EXTRACT - A.R. HELD 31/1/91
HANDLING BRIEF

RG/1185A.26/SMBMB

ANNEX E

Batch Release: Background Note

1. The National Biological Standards Board (NBSB) was established by the Biological Standards Act 1975 to be a body corporate having functions in relation to the establishment of standards for, the provision of standard preparations of, and the testing of biological substances.

2. The National Institute for Biological Standards and Control (NIBSC) has no separate statutory responsibilities under the Biological Standards Act. However, it is the laboratory which exercises the Board's functions on a day-to-day basis. One of these functions involves the testing of certain biological products for batch release.

3. In the application of the batch release procedure, the Licensing Authority requests that protocols and/or samples from each batch of product, subject to the procedure, are sent to NIBSC. Tests are undertaken at NIBSC and if the results are satisfactory, product is approved for release. In the event that the results are unsatisfactory, this information is put to the Licensing Authority.

4. There are four types of batch release procedure referred to as A, B, C and D. These require that,

A. The company supplies samples of the product and batch documents to the Institute. In addition, the company cannot sell the product until approval has been given.

B. The company supplies batch documents to the Institute. In addition, the company cannot sell the product until approval has been given.

C. The company supplies samples of the product and batch documents to the Institute and there is no restriction on sale.

D. The company supplies batch documents to the Institute and there is no restriction on sale.

5. In the past the batch release procedure has applied to certain products in the following classes:

5.1 Antibiotics.

5.2 Allergens.

5.3 Blood Products.

5.4 Hormones, extracted from human and animal tissue.

5.5 Vaccines, bacterial and viral.

6. As work on the framework directives on blood and immunological products progressed it became clear that the European directives did not permit the batch release of antibiotics. This having been recognised, the Institute reduced its involvement in this area of control.

7. In the future and upon implementation of these directives, certain products in the following classes may be subject to a batch release procedure, namely,

7.1 allergens;

7.2 blood products; and

7.3 immunologicals.

In these directives there is a restriction on the number of Member States that may be involved in the batch release of a

given product. The key message is that if one Member State has tested and released a product, this cannot be repeated by another Member State. This position is likely to influence the amount of batch release work done in various Member States. Some Member States have the capability of undertaking batch release testing, although most don't have as comprehensive a cover as NIBSC. Other Member States have no facilities.

8. A 'European Batch Release Procedure' has not yet been defined, but when it is, it will not be permissible for tests to be undertaken in more than one Member State. It is likely, too, that such tests will be undertaken by the country acting as the Rapporteur for the marketing authorisation application, or, in which the product is manufactured, if it has the appropriate testing facilities. These aspects imply a reduction in potential work in the area of batch release by virtue of the reduction in the number of classes of product involved and in the number of products for which the UK would have prime responsibility.