Safeguarding public health

MHRA

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UK GOVERNMENT RESPONSE TO THE EUROPEAN COMMISSION'S CONCEPT PAPER ON THE DELEGATED ACT ON THE CRITERIA TO BE CONSIDERED AND THE VERIFICATIONS TO BE MADE WHEN ASSESSING THE POTENTIAL FALSIFIED CHARACTER OF MEDICINAL PRODUCTS INTRODUCED IN THE UNION BUT NOT INTENDED TO BE PLACED ON THE MARKET

Please find attached the United Kingdom Government response to the European Commission's above concept paper. The UK welcomes the spirit of the delegated act in the global fight against falsified medicines. Our response highlights the practicalities involved.

Yours sincerely,

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In order to provide a fully considered response to this concept paper the UK feels that a number of terms need to be fully defined in order to establish the activities that will fall under this regime and by association the consignments that will be subject to the criteria and verifications proposed in the concept paper. The terms that the UK considers require further definition and the World Customs Organisation definition are detailed in the response to Consultation Item No 4.

Consultation Item No 1

Given that introduction is the act of importing a medicinal product from a third country into the EU without the intention of placing it on the market the UK has identified two main processes:

1. Products that are purchased by a customer in a 3rd country from a supplier in another 3rd country and that transit through the UK. No UK company takes title of the goods in this situation and they are only handled by freight forwarders, commercial airlines or shipping agents in the UK as they are moved from one carrier to the next.

2. Products that are purchased by a UK company from a supplier in a 3rd country for subsequent sale to a customer in another 3rd country. The imported product is not intended to be placed on the EU market. In this scenario the UK company takes title of the goods and will be required to hold a wholesale distribution authorisation. The site where the goods are received and stored will need to be named on that authorisation.

Both of these scenarios could be classed as introduction in that medicinal products are being brought into the UK but there is no intention to place them on the market. However regulation of these two scenarios varies significantly and developing a single set of criteria and verifications to address both is not feasible.

For Scenario 1 where medicines are in transit or transhipment checking Identity, Source and History is not possible. In these cases, the goods will usually only reside in the country for a matter of hours, there is no requirement to declare to customs the full details of the goods or apply a customs procedure code, and air waybills may only show the last segment of the journey and not the full route. Furthermore in the UK there are no customs powers to permit the detention of goods that are in transit or transhipment in order to facilitate routine regulatory verifications by medicine regulatory authorities. Given the volume of consignments that move through the UK every day it would not be feasible in the time available to isolate those that contain medicines and then verify the identity, source and history without disrupting the free movement of the goods (e.g. cause them to miss their planned onward flight/voyage out of the UK). Issues in this respect arise with access to the goods either due to the way they are stored e.g. on automated carousel racking

systems where consignments need to be individually requested and presented or physical access to controlled areas such as airside storage locations at airports by officers working for medicines regulators.

With respect to the risk to the free movement of goods that verifications of goods that are in transit or transhipment through the UK may cause, we would also like to draw Commissions attention to the CJEU Nokia / Phillips judgment, and the dispute brought before the WTO by India and Brazil against the EU (ref DS408) concerning generic medicine in transit, and ask for confirmation that what is being proposed in the concept paper complies with both this judgement and with WTO rules.

Although not possible for goods that are in transit or transhipment for those medicines that are in a customs suspensive regime, e.g. are not entered to free circulation in the EU and are located in a customs approved warehouse, then the checks and verifications in para 15, 16 and 17 are feasible but probably not practicable on a routine basis, not least because each verification will require the goods to be physically examined on site.

It is important to note that the owner of the medicines in a customs suspensive regime may well be located in a third country. We have a current example of medicines manufactured in India being stored in a customs approved warehouse in the UK with a probable destination to Africa whereby the owners of the medicines are located in a third country. There is no importer or wholesaler within the Union. The only check that could feasibly be made is that of assay of the active ingredient but the cost of validating such an assay would be prohibitive on a routine basis.

In scenario 2 it is envisaged that the wholesale distribution authorisation holder would be responsible for ensuring that the goods being introduced into the Union for subsequent resale and export to customers in third countries are not falsified, and that if there was any suspicion or evidence to suggest they were then they would be obligated to notify the regulatory authorities under Article 80 of the Directive.

Consultation Item No 2

As detailed above for medicines in transit and transhipment it is not possible to routinely carry out the verifications in paragraphs 15, 16 and 17 because of time restrictions and for these goods the owners are probably located in third countries.

It is therefore the UK view that the identification of consignments that are to be subject to the verifications stated in 15, 16 and 17 should be intelligence led. The UK Border Force already control consignments transiting through the UK for revenue purposes (to ensure there is no illicit diversion on to the UK/EU market without payment of import duty and VAT) and following identification of suspect loads of pharmaceutical products in the course of their routine customs work will notify the MHRA in order for further checks to be undertaken. From a medicines control perspective this cannot be considered to offer the regulatory authorities a means of operating a systematic, risk-based verification process, although through this exchange of information it may be possible for the MHRA to act, using its own powers, in the limited time that such goods are in the UK. Unfortunately though within the commercial systems that are used to track consignments around the globe there is a lack of information on the type of goods being shipped, and they can be manipulated to disguise the route taken prior to arriving in the Union and the final destination.

Consultation Item No 3

As already stated given the lack of available information for goods that are transiting through the Union in terms of their origin, route and final destination it is difficult to determine what triggers will prompt the checks and verifications being conducted and how a workable system of risk-based verification could be established.

However it can be foreseen that both Customs Border Officials along with Officers from the Medicines Regulator will be involved, (although Customs will play no part in the verifications carried out and will be unable to detain goods for verification purposes) and for medicines introduced into the Union, it is important that the current customs regime be fully utilised by all parties in the spirit of cooperation, efficiency and effectiveness. The customs Single Administrative Document (SAD) (Appendix A) is a standardised Form used throughout by the signatories of the Customs Convention. The following Box numbers on the Form provide key information for customs and medicines regulators:

Box 2	Consignor
Box 8	Consignee
Box 10	Country of first destination
Box 11	Trading company
Box 14	Declarant/Representative
Box 15	Country of despatch/export
Box 16	Country of origin
Box 18	Identity and nationality of means of transport at departure
Box 31	Description of goods
Box 33	Commodity Code
Box 37	Procedure

Box 33 Explained

The commodity code is the internationally agreed 10 digit codes for imports and 8 digit codes for export. Medicines come under Chapter 30 – Pharmaceutical Products (Appendix B). If the first two digits of the Code in Box 33 are 30 then this identifies the goods as pharmaceutical products. For example, if heparin was being imported or exported, the Commodity Code would be: 30 01 909100.

Box 37 Explained

The Customs Procedure Codes identify the customs regimes to which goods are being entered and from which they have been removed. For example, the Code 55 10 would mean that the medicines have been introduced under the Inward Processing Procedure in a customs warehouse and that in the exporting country they were designated for permanent export.

How can customs and medicines regulators work together?
The SAD data is entered onto customs databases and it is relatively easy to identify all imports and exports of medicines through the commodity code in Box 33. A daily, weekly or monthly printout could be obtained for all SAD Forms with a commodity code starting with 30 (Appendix C). However, as customs are bound by EU and national data protection laws, this arrangement would be subject to the identification of a legal gateway that permitted customs to disclose customs information to the medicines regulator. The quantity and frequency of disclosures would need to satisfy the tests of necessity and proportionality in relation to the objectives to be achieved.

Consultation Item No 4

To establish the activities that will fall under this regime and by association the consignments that will be subject to the criteria and verifications proposed in the concept paper the following terms need to be defined in the Delegated Act: *(WCO definitions included in italics)*

Transit; - T*he Customs procedure under which goods are transported under Customs control from one Customs office to another*

Transhipment - *The Customs procedure under which goods are transferred under Customs control from the importing means of transport to the exporting means of transport within the area of one Customs office which is the office of both importation and exportation.*

Appendix A

EUROPEAN COMMUNITY 1 2 3 4 5 6 7

A OFFICE OF DISPATCH/EXPORT

1 DECLARATION

Copy for the country of dispatch/export

1

2 Consignor/*Exporter* No

3 Forms | 4 Loading lists

5 Items | 6 Total packages | 7 Reference number

8 Consignee No

9 Person responsible for financial settlement No

10 *Country first destin.* | 11 *Trading country* | 13 *CAP*

14 Declarant/Representative No

15 Country of despatch/*export* | 15 C disp./*exp.* Code a b | 17 Country destin. Code a b

16 Country of origin | 17 Country of destination

18 Identity and nationality of means of transport at departure | 19 Ctr.

20 Delivery terms

21 Identity and nationality of active means of transport crossing the border

22 Currency and total amount invoiced | 23 Exchange rate | 24 Nature of transaction

25 Mode of transport at the border | 26 Inland mode of transport | 27 Place of loading

28 Financial and banking data

1

29 Office of exit | 30 Location of goods

31 Packages and description of goods — Marks and numbers — Container No(s) — Number and kind

32 Item No

33 Commodity Code

34 Country origin Code a b | 35 Gross mass (kg)

37 PROCEDURE | 38 Net mass (kg) | 39 *Quota*

40 Summary declaration/Previous document

41 Supplementary units

A.I. Code

44 Additional information/ Documents produced/ Certificates and authorisations

46 Statistical value

47 Calculation of taxes

Type	Tax base	Rate	Amount	MP
		Total:		

48 Deferred payment | 49 Identification of warehouse

B ACCOUNTING DETAILS

50 Principal No Signature:

C OFFICE OF DEPARTURE

51 Intended offices of transit (and country)

represented by

Place and date:

52 Guarantee not valid for

Code | 53 Office of destination (and country)

D CONTROL BY OFFICE OF DEPARTURE

Result:

Seals affixed: Number:

Identity:

Time limit (date):

Signature:

Stamp:

54 Place and date:

Signature and name of declarant/representative:

C88 (1-8)

PT (July 2003)

Appendix B

Section VI

Products of the chemical or allied industries (chapters 28 to 38)

30 Pharmaceutical products

01

Glands and other organs for organo-therapeutic uses, dried, whether or not powdered; extracts of glands or other organs or of their secretions for organo-therapeutic uses; heparin and its salts; other human or animal substances prepared for therapeutic or prophylactic uses, not elsewhere specified or included

02

Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses; antisera, other blood fractions and immunological products, whether or not modified or obtained by means of biotechnological processes; vaccines, toxins, cultures of micro-organisms (excluding yeasts) and similar products

03

Medicaments (excluding goods of heading 3002, 3005 or 3006) consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, not put up in measured doses or in forms or packings for retail sale

04

Medicaments (excluding goods of heading 3002, 3005 or 3006) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale

05

Wadding, gauze, bandages and similar articles (for example, dressings, adhesive plasters, poultices), impregnated or coated with pharmaceutical substances or put up in forms or packings for retail sale for medical, surgical, dental or veterinary purposes

06

Pharmaceutical goods specified in note 4 to this chapter

Section VI

Products of the chemical or allied industries (chapters 28 to 38)

30

Pharmaceutical products

01

Glands and other organs for organo-therapeutic uses, dried, whether or not powdered; extracts of glands or other organs or of their secretions for organo-therapeutic uses; heparin and its salts; other human or animal substances prepared for therapeutic or prophylactic uses, not elsewhere specified or included

- Extracts of glands or other organs or of their secretions
  - Of human origin 30 01 201000
  - Other 30 01 209000

- Other
  - Of human origin_30 01 902000
  - Other
    - Heparin and its salts_30 01 909100
    - Other_30 01 909800

Appendix C

Go Back | Print Window | Save File

IMPORT DETAILS SEARCH: Results returned for search on :
COMCODE/COMMODITY: 300

5000 Records found.

COMPANY NAME	COMCODE
1000 MILE SPORTSWEAR LIMITED 1000 MILE SPORTSWEAR LIMITED UNIT N PENFOLD TRADING ESTATE IMPERIAL WAY WATFORD WD24 4YY	• 30051000 Adhesive dressings and other articles having an adhesive laye r *Jan 2011 , Aug 2011*
151 PRODUCTS LIMITED 2ND FLOOR GLOBE HOUSE SOUTHALL STREET MANCHESTER M3 1LG	• 30051000 Adhesive dressings and other articles having an adhesive laye r *Jan 2011 , Feb 2011 , Mar 2011 , Apr 2011 , May 2011 , Jun 2011 , Jul 2011 , Aug 2011 , Sep 2011 , Oct 2011* • 30059050 Bandages & siam atl of tex mat, impr or covered with ph subs. ret sale for med,surgical,dental,veterinar pps *Jan 2011 , Mar 2011 , Apr 2011 , May 2011 , Jul 2011 , Aug 2011 , Oct 2011* • 30059099 Poultices,bandages other dressings not elsewhere/specified in retail forms for medical/surgical uses *Jan 2011 , Feb 2011 , Mar 2011 , May 2011 , Jul 2011 , Sep 2011 , Oct 2011* • 30065000 First-aid boxes and kits *Jan 2011 , Feb 2011 , Apr 2011 , May 2011 , Oct 2011* • 30069100 Appliances identifiable for ostomy use *Jul 2011*
2 B SCIENTIFIC LTD 77 HEYFORD PARK UPPER HEYFORD BICESTER OX25 5HD	• 30021010 Antisera *May 2011 , Oct 2011* • 30021099 Blood fractions o/t haemoglobin, blood globulins and serum glo bulins n.e.s *Feb 2011 , May 2011 , Sep 2011*
365 HEALTHCARE LIMITED UNIT 203 POINTON WAY STONEBRIDGE CROSS BUSINESS PARK HAMPTON LOVETT DROITWICH WR9 0LW	• 30059031 Gauze and articles of gauze:put up in retail forms for medica l/surgical uses *Jan 2011 , Feb 2011*