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COMMERCIAL IN CONFIDENCE

NOT FOR PUBLICATION

COMMITTEE ON SAFETY OF MEDICINES

WORKING PARTY ON BOVINE SPONGIFORM ENCEPHALOPATHY

PAPER II

CATEGORY 3: TISSUE IMPLANTS, OPEN WOUND DRESSINGS, SURGICAL  
MATERIALS, DENTAL AND OPHTHALMIC PRODUCTS WITH BOVINE INGREDIENTS

REVIEW OF POSITIVE RESPONSES TO QUESTIONNAIRE

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PAPER

TISSUE IMPLANTS, OPEN WOUND DRESSINGS, SURGICAL MATERIALS, DENTAL AND OPHTHALMIC PRODUCTS WITH BOVINE INGREDIENTS

REVIEW OF POSITIVE RESPONSES TO QUESTIONNAIRE

1. Introduction

27 positive responses to the Department of Health Questionnaire have been received.

All relate to products sourced from outside UK except Surgical Catgut

There are two broad categories: surgical implants and ophthalmic products.

2. Surgical Implants

Surgical implants of bovine origin derive from a range of tissues: intestine, skin, bone, blood and pericardium.

2.1 Bovine Small Intestine

This is the largest single category, comprising 9 product licences for surgical catgut, held by 3 Companies.

COMPANY	PL NUMBER	NAME	SOURCE
		Surgical Catgut	UK, Australasia
		Catgut plain, chromic	France, S America (mainly Brazil)
		Soft Catgut Braun (plain chromic)	France, S America (mainly Brazil)
		Sterilised Surgical Catgut (plain, chromic)	Australia, USA New Zealand
		Softgut Sterile Absorbable suture	Australia, USA New Zealand

Surgical Catgut is the only UK-sourced product and will be considered in a separate paper.

2.2 Skin

Bovine dermal collagen is present in 2 products for correction of tissue contour deformities by injection and 4 implantable haemostats.

PL NUMBER	NAME	SOURCE
		USA
		USA
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		W. Germany
		W. Germany
		France

2.3 Bone

Responses have been received on 3 products derived from bovine bone, used for grafting.

PL NUMBER	NAME	SOURCE
		W. Germany
C		Switzerland
		W. Germany, France Belgium, Luxemburg,

is to be withdrawn following Review action.

2.4 Blood

Two products contain fibrin from bovine plasma, one of which also contains collagen from hide.

PL NUMBER	PRODUCT	SOURCE
C	(fibrin prostheses)	Hungary
	(bone sealant fibrin plus collagen)	Hungary

2.5 Pericardium

One product for use as a graft in neurosurgery and derived from bovine pericardium, is sourced from West Germany (currently under S21(1) action).

2.6 Mixed Bovine Tissue

One product, fibrin sealant, contains bovine heparin and aprotinin (lung). This was turned down by Medicines Commission.

3. Ophthalmic Products

3.1 Pancreatic Chymotrypsin

Catarase (intracapsular cataract extraction) for intraocular use contains bovine pancreatic chymotrypsin sourced from USA and Canada.

3.2 Liver Catalase

Two contact lens care products, not for direct administration to the eye, contain bovine liver catalase.

PL NUMBER	NAME	SOURCE
		Europe
		Outside EEC

4. Bile Acids

Included with category 3 responses are two bile acids which are administered orally.

PL NUMBER	NAME	SOURCE
	Ursodeoxycholic acid DMF	Germany, Austria
	Chenodeoxycholic acid DMF	Germany, Austria

5. Medical Comment

- 5.1 There is only one UK sourced bovine product, Surgical Catgut and this will be considered in detail in an accompanying paper, because of the implications of the lymphoid content of the intestinal raw material.
- 5.2 The Working Party is asked to advise on the Secretariat stance to date, ie that on the basis of current knowledge the remaining CDSM products of non-UK origin do not give rise to concern, and that licensing action is not currently required.

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