

cc: eli ✓

Dr. Dr. Koel
Dr. Diermeyer ✓
Hru Schbauer

962/12.3.PS

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telex0218 85-03-12 13:17

attention mrs sperr

ref your telex no. 1246 11/3/85

i am amazed to hear that you can offer prothromplex tim 2 which heated for 5 hours at 60 deg centigrade. is this a new idea as we were firmly told that the process for treating prothromplex was tim 4 and that tim 2 was only for kryobulin. how can kryobulin tim 2 be 10 hours at 60 deg centigrade and prothromplex tim 4 be 5 hours at 60 deg centigrade.

as we predicted hospitals are now changing over to heat treated factor ix as there is no health service product available. there is a market for at least 12 million units and our competitors are already taking this business with their competitive prices. i appreciate your problems with prices in other countries but we cannot understand why this does not seem to bother all the other blood product companies alpha, travenol, cutter, armour who also sell in europe.

we could do well with a prothromplex tim 2 if we can move quickly and the price looks very interesting. as with the kryobulin it would probably have to be called prothromplex heat treated. we will need to decide very quickly whether to change to tim 2 and i therefore need the following information if you could direct it to the departments concerned.

1. how long would it take to produce a batch of prothromplex tim 2 including packaging and insert leaflet. if necessary packaging could be temporary packaging.
2. how does the tim 2 and tim 4 process compare for prothromplex what support data have you for this product. data on model viruses etc. please send all available data by express post.
3. how long would it take to prepare a product licence amendment - is the data available. our amendment for tim 4 has been turned down so instead of obtaining additional data for this amendment we could put in a new amendment for tim 2.
4. is the tim 2 process as effective. we will have to explain to customers why there was a need for a tim 4 process and then a change to tim 2.

please could you let me have this information as soon as possible so that we can quickly decide our best course of action and hopefully try and obtain some of the sales going to other companies.

kind regards
peter coombes
immuno ltd. #
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