you to an imminent development which will almost certainly entail approaches to the Prime Minister.

We want to reduce the cost of the NHS drug bill and have in mind a packet of policies and specific measures which we have already broached with senior representatives of the pharmaceutical industry. I attach a note which indicates what we have in mind. The industry will not like it. I know from private sources that they are preparing their defences which will certainly include Sir Austin Bide (GLAXO) approaching the Prime Minister; Sir Robin Ibbs (ICI) doing the same, Sir Graham Wilkins (BEECHAM) will be approaching the Chairman of the Conservative Party at the Department of Trade and Industry; and Mr Shepperd (BURROUGHS WELLCOME) will be pitching in to the City. We know that they will threaten to hold up investment decisions or target them abroad in support of their case.

I write not only to give you advance warning but also to urge that the Prime Minister backs us up with a robust response. There is no need, in my view, for her to get deeply involved. Her stance could be that she expects Norman Fowler to attack the costs of the NHS in every dimension and the drugs bill cannot be excluded. It is then up to the industry and the Department to reach a constructive understanding, which I believe we can do.

Yours ever.

Ken.

UK PHARMACEUTICAL INDUSTRY - POSSIBLE REDUCTION IN COST TO NHS

(Figures are estimates for calendar year 1983)

	£m	
1. Drug bill (cost of NHS prescribed medicines, excluding chemists' remuneration and wholesale discount).	1400	
2. Industry target profit (present PPRS rules).	240	(25%)
3. Industry actual profit (estimated and assessed by DHSS).	250	(26%)
4. Proposed adjustments (Note: these are my judgement of a likely outcome of negotiation; our opening bid will be more severe).		
a. cut in target profit of 4 percentage points - saving	40	
b. cut in tolerance allowed over target profit from 10 to 5 percentage points - saving	25	
c. cut in expenses on sales promotion allowed to be offset against profits, from 10% to 8% of sales - saving	28	
5. Total estimated annual savings 4a-c (equivalent to 5.7% off drug bill and 33% off target profits).	80	

NOTES

1. Items 2 and 3 - are return on historic capital employed.

2. Item 4b this tolerance (called the 'grey area') - is the additional profit permitted to companies over their targets to encourage efficiency and endeavour.

3. Item 5 total savings - is not the simple total of 4a to 4c because the elements of the PPRS interact. Full estimated annual savings would not be achieved for 2 or 3 years. The impact would vary as between individual companies as their performance varies - inevitably the companies making the biggest exessive profits would lose most.

4. Other elements in the overall "packet" of measures will be (a) action on closing a loophole which allows excessive parallel importing of medicines into this country and (b) action on the question of the Greenfield Report's views on "generic substitution" (the substitution of a cheaper generic version of the drug prescribed by a doctor).

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CHIEF SECRETARY TO THE TREASURY

Treasury Chambers, Parliament Street, SW1P 3AG

Rt Hon Norman Fowler MP
Secretary of State
Department of Health &
Social Security
Alexander Fleming House
Elephant & Castle
London SE1 8BY

1 August 1983

Dear Secretary of State,

PHARMACEUTICAL INDUSTRY

Thank you for your letter of 21 July.

I think that the cuts you seek in the PPRS ahead of the main review are very much a matter of negotiating judgement, which I regard as a matter for you. I am glad of your undertaking to secure £60 million (UK) in a full year, and on this basis I am content to leave the precise nature of the package to you. But it does seem to me that your present proposals are right, that you should treat them as firm objectives to be achieved, and that you should be reluctant to depart from them. The drugs industry will undoubtedly want to see some changes as a result of their talks with you, and this might be best achieved by your overbidding initially (with, say, a 5% cut in RoC), thus allowing you to treat the desired outcome as a fallback.

I assume that you have settled on the £60 million figure as the maximum achievable in practice. The corollary of course is that there are no further savings on drug prices available to meet the overall savings I shall be seeking on your programmes following the recent Cabinet discussion, and that the balance will need to come from elsewhere.

On generic substitution and parallel importing, I broadly agree with what you propose. Given the operation of the PPRS, there are no significant savings here. But I hope you would not rule out measures to encourage generic prescribing, perhaps as part of a Greenfield package, or the possibility for the future of encouraging imports as a means of encouraging competition in the drugs industry.

I am copying this letter to the recipients of yours.

Yours sincerely

PETER REES

(approved by the Chief Secretary & signed in his absence)

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Econ Pol; Public Expenditure; PA-23

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Prime Minister (4)

Mrs 21/7

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

Peter Rees QC MP
Chief Secretary to the Treasury
Treasury Chambers
Great George Street
LONDON SW1

21 July 1983

Dear Peter.

Pharmaceutical Industry

You will recall that I announced on 8 July that I had informed the pharmaceutical industry's representatives that I intended to save £25m on the NHS drugs bill in 1983/84 as part of the Government's measures to control public spending. Our officials have also been discussing a number of other matters which affect the pharmaceutical industry in the context of the recent PAC report on Dispensing of Drugs in the NHS and the announcement of the PPRS review earlier this year (a copy of the statement to the PAC is attached). I am now ready to put proposals to the industry which would reduce their profits in the coming years, ie after 1983/84, and enable us to make considerable savings in the NHS bill, mainly in the family practitioner services.

There are two preliminary points I should make. First, I need hardly say that there is consternation in the industry at the £25m cut (equivalent to a £50m, or 25 per cent reduction in profit in a full year), and acute anxiety about the future. We already know of companies which are holding up UK investment plans and foriegn owned firms which are rethinking their investment strategy. I must end the uncertainty as soon as possible, and I have promised the industry's representatives that I will put proposals to them before the end of July which will deal with the major matters outstanding with the industry, including the Greenfield Committee's recommendation on generic substitution and the problem of parallel importing.

Second, I have been able to persuade the industry to co-operate in achieving the £25m saving only on the assurance that the Government - unlike the Opposition - has no intention of damaging the industry which, as you will know, has an outstanding international reputation for its research and development of ethical medicines, contributes a net surplus of some £600m pa to our overseas trade, provides over 67,000 jobs, and attracts very considerable foreign investment. While there is no question of backing away from the Government's intention to reduce

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profit levels, I must discuss our proposals as a whole with the industry's representatives, and adjust them, if necessary, if it appears that particular measures would be damaging to the industry.

Pharmaceutical Price Regulations Scheme

Officials have started work on the review of the PPRS announced to the PAC, but this will take some months to complete, and therefore without waiting for this I propose to take the opportunity offered by the PAC report itself to reduce the profits we allow the industry on its sales to the NHS.

The PPRS is agreed between the Government and the industry, but decisions on profit levels and certain allowances are reserved to Ministers, subject to Treasury consent. I propose to attack on three fronts and reduce the return on capital (ROC) allowed to the industry, the area of flexibility above the ROC permitted individual companies to encourage efficiency and endeavour (the 'grey area'), and the expenditure on sales promotion allowed as expenses. The reductions would take effect from a current date, but would take some time to work through, and maximum savings would not be achieved for 2 or 3 years.

The 25 per cent return on capital (ROC) at present allowed to the industry was related to the return on non-competitive contracts recommended in the 1978 report of the Review Board on Government Contracts. The Board is due to report again at the end of this year and we will want to reconsider the ROC level in the light of its recommendations. Meanwhile I propose to aim for a reduction of 3 percentage points (ie from 25 per cent to 22 per cent). In practice, the scheme is at present running slightly over its target and we should therefore have to impose larger cuts when allocating targets to individual companies. Each precentage point reduction is worth approximately £10m pa off the NHS drug bill, so the effect of this proposal alone would be to take over £30m pa out of the industry's profits on sales to the NHS.

Second, I propose to aim for a reduction in the size of the 'grey area' from the present 10 to 5 percentage points above a company's target ROC. The grey area allows a company to retain extra profits above its target where this is due to introducing new products or through improving its efficiency and reducing costs. It is a matter of judgement how big a grey area is needed, but the present one is clearly too high. Savings from a reduction are impossible to quantify accurately, since they depend on the commercial decisions of the companies covered by the scheme, but our best guess is that a 5 point grey area might lead to savings of up to £25m pa for the first year or two, though this would fall as the new rules are applied.

Third, I propose that we should lower the ceiling of expenditure on sales promotion allowed under the PPRS. At present companies can charge in the price of NHS medicines up to approximately 10 per cent of the value of their sales. Expenditure over this figure is counted as profit. Each percentage point reduction in the permitted allowance is worth approximately £14m pa. I propose that we should reduce the allowance from 10 per cent to 8 per cent forthwith and seek further restrictions in later years. We might save £28m pa by this means.

The reductions described above are maximum figures. If achieved, they would lead, after two or three years, to annual savings of up to £70m pa, though savings in earlier years would be smaller. The industry's target profit from NHS sales is currently approximately £240m, and the effect of the cuts proposed above would be to reduce the target by something like 30 per cent. We cannot expect the industry to accept this without a fight. I shall therefore need to link these

E.R.

proposals with settlement of the other matters outstanding with the industry referred to in paragraph 2 above. From the industry's point of view, the most important of these is generic substitution.

Generic substitution

As we expected, comments on the Greenfield Report recommendation on the introduction of a form of generic substitution (the substitution by the pharmacist of a generic drug where one is available for the branded equivalent) have shown very limited support for the Committee's proposal. The industry point to damaging effects on foreign markets linked with the UK with loss of export earnings; and to the effect that Government endorsement of generic substitution would have on foreign investment in the UK. I do not believe they are entirely crying wolf, and I do not think that on merits the case for the introduction of generic substitution in the form proposed is proven. If, on the other hand, we consider the proposal strictly from the point of view of savings to the NHS, (and that, after all, is the only reason for considering generic substitution) there are better ways in which they can be achieved. I shall of course urge on the industry the merits of some form of generic substitution (perhaps on an "opting in" basis), but we cannot realistically expect to achieve both the savings from the changes in the PPRS proposed above, and the potential savings of £5m to £20m which might accrue if the Greenfield proposal could be introduced. Rightly or wrongly the industry feel extremely strongly about generic substitution, and we may need to give way here to achieve the wider objective. Nor must we overlook the fact that reductions in profit levels will work mainly through branded drug prices and will reduce the price differentials between branded and generic drugs, thus reducing potential savings from generic substitution on the Greenfield model.

Parallel Imports

Our concern here is to close a loophole in the import exemption order made under the Medicines Act which is at present being exploited and which carries a serious potential risk to health from uncontrolled medicines. We also need to meet the judgement of the European Court by introducing a licensing scheme for parallel imports from the EC, which will seek to ensure that these imports are safe and can be traced back if needed. Just before the election EQO agreed to our proposals which cover both these points together. There is little or no financial benefit to the NHS from what is at present happening: the beneficiaries are those chemists who are able to buy drugs cheaply in Europe, and the importers who have taken advantage of the present position. Meanwhile losses are being incurred by certain wholesalers and manufacturers. The industry will, however, be pleased that we are introducing measures to control the abuse.

Conclusion

I should be grateful to have your agreement and those of colleagues to whom this letter is copied to putting these proposals to the industry. I do not intend to put them forward as a basis for negotiation, since these are all matters falling to my discretion outside the detailed PPRS itself but I may want to be flexible to settle a total package provided that I secure £60m in a full year, bearing in mind that the Government will be looking again at profit levels when the Review Board reports in a few months time. A number of minor matters, including the point mentioned by the PAC about the position of small firms whose profits are determined on the basis of sales (rather than capital), would be picked up in the detailed review of the PPRS referred to above.

E.R.

I am copying this letter to the Prime Minister, the Chancellor of the Exchequer, Secretaries of State for Trade and Industry, Scotland, Wales and Northern Ireland. Achievement of the £25m savings in the current year, depends on the co-operation of the industry, and I must honour my undertaking to put proposals to them this month for settling the matters referred to above. It would therefore be very helpful to have a quick reaction to these proposals. I am, of course, ready for an urgent meeting.

NORMAN FOWLER

PERMANENT SECRETARY'S STATEMENT TO THE PAC

1. The PPRS was introduced by agreement between the Health Departments and the ABPI in 1978. It succeeded similar arrangements for regulating the prices paid for prescription medicines which had run since 1969. Before 1969 the Health Departments attempted to control the prices of individual medicines.

2. Ministers consider that it would now be appropriate to review the working of the scheme because:

a. it has been running, unaltered, in its present form for nearly 5 years during which time there have been important developments both within and outside the NHS.

b. pharmaceuticals account for about 10% of NHS expenditure and should not be exempted from the search for greater efficiency.

c. the pharmaceutical industry's ROC has been creeping up, and it is necessary to consider whether this is consistent with the purposes of the scheme.

Ministers will want particularly to consider:

i. the rate of ROC allowed to the industry;

ii. the incentives to efficiency and profit it offers to individual companies;

iii. the costs allowed as chargeable expenses under it; and

iv. the relationship to issues raised in the Greenfield Report.

3. Ministers therefore propose that the scheme should be reviewed by the Health Departments in consultation with other interested Departments and the industry to make sure that the interests of the patient, the taxpayer and the industry are being properly served, and to propose any changes that may be needed. They will, of course, want to take account of any views the PAC may express on the working of the scheme.