

Conson replace pages 9-10

MINUTES OF RTD MEETING 20 SEPTEMBER 1972. REVISED PAGES 9, 10 and 10a
ISSUED 25 OCTOBER 1972 TO REPLACE PAGES 9 AND 10 OF ORIGINAL MINUTES.

explained that under the Act the types of licence and certificates
of relevance to the NBTS were:

MANUFACTURING LICENCE

This licence authorised the holder to manufacture or assemble medicinal products.
It was envisaged that such licences would be framed in broad terms to cover the
manufacture of classes of products consistent with the licensee's possession of
the appropriate facilities, equipment, staff etc.

PRODUCT LICENCE

This licence relates to a specific product and may authorise the holder to
import, sell or supply the product or procure the manufacture or assembly of
the product for sale or supply.

CLINICAL TRIAL CERTIFICATES

A clinical certificate certifies that the licensing authority has consented to
the trial and authorises for the purpose of the trial the sale or supply of a
product or procuring its sale or supply or procuring its manufacture or assembly
for sale or supply. It was pointed out that it is not necessary to hold a
manufacturers licence for the manufacture of a product for the sole purpose of
a clinical trial. Furthermore a certificate is not required in respect of the
sale or supply etc of a product which is to the order of a doctor for
administration to a particular patient.

PRODUCT LICENCES AND CLINICAL TRIAL CERTIFICATES OF RIGHT

These licences and certificates which are granted on simple evidence of
entitlement relate to products which were on the market at 1 September 1971 and
to clinical trials in progress at that time, they permit dealings in the product
and the clinical trials to continue as before.

If the Medicines Act were applied to the NBTS the necessary licences and
certificates would have to be obtained. It was envisaged that each constituent

laboratory would require a manufacturing licence which would need to be held by the appropriate RHB. It would be drawn up in broad terms so as to permit manufacture of the classes of products eg 'preparations of human blood' - etc which the laboratory manufactured. The Department was now considering means of avoiding the need for multiple applications for product licences by constituent laboratories since most of them prepared the same products. It was likely that the DHSS would hold master product licences which would enable dealings in the particular products to be carried out at each centre.

asked whether the application of the Act to the NBTS would hinder unnecessarily the introduction of new forms of blood products. did not think it would, as a new product would normally first be tested on a restricted basis involving known doctors and patients. Such trials were usually arranged by a doctor on his own responsibility and arrangements exist whereby a clinical trial certificate is not required in such cases providing the doctor has notified the licensing authority of the trial or test, specifying the product, its intended use and by whom supplied, and the licensing authority has not within 21 days of such notification directed that these arrangements do not apply to the trial in question. If this preliminary trial were satisfactory, a wider clinical trial was normally undertaken and for this a clinical trial certificate would be needed before the trial could be begun.

said that the legal position in Scotland was such that no medical units could claim Crown Privilege so that the Medicines Act (1968) would apply to the laboratories of SNETA. said he thought it important that all transfusion laboratories should be treated alike; otherwise it might be assumed that there were differences between laboratories which necessitated their being treated in different ways and there was a possibility of different standards emerging.

said the Act might be applied to other NHS units besides RTCs, and that he was assessing the amount of extra administrative work that might fall on centres if the provisions of the Act were applied, even though the product licences might be held by DHSS itself.

In response to a question said that the Act did not require that any particular manufacturing process or procedure should be carried out by a qualified pharmacist but the regulations relating to applications for licences required details to be submitted to the licensing authority of the names and qualifications of the person in charge of production and quality control procedures.

After further discussion the meeting agreed in principle that the Medicines Act should be applied to NBTS. pointed out that legal and certain other aspects had still to be considered by DHSS.

said that he thought some of the recommendations in the document RTD(72)4, "Hospital Production and Quality Control of Parenteral Infusion Fluids" needed amplification and that others might be difficult to follow in RTCs. The meeting agreed that RTDs should send comments on this paper to

6. SUPPLY MATTERS:

a. - 40°C STORAGE CABINETS. A cabinet had been designed by Cliffco Low Temperature Ltd., Liverpool to meet the needs of PHLs and had been tested with satisfactory results. The details were:-

Cliffco Cabinet GC80/1400. Capacity 14 cu.ft.

Price £280. Agents: Boro' Laboratories and Appliance Co. Ltd.,
1 Station Buildings, Catford, London, SE6.
Tel: 01 690 2901

b. ABBOTT TRANSFUSION GIVING SETS. reported that Messrs Abbott had announced very suddenly just before deliveries were expected to begin, that they would not in future supply transfusion equipment.

c. BLOOD AND BLOOD PRODUCTS EQUIPMENT SUB-COMMITTEE

The minutes of the first meeting (document RTD(72)6) were noted.

d. TRANSFUSION GIVING SETS - REDESIGNED PIERCING NEEDLE.

confirmed that each centre would shortly receive for trial 150 sets each from Messrs. Avon Medical Ltd. and Messrs. Travenol Laboratories Ltd. and asked that the questionnaire should be returned to Mr Hanson with as little delay as possible.

e. "LITTLE SISTER" AUTOCLAVE

reported that representatives of Supply Division were to meet and (PHLS) and a representative of the Sheffield RHB engineering section in the near future to discuss the complaints reported

7. ROUND TABLE BLOOD DONOR RECRUITMENT SCHEME

It was reported that the National Association of Round Tables had offered to use their organization to assist in enrolling blood donors and that a message from the Parliamentary Under Secretary of State had appeared in the Association's magazine, "News and Views", Sept. 1972. The Association's generous offer of help had been made through RDO Leeds (RDO Minutes, 24 May 1972).

8. DATE OF NEXT MEETING. This was arranged for Wednesday, 25 October 1972.

RTD MINUTES 20 SEPTEMBER 1972

APPENDIX 1.

SUMMARY OF RESULTS OF TESTS FOR AUSTRALIA ANTIGEN AND ANTIBODY IN DONORS RECEIVED FROM RTCs UP TO SEPTEMBER 1972.A. SHEFFIELD (1) (April-October 1971; first six months)

	Number	Antigen Positive	Antibody Positive
All donations	56,057	41 (1: 1367)	19 (1: 2950)
General public	54,557	38 (1: 1462)	17 (1: 3208)
University etc.	1,222	1 (1: 1222)	1 (1: 1222)
Prisons etc.	278	2 (1: 139)	1 (1: 278)

(2) (November 1971-April 1972; second six months)

All donations	51,594	15 (1: 3439)	2 (1: 25,797)
General public	50,005	13 (1: 3846)	2 (1: 25,002)
University etc.	1,163	0	0
Prisons etc.	426	2 (1: 213)	0

B. TOOTING (1) (February-May 1972; first 4 months).

All donations	71,794	49 (1: 1465)	428 (1:561)
General public	66,022	38 (1: 1737)	98 (1:674)
University etc.	1,751	1 (1: 1751)	6 (1:292)
Armed Forces	1,451	0	2 (1:726)
Prisons etc.	570	2 (1: 285)	8 (1:71)
New donors	2,000	8 (1: 250)	14 (1:143)

(2) (June-August 1972)

All donations	56,877	50 (1: 1138)	117 (1:486)
General public	49,207	30 (1: 1640)	84 (1:586)
University etc.	729	0	0
Armed Forces	0	0	0
Prisons etc.	1,004	6 (1: 67)	10 (1:100)
New donors	5,937	14 (1: 424)	23 (1:258)

C. BRISTOL (November 1971-16 May 1972)

All donations	66,799	42 (1: 1590)	40 (1:1670)
General public	61,044	34 (1: 1801)	32 (1:1908)
University etc.	2,618	2 (1: 1309)	2 (1: 1309)
Armed Forces	2,164	4 (1: 541)	5 (1:433)
Prisons etc.	973	2 (1: 486)	1 (1:973)

D. CAMBRIDGE (January 1971-February 1972)

All donations	23,390	16 (1: 1462)	12 (1:1941)
General public	19,438	13 (1: 1494)	10 (1:1944)
University etc.	1,527	1 (1: 1527)	0
Armed Forces	1,449	0	0
Prisons etc.	976	2 (1: 488)	2 (1:488)

E. WESSEX (October 1971-June 1972)

All donations	46,752	18 (1: 2597)	-
General public	42,675	9 (1: 4742)	-
Armed Forces	2,401	3 (1: 800)	-
Prisons etc.	1,676	6 (1: 279)	-

Copy -

> Returns to be sent to
 at ONE MONTH
 intervals, for submission to
 the DHSS, as from 1st Oct. 1972
 27.10.72

