DEPARTMENT OF HEALTH

DEPARTMENTAL RECORD OFFICE.
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TITLE OF BODY INITIATING FILE (IF NOT DHSS/DH)

PRO CLASS	PIECE NUMBER
MH148	1044

(write BOLDLY in black chinagraph pencil or black crayon)

FILE REFERENCE DETAIL	Volume or Part.
WHO/19/6	

~~A/W47/307~~

DATES COVERED (In years)
FROM 1974 TO 1984

SUBJECT OR TITLE
WORLD HEALTH ORGANISATION BLOOD TRANSFUSION.

PRO CLOSURE LABEL
CLOSED UNTIL 2015

GRO-C

DRO 12

8A

NBTS FACILITIES AND PRODUCTION

NOTE OF AN OFFICE MEETING HELD ON 12 MAY 1976

Present: Mr Draper (Chairman)
Dr Maycock
Mr Dutton
Mr P Jones
Dr Waiter
Mr Cleasby

THE POSSIBLE GROWTH OF PAID DONOR PANELS

1. Following receipt in the Department of a letter from Serolbgical Products seeking approval to establish a panel of paid plasma donors, the meeting had been convened to consider the likelihood of this and any other similar proposals damaging the NBTS to such an extent that changes in policy were needed. It was agreed that, regardless of the outcome of this consideration, Serological Products should be told that their proposal did not find favour with the Department.

2. Dr Maycock and Dr Waiter expected that the demand by clinicians for blood products - not only Factor VIII - would rise substantially in the future. Commercial manufacturers would identify these trends and envisage a ready market for their products, particularly if UK self-sufficiency could not be achieved. To help satisfy the demand, the Department would not rule out an arrangement by which commercial manufacturers took blood from the NBTS for processing and then returned the products to the NHS, provided that undue profits did not accrue to the firm as a result. However, it was possible that some manufacturers would seek to collect blood or plasma from paid donor panels. A number of firms had already made informal approaches and it seemed that only Departmental disapproval was restraining them from setting up panels. It was understood that there was no legal power to prohibit paid donations in the UK, although firms would be aware of the Government's support for the WHO resolution on national self-sufficiency in blood and blood products derived from voluntary unpaid donations.

3. Mr Draper did not think that proposals for legislation against paid donor panels would be acceptable to Ministers at present, especially as previous attempts to establish paid donor panels had been resisted successfully through persuasion. He thought that firms proposing to set up paid donor panels would appreciate that legislation could always be resorted to, if necessary, and they would be reluctant therefore to invest money in projects of which the Department did not approve.

ALTERNATIVES TO LEGISLATION

4. It was agreed that there were 3 methods of meeting the anticipated demand for blood and blood products, which was expected to build up rapidly as more components were required:

a. To allow health authorities sufficient funds to purchase the additional quantities of products which they required, if the NBTS could not meet the demand; knowing that much of the blood in the imported preparations would come from countries which could not afford its loss.

b. To meet any additional requirements by allowing commercial manufacturers in the UK to obtain blood from paid donations.

c. To expand NBTS collection and production in a move towards self-sufficiency: there were indications that this might mean doubling the NBTS effort over the next few years.

A policy decision by Ministers would be required.

5. Option (c) was favoured, but the following difficulties were recognised:

i The limited availability of money would necessitate arguing the case for NBTS expansion against the claims of other service developments; it was noted that the proposal did not appear in the Department's Consultative document on priorities.

ii It would be difficult to justify doubling the size of the NBTS effort merely to cater for the needs of one particular group of patients; it was therefore necessary to look at blood collection and the utilisation of blood and blood components against the needs of the NHS as a whole.

iii Apart from the pressure from and on behalf of Haemophilia patients, there was no discernible pressure on either the Department or Ministers which suggested that there were widespread shortages of blood or blood products.

It was agreed that it might be necessary to persuade health authorities to use money which they would otherwise have used to buy commercially manufactured products to improve NBTS facilities, or to arrange that a proportion of their total allocations were withheld centrally for NBTS use.

SOME CONSIDERATIONS RELEVANT TO THE DEPARTMENT'S REVIEW OF MEANS OF PREVENTING THE SETTING UP OF COMMERCIAL BLOOD BANKS AND THE ESTABLISHMENT OF PAID DONOR PANELS IN THE U.K.

1. Present consideration of this topic has arisen out of a suggestion by Serological Products Ltd that they should obtain plasma in the U.K. They point out that they have supplied UK hospitals with Factors VIII and IX for three years and Human Albumin Fraction for eleven years, all derived from plasma obtained in Austria and Germany. They argued that experience in Austria indicates that paid and voluntary arrangements can co-exist without clashing and seek official approval to create one or more donor panels of paid plasma volunteers in the U.K.

2. Some four years ago a Dr Hart proposed to embark on a scheme for collecting blood on behalf of a pharmaceutical firm, the donors receiving a cheque made out to a local charity. Dr Hart appears to have had some financial involvement. Legislation was considered as a means of preventing the development and the proliferation of similar schemes which it was feared might follow. While it was agreed that legislation might be necessary, it was considered by the Permanent Secretary to be a court of last resort. Subsequently, efforts were directed mainly to persuading the charities concerned not to participate.

The pros and cons of legislation were not argued at the time - at least there is no record of the considerations - but it can be inferred from the Permanent Secretary's observation that legislation would only be considered if it was apparent that there was no other means of curbing a development which would otherwise be damaging to the NHS.

3. Possibilities other than new legislation which might be considered include:

(a) Persuasion. This is unlikely to be effective with companies accustomed to operating internationally who feel that experience in other countries justifies their proposal. It would be interesting if we could discover why Serologicals believe that they need official approval to their proposal.

(b) Use of the Medicines Act. It is possible that the Act contains some provision which might be used but there may be opposition from within the Department if it were suggested that the Act should be used for purposes for which it was not intended.

(c) Use of some existing Statute other than the Medicines Act. There may be some Statute which could be used to prevent the handling of human blood and blood products by all and sundry but we might find that invoking it created unforeseen problems.

4. New Legislation

(a) Feasibility. It is understood that the scope of the current Bill is not such as to accommodate an addition for this purpose.

Further enquiries would have to be made before we could assess the likelihood of fitting legislation into some other forthcoming Bill or of introducing a Bill expressly for this purpose.

(b) Enforcing legislation and exemptions. Advice would be necessary on the likelihood of being able to enforce legislation effectively and the dangers of clandestine operations. Some exemptions may be necessary to enable blood to be used by commercial firms for experimental purposes eg developing cell counting apparatus.

(c) Ethical considerations. There is every reason for wishing to continue with the present voluntary donation system. It has served the country well; it affords a great deal of satisfaction to a great number of people; it provides the quality of blood needed; it avoids high monetary values being placed on rare groups - and there are probably many other reasons. Furthermore the WHO has strongly endorsed the voluntary principle.

Nevertheless, it is a far cry from fostering the voluntary system to legislating to prevent firms from purchasing blood since such legislation would have the effect of preventing a person from disposing of part of his tissues except to the State, even though there was a patient in need and the prospective donor had every intention of passing the payment for the blood on to charity.

An underlying fear of the paid donor system arises from a doubt as to whether, under such a system, all the blood or blood products collected would come from the right type of donor with the attendant risk of adding to the pool of hepatitis. One solution to the current problem might be to make Medicines Act regulations so stringent that no firm could operate successfully. Before doing so, however, we would need to be sure that the NHS can operate successfully without the commercial producers remembering that UK legislation will not prevent

commercial firms from extending the range of blood products available and we could not long sustain a situation where products were available in other countries but not here. It is becoming apparent that to achieve NHS self-sufficiency in blood products in a situation where the range and utility is increasing rapidly is a much bigger undertaking than was formerly appreciated and may require much broader planning and possibly the injection of much more capital than has been contemplated so far.

11 May 1976

T E DUTTON
HS2A

162 Regent Street, London W1R 5TG
Telephone 01 GRO-C
Telegrams Pharmapress London W1
Telex Pharmind Westchan Lon GRO-C

The Association of the
British Pharmaceutical Industry

ADM/SRB

17 September 1976

A. Beard, Esq.,
Department of Health and Social Security,
14 Russell Square,
London,
WC1B 5EP

Dear Alan,

Blood and Blood Components

You may know that the World Health Organisation has circulated a draft paper entitled "Good Manufacturing Practices for Blood and Blood Components". For your convenience, a copy of the paper is enclosed.

We understand that this document was prepared by authors acting as WHO experts with a view to its use in connection with the eventual implementation of a resolution relating to blood and blood components which was adopted by the World Health Assembly in 1975.

We are particularly concerned about the proposal to ban the remuneration of persons providing their blood. We believe that if such a prohibition were to be enforced it would render it virtually impossible to continue with the manufacture and marketing of such products as antitoxins prepared from human blood.

It is important that it continues to be possible, for example, to collect human blood from immune donors and to prepare from it human immunoglobulins such as tetanus immunoglobulin. The potential for the development of these is such that with the much increased dangers involved in the use of equine sera as a source of passive immunity in dealing with accidents and acute infections, there appears to be no reason why there should not in the future be a range of immunoglobulins to replace all the present equine sera.

Human blood is also needed for the manufacture of many other products, such as certain diagnostic agents.

If the remuneration of donors were not permitted, it would be unlikely that adequate supplies of blood would be forthcoming over and above the needs of the transfusion service. This would become increasingly the case, if, in the future, human immunoglobulin were made available in even a small proportion of the volume of equine sera used at the present time.

Continued .....

We see no reason why a person willing to undergo the inconvenience and discomfort of a blood donation for this purpose should not be financially recompensed.

We are also concerned about the proposal that only official collection of blood be allowed. We accept that there is a need for a degree of Government control but we see no reason why the manufacturer should be prohibited from arranging collection with Government approval. We recognise that a tightening up of the legislation in some countries is desirable, if only to avoid the abuses that have occurred in certain of them. In our view, however, this could be best achieved by a system of Government licensing of blood products and authorised blood collectors. The licensing of collectors could then be made subject to such terms and conditions as were considered desirable, while at the same time providing a system which would not be so inflexible as to stifle potentially valuable medical advances.

If the WHO proposals were to be adopted throughout the world, it is most unlikely that the United Kingdom would be able to continue to import these products in the way in which it does now, and important medical agents would cease to be available.

We would be grateful if you will look into this matter for us and urge the United Kingdom Government to take the view that remunerated commercial collection of blood should be allowed.

We appreciate that the Government is bound to be influenced by a wish to continue with the present national blood transfusion service on an unremunerated basis. However, we hope that there will be an appreciation of the difference in the public mind between donating for transfusion purposes and donating for purposes of commercial manufacture.

It would be helpful to have your guidance as to the precise legal position in the United Kingdom at the present time. Would it be contrary to law for a manufacturer to take blood from donors for use in the manufacture of blood components, and for him to make payments to donors in respect of this? At the moment, all blood components used in manufacture appear to be imported.

Yours sincerely,

GRO-C

A.D.W. Massam
Assistant Secretary.

162 Regent Street London W1R 6DD
Telephone GRO-C

Mr Beard

cc Dr Harris
Dr Maycock
Mr Seabourn
Dr Kilgour
Dr Walter
Miss Duncan
Mr Dutton (with papers)

BLOOD AND BLOOD COMPONENTS : LETTER FROM ABPI

1. The papers which you passed to Mr Bishop have, in his absence, reached me through Miss Duncan and Dr Maycock. Dr Maycock has given me some of the background and has stressed that at this time neither of the two documents which Mr Masaan has sent you has any formal standing.

2. This is a very tricky matter. The previous Minister of State(Health) took a strong line that we should fully support the WHO recommendations both that all blood should be collected on a voluntary and non-remunerated basis and also that each country should strive to become self-sufficient in blood products as rapidly as possible. It appears that the ABPI are specifically seeking Departmental endorsement for their view that "remunerated commercial collection of blood should be allowed". This Branch has so far taken the lead on these policy matters, but I fully appreciate that Supply Division and Medicines Division are very much involved. I am copying the papers to Mr Seabourn and Dr Kilgour as they have general co-ordinating responsibilities in regard to WHO matters.

3. Dr Maycock has suggested that an office meeting should be held to discuss the reply to ABPI. I think that this would be desirable because it seems very likely that we will have to put the question to Ministers again for their endorsement and I am asking Mr Dutton to pursue this urgently.

GRO-C

M W Draper
HS2A
1212 HANH X GRO-C

14 October 1976

Mr Hoy

I have looked up the 1975 WHA discussion. Have we any other papers e.g. the brief and submission to MPS that I should see?

GRO-C: Dentom
15.10.76

20915

NBTS FACILITIES AND PRODUCTION

NOTE OF AN OFFICE MEETING HELD ON 12 MAY 1976

Present: Mr Draper (Chairman)
Dr Maycock
Mr Dutton
Mr P Jones
Dr Waiter
Mr Cleasby

THE POSSIBLE GROWTH OF PAID DONOR PANELS

1. Following receipt in the Department of a letter from Serolbgical Products seeking approval to establish a panel of paid plasma donors, the meeting had been convened to consider the likelihood of this and any other similar proposals damaging the NBTS to such an extent that changes in policy were needed. It was agreed that, regardless of the outcome of this consideration, Serological Products should be told that their proposal did not find favour with the Department.

2. Dr Maycock and Dr Waiter expected that the demand by clinicians for blood products - not only Factor VIII - would rise substantially in the future. Commercial manufacturers would identify these trends and envisage a ready market for their products, particularly if UK self-sufficiency could not be achieved. To help satisfy the demand, the Department would not rule out an arrangement by which commercial manufacturers took blood from the NBTS for processing and then returned the products to the NHS, provided that undue profits did not accrue to the firm as a result. However, it was possible that some manufacturers would seek to collect blood or plasma from paid donor panels. A number of firms had already made informal approaches and it seemed that only Departmental disapproval was restraining them from setting up panels. It was understood that there was no legal power to prohibit paid donations in the UK, although firms would be aware of the Government's support for the WHO resolution on national self-sufficiency in blood and blood products derived from voluntary unpaid donations.

3. Mr Draper did not think that proposals for legislation against paid donor panels would be acceptable to Ministers at present, especially as previous attempts to establish paid donor panels had been resisted successfully through persuasion. He thought that firms proposing to set up paid donor panels would appreciate that legislation could always be resorted to, if necessary, and they would be reluctant therefore to invest money in projects of which the Department did not approve.

ALTERNATIVES TO LEGISLATION

4. It was agreed that there were 3 methods of meeting the anticipated demand for blood and blood products, which was expected to build up rapidly as more components were required:

a. To allow health authorities sufficient funds to purchase the additional quantities of products which they required, if the NBTS could not meet the demand; knowing that much of the blood in the imported preparations would come from countries which could not afford its loss.

b. To meet any additional requirements by allowing commercial manufacturers in the UK to obtain blood from paid donations.

c. To expand NBTS collection and production in a move towards self-sufficiency; there were indications that this might mean doubling the NBS effort over the next few years.

A policy decision by Ministers would be required.

5. Option (c) was favoured, but the following difficulties were recognised:

i The limited availability of money would necessitate arguing the case for NBTS expansion against the claims of other service developments; it was noted that the proposal did not appear in the Department's Consultative document on priorities.

ii It would be difficult to justify doubling the size of the NBTS effort merely to cater for the needs of one particular group of patients; it was therefore necessary to look at blood collection and the utilisation of blood and blood components against the needs of the NHS as a whole.

iii Apart from the pressure from and on behalf of Haemophilia patients, there was no discernible pressure on either the Department or Ministers which suggested that there were widespread shortages of blood or blood products.

It was agreed that it might be necessary to persuade health authorities to use money which they would otherwise have used to buy commercially manufactured products to improve NBTS facilities, or to arrange that a proportion of their total allocations were withheld centrally for NBTS use.

9A

MEETING TO CONSIDER MEANS OF PREVENTING THE SETTING UP OF COMMERCIAL BLOOD BANKS AND THE ESTABLISHMENT OF PAID DONOR PANELS IN THE U.K.

The attached paper reviews the consibration already given to this topic which arose mainly out of a proposal by a Dr Hart to arrange blood giving sessions outside the NHS. Legislation was considered but it was deemed by Sir Alan Marre to be a court of last resort. There is no indication in the papers whether this was because of difficulty of fitting a Bill into the legislative time-table, uncertainty about the effectiveness of such legislation, ethical considerations or political considerations.

The purpose of the paper is to promote discussion and it is suggested that if further examination indicates that there may be no effective alternative to legislation the possibility might be examined under the first three headings referred to above, ie

(a) The feasibility of fitting legislation into any current Bills or projected Bills or promoting a Bill expressly for this purpose;

(b) The problems of enforcing legislation and any exemptions which might have to be catered for;

(c) Ethical considerations.

T E DUTTON
HS2A
11 May 1976

Mr Draper
Dr Maycock
Dr Raison
Dr Waiter
Mr Cleasby

SOME CONSIDERATIONS RELEVANT TO THE DEPARTMENT'S REVIEW OF MEANS OF PREVENTING THE SETTING UP OF COMMERCIAL BLOOD BANKS AND THE ESTABLISHMENT OF PAID DONOR PANELS IN THE U.K.

1. Present consideration of this topic has arisen out of a suggestion by Serological Products Ltd that they should obtain plasma in the U.K. They point out that they have supplied UK hospitals with Factors VIII and IX for three years and Human Albumin Fraction for eleven years, all derived from plasma obtained in Austria and Germany. They argued that experience in Austria indicates that paid and voluntary arrangements can co-exist without clashing and seek official approval to create one or more donor panels of paid plasma volunteers in the U.K.

2. Some four years ago a Dr Hart proposed to embark on a scheme for collecting blood on behalf of a pharmaceutical firm, the donors receiving a cheque made out to a local charity. Dr Hart appears to have had some financial involvement. Legislation was considered as a means of preventing the development and the proliferation of similar schemes which it was feared might follow. While it was agreed that legislation might be necessary, it was considered by the Permanent Secretary to be a court of last resort. Subsequently, efforts were directed mainly to persuading the charities concerned not to participate.

The pros and cons of legislation were not argued at the time - at least there is no record of the considerations - but it can be inferred from the Permanent Secretary's observation that legislation would only be considered if it was apparent that there was no other means of curbing a development which would otherwise be damaging to the NHS.

3. Possibilities other than new legislation which might be considered include:

(a) Persuasion. This is unlikely to be effective with companies accustomed to operating internationally who feel that experience in other countries justifies their proposal. It would be interesting if we could discover why Serologicals believe that they need official approval to their proposal.

(b) Use of the Medicines Act. It is possible that the Act contains some provision which might be used but there may be opposition from within the Department if it were suggested that the Act should be used for purposes for which it was not intended.

(c) Use of some existing Statute other than the Medicines Act. There may be some Statute which could be used to prevent the handling of human blood and blood products by all and sundry but we might find that invoking it created unforeseen problems.

4. New Legislation

(a) Feasibility. It is understood that the scope of the current Bill is not such as to accommodate an addition for this purpose.

Further enquiries would have to be made before we could assess the likelihood of fitting legislation into some other forthcoming Bill or of introducing a Bill expressly for this purpose.

(b) Enforcing legislation and exemptions. Advice would be necessary on the likelihood of being able to enforce legislation effectively and the dangers of clandestine operations. Some exemptions may be necessary to enable blood to be used by commercial firms for experimental purposes eg developing cell counting apparatus.

(c) Ethical considerations. There is every reason for wishing to continue with the present voluntary donation system. It has served the country well; it affords a great deal of satisfaction to a great number of people; it provides the quality of blood needed; it avoids high monetary values being placed on rare groups - and there are probably many other reasons. Furthermore the WHO has strongly endorsed the voluntary principle.

Nevertheless, it is a far cry from fostering the voluntary system to legislating to prevent firms from purchasing blood since such legislation would have the effect of preventing a person from disposing of part of his tissues except to the State, even though there was a patient in need and the prospective donor had every intention of passing the payment for the blood on to charity.

An underlying fear of the paid donor system arises from a doubt as to whether, under such a system, all the blood or blood products collected would come from the right type of donor with the attendant risk of adding to the pool of hepatitis. One solution to the current problem might be to make Medicines Act regulations so stringent that no firm could operate successfully. Before doing so, however, we would need to be sure that the NHS can operate successfully without the commercial producers remembering that UK legislation will not prevent

commercial firms from extending the range of blood products available and we could not long sustain a situation where products were available in other countries but not here. It is becoming apparent that to achieve NHS self-sufficiency in blood products in a situation where the range and utility is increasing rapidly is a much bigger undertaking than was formerly appreciated and may require much broader planning and possibly the injection of much more capital than has been contemplated so far.

11 May 1976

T E DUTTON
HS2A

DRAFT NOTE FOR MINISTER OF STATE

Mr Lillywhite

BLOOD AND BLOOD COMPONENTS

1. Minister of State may wish to be aware of a potentially difficult problem involving the collection of blood in the UK.

2. The National Blood Transfusion Service (NBTS) collects blood and blood components from donors who give voluntarily and without receiving payment. This is in line with WHO policy and the UK has publicly supported the principle of national self-sufficiency in blood and blood products based on voluntary unpaid donors as set out in 1975 World Health Assembly Resolution WHA 28.72 (copy at A opposite). It is also in line with the thinking of the Public Health Committee of the Council of Europe that blood should be collected on a non-commercial basis. At present the NBTS is able to meet NHS demands for whole blood (although there are occasional shortages in the two South Thames Regions for reasons unconnected with the voluntary donor principle) and it is seeking to achieve self-sufficiency in blood components, although there still is some way to go particularly with supplies of Factor VIII used in the treatment of haemophilia. £½ million was made available in 1975 from central money specifically to boost NBTS production of Factor VIII and production is well on target, but the upsurge in the demand for this material due to the introduction of new methods of treatment has meant that there is still considerable dependency on commercially produced Factor VIII concentrate.

3. In the past there has been an occasional attempt to set up a private blood donor panel, usually based on some kind of payment for the blood taken. The Department has, so far, always succeeded in persuading the sponsors not to proceed with these schemes. Over the last 12 months, however, we have had approaches from a number of firms either actively engaged in, or believed to be interested in, the manufacture of blood products (Travenol, Serological (now Immuno) Products, Burroughs Wellcome) proposing various arrangements whereby these firms could begin manufacturing blood products in the UK using blood and plasma collected from UK donors. The Association of the British Pharmaceutical Industry have recently asked the Department to reconsider its support for the WHA Resolution referred to above and to take the view that remunerated commercial collection of blood for the purposes of manufacturing blood products should be allowed (copy at B opposite). The Association also asks for clarification of the legal position appertaining to the collection of blood. The New Zealand Department of Health, which is also

interested in this problem, is seeking copies of any UK regulations covering current practices regarding the sale of blood and blood products.

4. The possibility of introducing legislation to formally protect the position of the NBTS and prohibit payment for blood and blood components has previously been considered but it has always been regarded as a last resort. As far as is known the commercial blood products which the NHS purchases are derived from blood collected abroad and apart from any other considerations it would be difficult to represent Government policy as being consistent, if it promoted legislation which attempted to prohibit paid donations in the UK while permitting the manufacture, purchase and use within the NHS of blood products derived from blood collected abroad principally if not entirely from paid donors.

5. The NHS will be dependent for certain of its blood products upon commercial sources for some time to come. Even if the considerable sums of money which will be needed if the NHS is to achieve complete self-sufficiency were available immediately it would probably take two years or possibly more before this could be achieved. The industry's activities, being based on blood collected abroad, have not affected the availability of blood to the NBTS and, in a sense, could be said to have complemented the activities of Blood Transfusion Centres by providing essential components which the NHS is at present unable to provide for itself. The setting up of paid donor panels in the UK, quite apart from philosophical and other considerations, could affect the availability of blood to the NBTS. It is proposed therefore when replying to the Association to make it quite clear that the Government has no intention of withdrawing its support in principle to the WHO resolution; that, while it recognises the part which the industry is playing in meeting the world requirements for blood products, the aim is NHS self-sufficiency; and that the Government would be seriously concerned if any developments were to take place which appeared likely to be detrimental to the operation and development of the NBTS.

6. Minister's endorsement of this line is sought.

D W Marsum Esq
The Association of the British
Pharmaceutical Industry
162 Regent Street
London W1R 6DD

III/B15/34

Your ref ADWM/SWB
Our ref III/B15/34

BLOOD AND BLOOD COMPONENTS

You wrote to Alun Beard on 17 and 20 September about the collection of blood for use in the manufacture of blood products. I am replying to your letters, having recently taken over administrative responsibility in the Department for the National Blood Transfusion Service and for policy on the supply of blood and blood products to the National Health Service. I am sorry that it has not been possible to send you an earlier reply, but you will understand that the issues raised are complex.

2. The document entitled "Good Manufacturing Practices for Blood and Blood Components", enclosed with your first letter, is a copy of an internal working paper drawn up at the invitation of the Director-General of the World Health Organisation as a contribution to the formulation of guidance to WHO member states. The Organisation has accorded the document no official status and indeed I understand that it has since been revised, although I believe that the sense of the recommendations has not been changed. Once any firm proposals on this subject have been agreed within WHO, it will be for the World Health Assembly to decide whether or not such proposals should become the basis for recommendations on or about national policies. In the absence of formal proposals, I think it would be inappropriate for me to offer detailed comment on the working paper and on the points of detail raised in your letter.

3. Although in practice there have been virtually no cases of private collection of human blood in the United Kingdom, regulations regarding this matter were made in 1963 - The Therapeutic Substances (Manufacture of Preparations of Human Blood) Regulations (S.I. 1963 - No. 1456). As you will know from the discussions you have had with our Medicines Division about the replacement of the controls under the Therapeutic Substances Act, it is the Department's intention that in due course similar provisions will be given statutory effect under the Medicines Act either by Standard Provisions or by the inclusion of suitable entries in the compendium. My colleagues will be consulting you about this in due course. If in the meantime anyone made an application for the grant of a product licence or a

/manufacturer's

manufacturer's licence in relation to the preparations of human blood, the licensing authority, subject to the advice of the Committee on Safety of Medicines, would almost certainly propose the inclusion of conditions of the same sort in the licence. Any such regulations would apply to medicinal products consisting of or including preparations of blood and, by virtue of the Medicines (Control of Substances for Manufacture) Order 1971, preparations of blood when manufactured or supplied for use as an ingredient in a medicinal product for human use; but they would not apply to human blood used for the manufacture of other products such as certain diagnostic agents - although of course such preparations of blood could be brought within the controls of the Medicines Act by an Order under Section 104.

4. In drafting any new Statutory Provisions, recommendations from WHO would obviously be relevant. The Government is firmly committed to the principles of World Health Assembly Resolution No. WHA 28.72, dated 29 May 1975, which urges member states "to promote the development of national blood services based on voluntary non-remunerated donation of blood". The National Blood Transfusion Service was founded on this concept and it is the Government's intention that it should remain the guiding principle. In practical terms the aim is to achieve National Health Service self-sufficiency. The substantial increase in NBTS production of Factor VIII freeze-dried concentrate is an example of this policy in practice.

5. From what I have said you will appreciate that although there are at present no legal sanctions specifically directed at the rewarding of donors, the Government would need urgently to consider the position if it became apparent that attempts were being made to establish paid donor panels in the UK, particularly if these were to be in a form which might appear to give rise to any possible detriment to the interests of the National Health Service and the voluntary donor principle.

A L PERROTT

15H

a/10

cc. Dr [illegible]
Mr [illegible]

Can you help Mr Harley?

GRO-C: ELH 28/8/80

Dr Oliver
Dr Walford
Dr Wintersgill

BLOOD PRODUCTS

In connection with the paper on Beechams' interest, which we are drafting for submission to Ministers, I thought it worthwhile establishing whether, as is often asserted, there really is a WHO resolution calling for national self-sufficiency in blood products. Perhaps I am the only one in the dark about this, but you may be interested in what I have found.

A WHA (not WHO) resolution of 1975 (WHA 28.72) urged Member States 'to promote the development of national blood services based on voluntary non-remunerated donation of blood' and 'to enact effective legislation governing the operation of blood services and to take other actions necessary to protect and promote the health of blood donors and of recipients of blood and blood products'. The phrase 'national self-sufficiency' seems to have originated in a letter written in 1975 by Dr David Owen, and to refer to AHG concentrate.

The idea of national self-sufficiency of course follows logically from that of the voluntary non-remunerated donation of blood (and perhaps, in this country, from the idea of protecting recipients of blood products). But I feel that the resolution as worded has a slightly different slant, and is aimed rather more precisely at some of the problems we shall have to outline in the paper.

19th August 1980

GRO-C
J HARLEY
HS2A
1209 Hannibal House
Ext GRO-C

cc

Dr Harris
Mr Wormald (o/r)
Mr Hart (o/r)
Mrs Firth
Mr Brechin
Mr Connor (o/r)
Mrs Yuille
Dr Tovey (o/r)

Mr Parker

Mr Harley presumably came to us for help. There are of course no "WHO resolutions" and we could explain.

GRO-C 21/8

NO ?! [illegible] 25/8

Mr Harley

BLOOD PRODUCTS

Dr Harris has sent to me (and to Mr Seabourn in IR1) a photocopy of your minute to Drs Oliver, Walford and Wintersgill of 19 August. Dr Harris thought that from our close connections with the WHO we might be able to through some light on the Organisation's alleged policy calling for national self-sufficiency in blood products. Incidentally, in your minute you implied that there is a difference between a WHA and WHO resolution - the two are really the same thing, because the WHA (World Health Assembly) is the name given to the collective meeting of representatives of the World Health Organisation (ie the latter's governing body).

I am aware that it has been asserted frequently before that there is a WHO policy calling for national self-sufficiency in blood products. You are right in believing that this has not been encapsulated formally in a WHA resolution (nor to the best of my knowledge was it included in the draft for "Good Manufacturing Practices for Blood and Blood Components" which stemmed from the WHA resolution of 1975 (WHA 28.72) to which you refer. I have a feeling (and I use the word advisedly) that it comes from one of the WHO Technical Reports (of which there are a large number (covering a wide range of subjects - the latest is Report No 647). I have been unable to find it by a quick flick through my own copies of the Reports, however I was speaking to WHO Geneva and took the opportunity to ask them about this one. Unfortunately, the individual primarily concerned with blood products is on leave at the moment but the person I spoke to is going to look into it and ring me back - I will let you know as soon as I hear from him.

GRO-C

DR IAN T FIELD
MED IH
Room C319 AFH
Ext GRO-C

26 August 1980

GRO-C

Copies to: Dr Harris
Dr Oliver
Dr Wintersgill
Dr Walford
Mr Seabourn

I assumed Mr Harley had
come to IR to take the stated

GRO-C

Mrs Cole

File a Copy

GRO-C

Mr Harley

GRO-C

19A

W47/304

BLOOD PRODUCTS

Further to my minute of 26 August my attention has been drawn by the International Relations Division to the fact that my comment to you concerning the WHO paper "Good Manufacturing Practices for Blood and Blood Components", which itself had stemmed from the WHA Resolution of 1975 (WHA 28.72), was based on an early draft and that this division had not been shown the subsequent more definitive version. In the subsequent version there is a sentence which does not appear in the original draft. This reads -

> "Each country should aim to collect from its own population blood and plasma sufficient for its national needs".

Clearly this statement is much closed to the format which we have all been discussing in the current exchanges of minutes.

GRO-C

DR IAN T FIELD
MED IH
Room C319 AFH
Ext GRO-C

9 September 1980

Copies to: Dr Harris
Dr Oliver
Dr Wintersgill
Dr Walford
Mr Seabourn
Mr Parker