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WHO CERTIFICATION SCHEME
ON THE QUALITY OF PHARMACEUTICAL PRODUCTS
MOVING IN INTERNATIONAL COMMERCE

With updated list of
Participating Countries

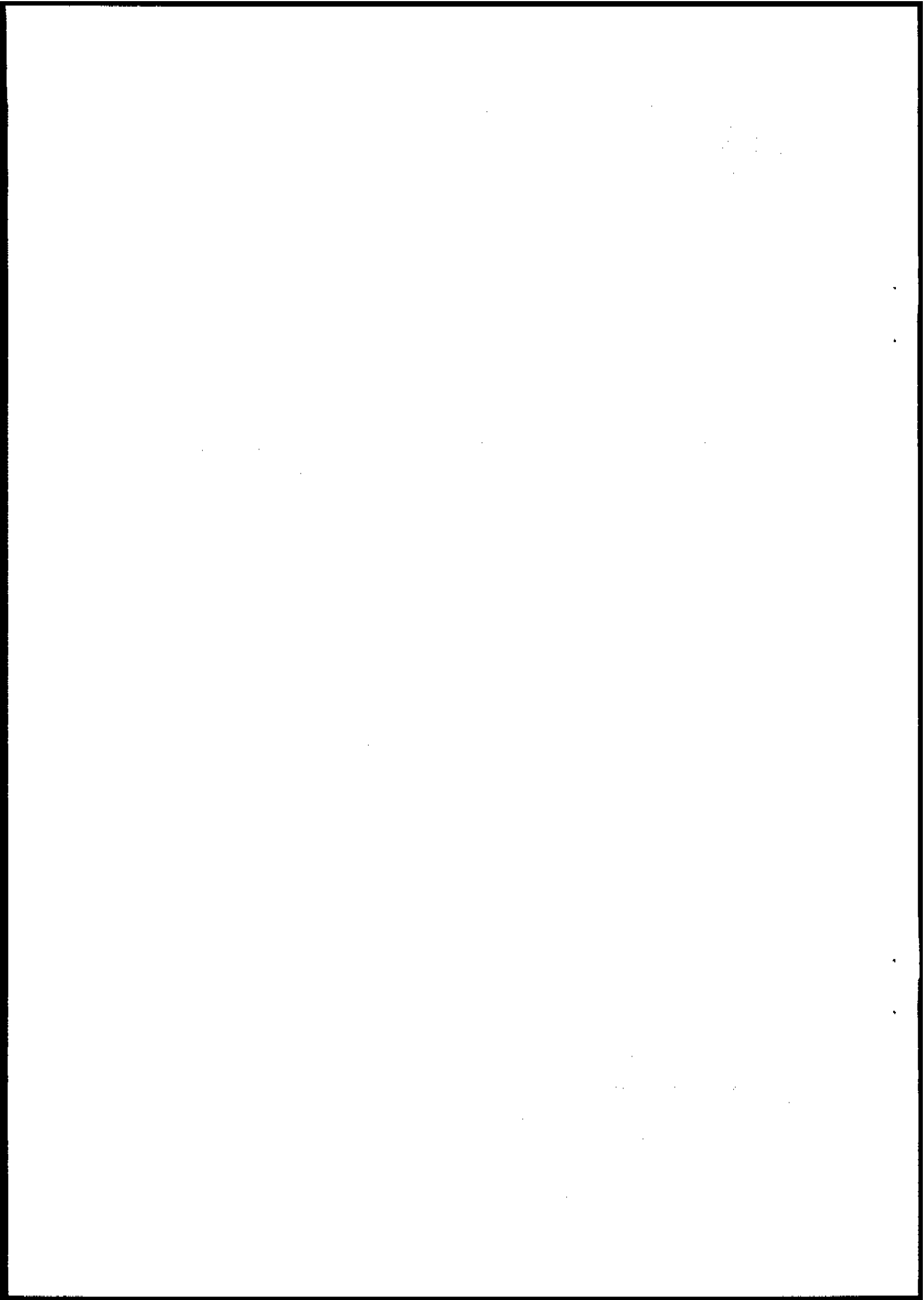
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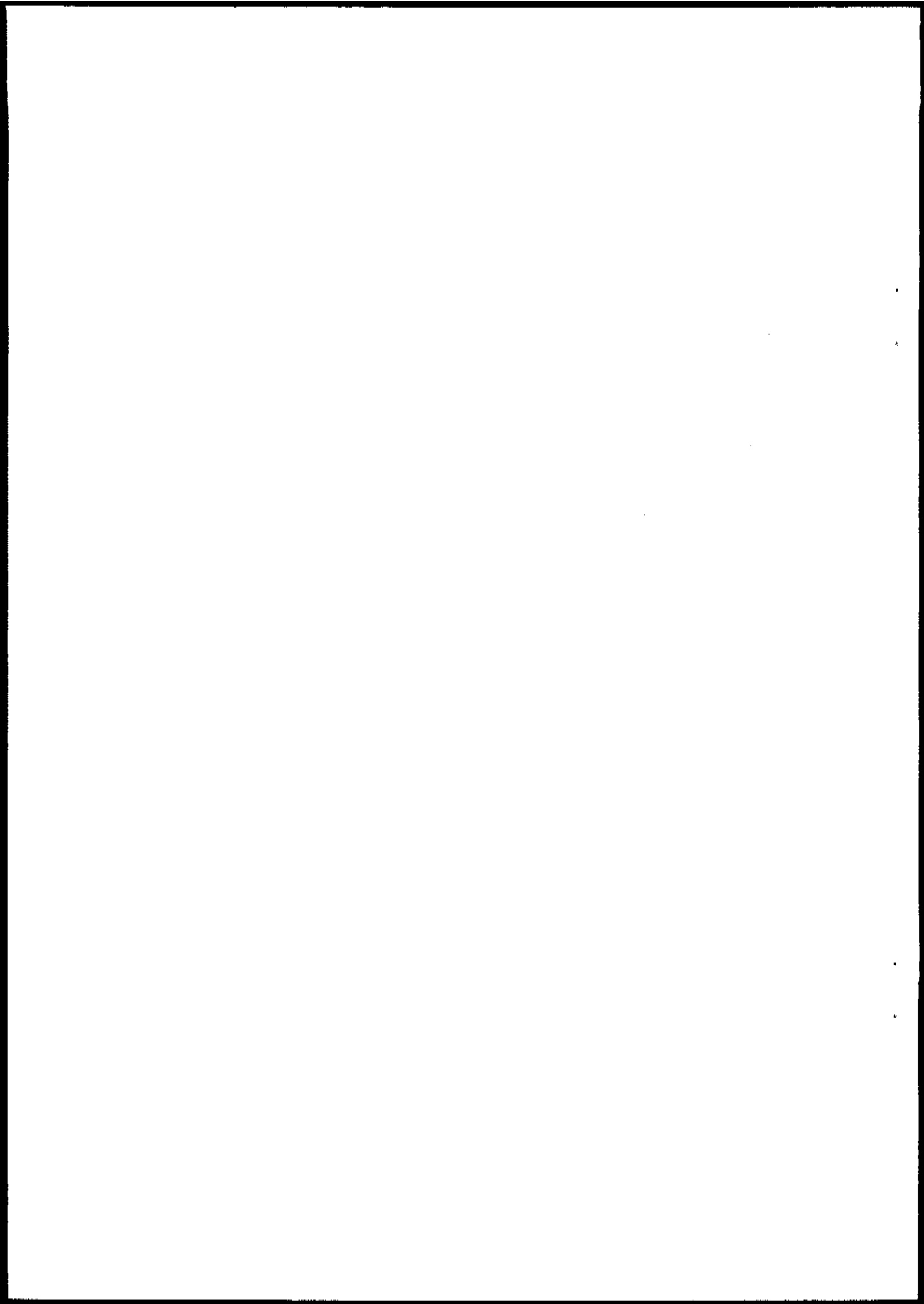


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I. Introduction

For many years the World Health Organization has expressed concern that drugs intended for export have not always been subjected to the same control procedures as those produced for the home market. In this case developing countries lacking adequate drug regulatory systems and laboratory facilities for drug analysis are placed at a particular disadvantage. To redress this unsatisfactory situation, WHO has sought to extend and unify schemes already operated by the health authorities of some exporting countries who issue a certificate on request to foreign importers in respect of drugs that have been subjected to statutory control.

Initial proposals for a basis for an international certification scheme were provisionally adopted by the World Health Assembly in 1969 (WHA22.50). The Scheme was subsequently amended in 1975 (resolution WHA28.65) and in 1988 (resolution WHA41.18). Since then a set of Guidelines for the implementation of the Scheme were endorsed by the World Health Assembly in May 1997 (resolution WHA50.3).

The Scheme covers any medicine intended for human use, or a veterinary product administered to food-producing animals, presented in its finished dosage form or as a starting material, when it is subject to control by legislation in the exporting Member State and in the importing Member State.

The objectives of the Scheme are to provide a simple administrative mechanism whereby importing countries can:

1. obtain assurance that a given product has been authorized to be placed on the market in the exporting country, and, if applicable, obtain information on the reasons for a product not being authorized to be placed on the market in the country of export;
2. obtain assurance that (a) the manufacturing plant in which the product is produced is subject to inspections at suitable intervals and (b) conforms to requirements for good practices in the manufacture and quality control of drugs, as recommended by the World Health Organization.
3. obtain copies of all information and labelling supplied with the product, as provided on packaging materials and package inserts, and whether directed to the prescriber or the patient, that have been approved by the competent authority in the exporting country, together with the date(s) on which such approval was accorded.
4. exchange information on the implementation of inspection and controls exercised by the authorities in the exporting country. In the case of serious quality defects in the importing or the exporting country, such information and requests for enquiries may also be exchanged.

The Guidelines for implementation of the WHO Certification Scheme as adopted by the World Health Assembly in resolution WHA50.3 in May 1997 are reproduced in Annex 2. They are intended to promote and facilitate use of the Scheme.

To date 141 Member States have informed WHO of their wish to participate in the Scheme through designated national authorities.

For any further information on the WHO Certification Scheme, please contact Drug Regulatory Support, Division of Drug Management and Policies, World Health Organization, 1211 Geneva 22. Tel: 41 22 791 3661: Fax: 41 22 791 0746.

II. ALPHABETICAL LIST OF ADDRESSES OF COMPETENT AUTHORITIES OF PARTICIPATING COUNTRIES

COUNTRY	COMPETENT AUTHORITY
Afghanistan (letter of 29 August 1980)	Department of Pharmaceutical Affairs Drug Control Laboratory Ministry of Public Health P.O. Box 33 Kabul Tel: 61166
Algeria* (see letter of 14 June 1994)	Direction de la Pharmacie Ministere de la Santé publique Chemin Mohamed Gacem, 128 El-Madania 16000 Alger
Angola (letter of 23 January 1980)	Direção Nacional de Medicamentos e Equipamentos C.P. 50 Luanda
Argentina (letter of 4 August 1977)	Dirección Nacional de Medicamentos, Alimentos y Tecnología Médica Ave. de Mayo 869 Buenos Aires Tel: 54 1 342 9637/3933 Fax: 54 1 342 1997
Armenia (letter of 14 July 1992)	Director of the Drug and Medical Technology Administration Ministry of Health 6, Yekmalian St. 375002 Yerevan Tel: 885 3742 53 35 78 Fax: 885 3742 52 17 72
Australia* (letters of 26 May 1976, 16 January 1989 and 25 January 1996)	Therapeutic Goods Administration GPO Box 100 Woden ACT 2606 Tel: 0061 06 289 8600 Fax: 0061 06 289 7464
Austria* (letter of 5 May 1978)	Federal Ministry of Health and Consumer Protection) 2, Radetzkystrasse A-1031 Vienna Tel: 43 1 711/46 73 Fax: 43 1 714 92 22
Bangladesh (letter of 15 March 1989)	Drug Administration 105-106 Motijheel Commercial Area Dhaka 1000 Tel: 880 2 23 61 26/86 81 66 Fax: 880 2 83 35 97

* See also text of reply reproduced in Section III

- Bahrain*
(letter of 6 June 1979)
- Pharmacy and Drug Control
Ministry of Health
P.O. Box 12
Manama
Tel: 0973 244 017
Fax: 0973 2 71 071
- Barbados*
(letter of 3 March 1983)
- The Barbados Drug Service
Ministry of Health
Jemmots Lane
St Michael
Tel: 809 426 5080
Fax: 809 426 5570
- Belgium
(letters of 12 October 1977 and
17 October 1994)
- Inspection générale
de la Pharmacie
Ministère de la Santé publique et de
la Famille
Cité administrative de l'Etat
Quartier Vésale 325
1010 Brussels
Tel: 32 2 210 4918
Fax: 32 2 210 4922
- Benin
(letter of 24 November 1982)
- Ministère de la Santé publique
Direction des Pharmacies
B.P. 2048
Cotonou
Tel: 229 30 02 47
- Bhutan
(letter of 11 July 1989)
- Directorate of Health Services
Royal Government of Bhutan
Thimphu
Tel: 975 2 23454
Fax: 975 2 23527
- Bolivia
(letter of 18 September 1979)
- Departamento Nacional de Medicamentos,
Farmacias y Laboratorios
Ministerio de Prevision Social y
Laboratorios
Plaza de l'Estudiante s/n
La Paz
Tel: 591 2 375 467-471
Fax: 591 2 391 590
- Botswana
(letter of 14 September 1982)
- Drug Regulatory Unit
Ministry of Health
Private Bag 0038
Gaborone
Tel: 267 35 22 64
Fax: 267 35 31 00

* See also text of reply reproduced in Section III

- Brazil
(letter of 23 September 1980)
- Director, Instituto Nacional de
Controle de Qualidade em Saude (INCQS)
Fundação Oswaldo Cruz
Av. Brasil 4365
Manguinhos
21 04 Rio de Janeiro, RJ
- Bulgaria*
(letters of 2 July 1982
and 13 March 1997)
- National Drug Institute
26, Yanko Sakazov Boulevard
1504 Sofia
Tel: 3592 44 65 66
Fax: 3592 44 26 97
- Burkina Faso*
(letter of 29 September 1981)
- Direction des Services pharmaceutiques
Ministère de la Santé
03 B.P. 7002
Ouagadougou 03
Tel: 30 71 77
Fax: 31 26 34
- Burundi
(letter of 8 February 1986)
- Bureau de l'Inspection et de la Planification
Ministère de la Santé Publique
B.P. 1820
Bujumbura
- Cambodia*
(letter of 31 December 1993)
- Monsieur le Directeur-Général
des médicaments et de l'approvisionnement
Ministère de la Santé
Rue Kampuchea Vietnam
Phnom-Penh
Tel: 855 23 26211
- Cameroon, United Republic of
(letter of 15 March 1982)
- Direction de la Santé
Ministère de la Santé publique
Yaoundé
Tel: 237 22 41 44
Fax: 237 23 41 44
- Canada*
(letters of 23 February 1983
and 6 December 1996)
- Director General
Drugs Directorate
Health Protection Branch
Health Canada
Tunney's Pasture
Ottawa, Ontario K1A 0L2
Tel: 1 613 957 0371
Fax: 1 613 941 6458
- Cape Verde
(letter of 14 April 1984)
- Direction General of Pharmacy
Ministry of Health
Government Palace
P.O. Box 47
Praia
- Central African Republic
(letter of 22 July 1980)
- Direction des Services pharmaceutiques
B.P. 313
Bangui

* See also text of reply reproduced in Section III

Chad
 (letters of 6 February 1986,
 10 October 1988 and October 1994)

La Direction des Pharmacies
 et des Laboratoires d'Analyses
 Ministère de la Santé Publique
 Direction des Pharmacies
 B.P. 440
 N'djamena
 Tel: 00235 51 55 87/51 61 55
 Fax: 00235 51 51 87

Chile*
 (letters of 9 July 1979 and
 18 August 1980)

Departamento de Control Nacional
 Instituto de Salud Publica de Chile
 Ministerio de Salud
 Avda Marathon 1000
 Casilla 48
 Santiago
 Tel: 56 2 239 1105
 Fax: 56 2 237 1504

Congo
 (letters of 1 March and
 17 June 1978)

Direction des Pharmacies, du Médicament
 et des Laboratoires
 Ministère de la Santé publique et des
 Affaires sociales
 B.P. 78
 Brazzaville

Congo, The Democratic Republic of
 (letter of 5 April 1998)

Direction de la Pharmacie, des Médicaments et
 des Laboratoires
 Département de la Santé publique
 B.P. 11.998
 Kinshasa 1

Costa Rica*
 (letters of 23 August 1979 and
 5 February 1993)

Departamento de Drogas,
 Controles y Registro
 Ministerio de Salud
 Apdo 10.123
 San José
 Tel: 506 222 14 20
 Fax: 506 222 14 20

Cuba*
 (letter of 18 June 1997)

Centro para el Control Estatal de la
 Calidad de los Medicamentos
 Ave. 17 Nro 20005 e/200 202
 Apartado Postal 16065
 Siboney, Playa
 Ciudad de La Habana, C.P. 11600
 Fax: 21 4023

Cyprus
 (letter of 3 March 1976)

The Drugs Council
 Ministry of Health
 Vironos Avenue No. 111475
 Nicosia
 Tel: 357 2 302 001
 Fax: 357 2 302 721

* See also text of reply reproduced in Section III

Czech Republic
(letter of 25 March 1991)

Director
State Institute for Drug Control
Skrobarova 48
10041 Praha 10
Tel: 422 6731 1153
Fax: 422 6731 1153

Democratic Yemen
(letter of 12 July 1982)

The Assistant Deputy Minister
for Pharmaceutical Services
Ministry of Public Health
P.O. Box 4200
Khormaksar - Aden

Denmark*
(letters of 29 November 1977 and
19 October 1994)

The National Board of Health
Medicines Division
378 Frederikssundsvej
2700 Bronshoj
Tel: 0045 44 8891 11
Fax: 0045 42 8470 77

Djibouti*
(letter of 16 August 1980)

Ministère de la Santé publique
Inspection de la Pharmacie
B.P. 44
Djibouti
Tel: 253 351491
Fax: 253 356300

Dominican Republic*
(letter of 16 October 1992)

Departamento de Drogas y Farmacias
Secretario de Estado de Salud
Publica y Asistencia Social
A. Tiradentes, esq. Ave. San Cristobal
Santo Domingo
Tel: 809 566 5988
Fax: 809 566 9241

Ecuador
(letters of 31 October 1985 and
20 January 1993)

Direccion de Control Sanitario Publica
Ministerio de Salud Publica
Juan Larrea 444 y Riofrio
Quito
Tel: 541 851
Fax: 569 786/504 322

Egypt*
(letters of 16 November 1976 and
26 July 1977)

Central Department of Pharmaceutical Affairs
Ministry of Health
22 El Falaky St.
Cairo
Tel: 354 9227
Fax: 354 2627

El Salvador*
(letters of 19 January 1978 and
13 October 1993)

Conseja Superior de Salud Publica
Av. Espana 736
San Salvador
Tel: 21 0497/22 3348

Equatorial Guinea
(letter of 28 August 1991)

Servicio de Farmacia y Suministros medicos
Ministerio de Sanidad y Medio Ambiente
Malabo

* See also text of reply reproduced in Section III

Ethiopia
(letter of 26 May 1979)

Pharmacy Department
Ministry of Health
P.O. Box 31725
Addis Ababa
Tel: 251151 790/151 793
Fax: 251 512 643

The European Agency for
the Evaluation of
Medicinal Products*
(8 May and 3 June 1996)

EMEA Certification Scheme
Technical Co-ordination
The European Agency for the
Evaluation of Medicinal Products
7 Westferry Circus
Canary Wharf
London E14 4HB
United Kingdom
Tel: 44 171 418 8400
Fax: 44 171 418 8551

Fiji*
(letter of 30 December 1980)

Acting Permanent Secretary
Ministry of Health
Government Pharmacy
P.O. Box 106
Suva
Tel: 679 315 022
Fax: 679 320 163

Finland*
(letter of 28 June 1977)

National Agency for Medicines
Box 55
Siltasaarenkatu 18A AFIN
00301 Helsinki
Tel: 358 0 396 72 116
Fax: 358 0 714 469

France*
(letters of 23 December 1976,
2 February 1984 and 6 June 1995)

Agence du Médicament
143/147 Boulevard Anatole France
93285 Saint Denis Cedex
Tel: 33 1 48 13 20 18
Fax: 33 1 48 13 20 97

Gabon*
(letter of 12 November 1981)

Direction Generale de la Pharmacie
Inspection General de la Santé
B.P. 2279
Libreville
Tel: 241 76 35 90

Germany*
(letters of 23 July 1985,
15 October 1986 and 18 August 1993)

For products intended for human use

The Federal Minister for Youth
Family Affairs and Health
Kennedyallee 105-107
53131 Bonn

For products intended for veterinary use

The Federal Minister for Youth
Family Affairs and Health
Post Office Box 20 04 90
53131 Bonn

* See also text of reply reproduced in Section III

Germany (continued)

For sera and vaccines
 The Federal Minister of Food
 Agriculture and Forestry
 Post Office Box 14 02 70
 53001 Bonn

LaenderHealth Authorities

Baden-Wuerttemberg

Regierungsprasidium Stuttgart
 Postfach 10 60 27
 70049 Stuttgart

Regierungsprasidium Karlsruhe
 Postfach 5343
 76035 Karlsruhe

Regierungsprasidium Freiburg
 79083 Freiburg i.Br.

Regierungsprasidium Tuingen
 Postfach 2666
 72016 Tuingen

Bayern

Regierung von Oberbayern
 Maximilianstrasse 39
 80538 Munchen

Regierung von Niederbayern
 Regierungsplatz 540
 84028 Landshut

Regierung der Oberpfalz
 Emmeransplatz 8
 93047 Regensburg

Regierung von Oberfranken
 Ludwigstrasse 20
 95444 Bayreuth

Regierung von Mittelfranken
 Promenade 27
 91522 Ansbach

Regierung von Unterfranken
 Peterplatz 9
 97070 Wurzburg

Regierung von Schwaben
 Fronhof 10
 86152 Augsburg

Berlin

Senatsverwaltung fur Gesundheit
 Parochialstr. 1-3
 10179 Berlin

Germany (continued)

Brandenburg	Landesamt für Soziales und Versorgung Abteilung Landesgesundheitsamt Dezernat Arzneimittel und Apothekenwesen Tornowstr. 51 14473 Potsdam
Bremen	Senator für Gesundheit Jugend und Soziales Grosse Weidestr. 4-16 28195 Bremen
Hamburg	Freie und Hansestadt Hamburg Behörde für Arbeit Gesundheit und Soziales - Amt - G Tesdorpfstr. 8 20148 Hamburg
Hessen	Regierungspräsidium Luisenplatz 2 64283 Darmstadt
	Regierungspräsidium Giessen Ludwigsplatz 13 35390 Giessen
	Regierungspräsidium Kassel Steinweg 6 34117 Kassel
Mecklenburg-Vorpommern	Arzneimittelüberwachungs- und Prüfstelle des Landes Mecklenburg-Vorpommern Wismarsche Str. 298 19055 Schwerin
Neidersachsen	Bezirksregierung Braunschweig Postfach 3247 38022 Braunschweig
	Bezirksregierung Hannover Postfach 203 30002 Hannover
	Bezirksregierung Lüneburg 21332 Lüneburg
	Bezirksregierung Weser-Ems 26106 Oldenburg
Nordrhein-Westfalen	Regierungspräsident Arnsberg Seibertzstr. 1 59821 Arnsberg

Germany (continued)

	Regierungsprasiden Detmold Leopoldstr. 13-15 32756 Detmold
	Regierungsprasident Dusseldorf Georg-Glock-Str. 4D 40474 Dusseldorf
	Regierungsprasident Koln Zeughausstr. 48 50667 Koln
	Regierungsprasident Munster Domplatz 1-3 48143 Munster
Rheinland-Pfalz	Ministerium fur Arbeit Soziales, Familie und Gesundheit Bauhofstr. 9 55116 Mainz
Saarland	Ministerium fur Frauen, Arbeit Gesundheit und Soziales Franz-Josef-Roder-Str. 23 66119 Saarbrucken
Sachsen	Regierungsprasidium Chemnitz Bruckenstr. 10 09111 Chemnitz
	Regierungsprasidium Dresden August-Bebel Str. 19 01219 Dresden
	Regierungsprasidium Leipzig Karl-Liebknecht.Str.145 04277 Leipzig
Sachsen-Anhalt	Landesamt fur Versorgung und Soziales Neustadter Passage 9 06122 Halle
Schleswig-Holstein	Arzneimitteluberwachungsstelle Schleswig-Holstein Holzkoppelweg 5 24118 Kiel
Thuringen	Thuringer Ministerium fur Soziales und Gesundheit Wermner-Seelenbinder-Str.14 99096 Erfurt

- | | |
|--|--|
| Ghana
(letter of 3 July 1979) | Registrar
Pharmacy Board
P.O. Box 10344
Accra
Tel: 233 21 223 894
Fax: 233 21 22 9573 |
| Greece*
(letter of 27 January 1987) | National Drug Organization (EOF)
4 Voulis Str.
Athens 10562
Tel: 3 01 522 7360
Fax: 3 01 522 2393 |
| Guatemala
(letter of 25 May 1979) | Division de Registros y Control de
Medicamentos y Alimentos
10 avenida 14-00, zona 1
01001 Guatemala
Tel: 0502 2 27303
Fax: 0502 2 515309 |
| Guinea
(letter of 12 September 1980) | Directeur des Services pharmaceutiques
Ministère de la Santé
B.P. 585
Conakry |
| Guinea-Bissau
(telex of 16 May 1986) | Secrétaire Général
Ministère de la Santé publique
P.O. Box 50
Bissau
Tel: 245 25 3140
Fax: 245 20 17 07 |
| Guyana*
(letter of 21 January 1980) | The Government Analyst
Food and Drugs Department
Ministry of Health
Mudlot
Kingston, Georgetown
Tel: 56482
Fax: 56985 |
| Haiti (Republic of)
(letter of 30 January 1984) | Ministère de la Santé
Palais des Ministères
Port-au-Prince
Tel: 22 7705 |
| Honduras*
(letters of 9 September 1991 and
15 December 1992) | Division de Farmacia
Ministerio de Salud Publica
Tegucigalpa
Tel: 504 22 2400
Fax: 504 38 1732 |

* See also text of reply reproduced in Section III

Hungary*
(letters of 8 August 1983
and 22 December 1996)

National Institute of Pharmacy
P.O. Box 450
1372 Budapest 5
Tel: 36 1 117 4044
Fax: 36 1 118 1167

Iceland
(letter of 6 July 1977)

Pharmaceutical Affairs
Ministry of Health
Laugavegu 116
IS-105 Reykjavik
Tel: 354 560 9700
Fax: 354 551 9165

India*
(letters of 16 May 1978
and 10 August 1990)

For the exchange of information:
Drugs Controller (India)
Ministry of Health and Family Welfare
Nirman Bhawan
New Delhi

State

For certificates of pharmaceutical
products:

Andhra Pradesh

Drugs Controller & Food (Health)
Authority
Z.P. -I- 168
Tarnaka
Secunderabad 500017

Delhi

Director of Health Services
Delhi Administration
15 Sham Nath Marg
Delhi 54

Gujarat

The Commissioner
Food and Drugs Control Administration
Dr Jivraj Bhavan
Block No. 8. 1st Floor
Old Sachivalaya
Gandhinagar 382 010

Kerala

Drugs Controller
Kerala Public Health Laboratory
P.O. Red Cross Road
Trivandrum 1

Karnataka

Drugs Controller, Karnataka
Palace Road
P.B. No. 5377
Bangalore 560001

* See also text of reply reproduced in Section III

India (continued)

Maharashtra	Commissioner of Food & Drugs Administration Maharashtra State Griha Nirman Bhawan Opp. Kala Nagar, Bandra (East) Bombay 51
Tamil Nadu	Director of Public Health and Preventive Medicine 79-81 Anna Salai Madras 6
Uttar Pradesh	Food & Drugs Controller Directorate of Medical & Health Services Lucknow
West Bengal	Director of Drugs Control West Bengal, College Square (West) Calcutta 73
Assam	Drugs Controller (Assam) Directorate of Health Services, Assam Guahati-6
Bihar	Drugs Controller (Bihar) Directorate of Health Services 4th Floor, Vikas Bhavan New Secretariat Patna-15
Haryana	Drugs Controller (Haryana) Directorate Health Services (Hospitals) Show Room No. 66, Sector-26 Chandigarh
Jammua and Kashmir	Drugs Controller (Jammu and Kashmir) Directorate of Health Services, Jammu Sri Nagar
Himachal Pradesh	Drugs Controller-cum-Director Health Services (Himachal Pradesh) Shimla-171004
Madhya Pradesh	Food and Drugs Controller (Madhya Pradesh) Food and Drugs Administration Idget Hills Bhopal
Orissa	Drugs Controller (Orissa) Drugs Control Administration Building Nandam Kanann Road Bhavaneshwa-5

Rajasthan	Drugs Controller and Director Directorate of Health Medical Services Jaipur
Goa	Drugs Controller (Goa) Directorate of Health Services Panaji-403001
Pondicherry	Commissioner Food and Drugs Administration P.B. No. 504 Rooman Relland Street Pondicherry-685001
Chandigarh (.T.)	Drugs Controller and Additional Director of Health Services Chandigarh Administration Chandigarh (U.T.) 160016
Punjab	Drugs Controller (Punjab) Sector-7-C Show Room No. 11A Manhoya Marg Chandigarh 160019
Indonesia (letter of 23 June 1983)	Director-General Drug and Food Ministry of Health Jalan Percetakan Negara 23 Jakarta 10560 Tel: 62 21 424 4755 Fax: 62 21 424 3605
Iran, Islamic Republic of (letters of 31 January 1978 and 29 July 1996)	General Department for Control of Pharmaceutical Affairs, Sanitary Articles and Cosmetaics Ministry of Health P.O. Box 310, Hafez Avenue Teheran 11344 Tel: 98 21 670 911 Fax: 98 21 675 868
Iraq (telex of 26 February 1983)	State Establishment for Pharmaceutical drugs and Medical Appliances Ministry of Health P.O. Box 2163 Baghdad Tel: 964 1 776 1970 Fax: 964 1 538 8926

- Ireland*
(letter of March 1985)
- Department of Health
Public Health Division
Custom House
Dublin 2
- Israel
(letters of 9 March 1978,
19 September 1979 and 29 October 1991)
- Institute for Standardization and
Control of Pharmaceuticals
Ministry of Health
P.O. Box 1457
Jerusalem 91013
Fax: 972 2 650 684
- Italy
(letter of 17 March 1976)
- Pharmaceutical Department
Ministero della Sanita
Viale della Civiltà Romana 7
00144 Rome
Tel: 39 6 592 5863
Fax: 39 6 5994 3365
- Ivory Coast*
(letter of 24 June 1986)
- Direction des Services pharmaceutique
Ministère de la Santé
B.P. V-5
Abidjan
- Jamaica*
(letter of 12 August 1980)
- Director of Pharmaceutical Services
Pharmaceutical Services Division
Ministry of Health and Social Security
10 Caledonia Avenue
P.O. Box 472
Kingston 5
Tel: 809 929 5811
Fax: 809 926 7902
- Japan*
(letter of 21 October 1976)
- Pharmaceutical Affairs Bureau
Ministry of Health and Welfare
1-2-2 Kasumigaseki, Chiyoda-ku
Tokyo 100-45
Tel: 3 3591 9646
Fax: 3 3597 9534
- Jordan
(letter of 16 July 1977)
- Drugs Directorate
Ministry of Health
P.O. Box 86
Amman
Tel: 962 6 665 131
Fax: 962 6 693 051

* See also text of reply reproduced in Section III

Kenya
(letter of 25 January 1985)

Deputy Chief Pharmacist
Ministry of Health
P.O. Box 30016
Nairobi
Tel: 254 2 726 963
Fax: 254 2 718 073

Korea, Republic of
(letter of 28 June 1977)

Pharmaceutical Affairs Bureau
Ministry of Health and Welfare
1, Chungong-dong
Kwachun City 427 760, Kyung Ki Province
Tel: 822 503 7551
Fax: 822 504 1456

Kuwait*
(letter received 12 January 1983 and
25 October 1994)

Drug Control and Registration Centre
Ministry of Public Health
P.O. Box 4575
13046 Safat
Tel: 00965 4831038
Fax: 00965 4811267

Lao People's Democratic Republic
(letter of 17 August 1994)

Direction de l'Alimentation et de la Pharmacie
Ministère de la Santé
Vientiane
Tel: 856 21 214 014
Fax: 856 21 214 015

Lesotho
(letter of 16 October 1986)

Director of Health Services
Ministry of Health
P.O. Box 514
Maseru 100
Tel: 324 404
Fax: 700 002

Liberia
(letter of 20 July 1978)

The Chief Pharmacist, R.L.
Division of Pharmacy
Ministry of Health & Social Welfare
P.O. Box 900
Monrovia

Libyan Arab Jamahiriya
(letter of 28 December 1981)

Pharmacy & Medical Equipment Department
Central Medical Stores
Sawia Street
Box 2317
Tripoli
Tel: 218 21 360 6683
Fax: 218 21 360 8007

Luxembourg*
(letter of 12 March 1986)

Direction de la Santé
Division de la Pharmacie et des Médicaments
10 rue C.M. Spoo
2546 Luxembourg
Tel: 352 478 55 90
Fax: 352 22 44 58

* See also text of reply reproduced in Section III

Madagascar*
(letter of 29 August 1980)

Direction des Pharmacies et
Laboratoires
Ministère de la Santé
Avenue Jean Ralaimongo
B.P. 88
Antananarivo
Tel: 261 223 697
Fax: 261 229 729

Malawi
(letter of 13 July 1982)

Chief Pharmacist
Ministry of Health and Population
P.O. Box 30377
Lilongwe 3
Tel: 265 783 004
Fax: 265 783 109

Malaysia*
(letters of 16 November 1982,
9 June 1993 and 26 December 1996)

National Pharmaceutical Control Bureau
Ministry of Health Malaysia
Jalan Universiti
P.O. Box 319,
46730 Petaling Jaya
Tel: 603 757 4910
Fax: 603 756 2924

Maldives*
(letter of 12 September 1982)

Ministry of Health and Welfare
Ghazee Building
Malé 20-05
Tel: 960 324 522
Fax: 960 328 889

Mali
(letter of 4 November 1981)

Directeur générale
Office malien de Pharmacies (O.M.P.)
B.P. 1746
Bamako

Malta*
(letter of 27 August 1986 and
24 October 1994)

Department of Health
15 Merchants Street
Valletta VLT 03
Tel: 00356 224071
Fax: 00356 242884

Mauritania
(letter of 2 June 1979)

Direction de la Santé publique
BP 177
Nouakchott

Mauritius*
(letter of 1 August 1977)

Chief Government Pharmacist
Ministry of Health
5th Floor Emmanuel Anquetel Building
Port Louis
Tel: 201 1367
Fax: 212 9406

* See also text of reply reproduced in Section III

Mexico
(letters of 9 July 1982, 18 October 1988
and 11 January 1993)

Director General de Control
de Insumos para la Salud
Mariano Escobedo 373, 6 piso
Col Chapultepec Morales
Del Miquel Hidalgo
C.P. 11570
Mexico, D.F.
Tel: 525 254 2525
Fax: 525 250 6962

Mongolia*
(letter of 14 July 1994)

Directorate of Medical Services
Ministry of Health and Social Welfare
Karl Marx Street-2
Ulaanbaatar - 11
Tel: 976 1 32 78 74
Fax: 976 1 32 12 78

Morocco
(letter of 1 September 1988)

Service Central de la Pharmacie
Ministere de la Sante Publique
Rabat
Tel: 07 76 65 95
Fax: 07 76 22 14

Mozambique
(letter of 4 September 1979)

Secretariado para a Cooperaçao
Internacional
Serviçao Farmacéutico
Ministerio da Saude
P.O. Box 264
Maputo
Tel: 258 1 424 792
Fax: 258 1 427 133

Myanmar
(letter of 11 September 1979)

Food and Drug Administration
No 35 Minkyaung Road
Dagon Township
Yangon
Tel: 951 245 332

Namibia, Republic of*
(letter of 15 January 1992 and
18 October 1994)

Medicines Control Council
Ministry of Health and Social Services
P.B. 13366
Windhoek
Tel: 264 61 2032861
Fax: 264 61 2272988

Nepal
(letter of 11 March 1984)

Chief Drug Administrator
& Head of Department
Department of Drug Administration
Ministry of Health
Thapathali
Kathmandu
Tel: 977 2 21 6258
Fax: 977 1 22 2996

* See also text of reply reproduced in Section III

Netherlands
(letters of 1 August 1983 and
1 December 1995)

Public Health Supervisory Service of
the Netherlands
The Inspectorate of Health Care
Sir W. Churchillaan 362
P.O. Box 5850
2280 HW Rijswijk
Tel: 0031 70 3406839
Fax: 0031 70 3407159

New Zealand
(letters of 18 December 1975,
1 June 1992 and 24 October 1994)

Therapeutics Section
Department of Health
P.O. Box 5013
Wellington
Tel: 0064 4 496 2088
Fax: 0064 4 496 2340

Nicaragua*
(letters of 20 March 1984 and
10 December 1992)

Dirección General de Normalización
de Insumos Medicos
Ministerio de Salud Publica
Managua
Tel: 505 289 7164
Fax: 505 289 7483

Nigeria
(letter of 5 March 1980)

National Agency for Food and Drugs
Administration and Control (NAFDAC)
Federal Ministry of Health
P.M.B 12525
Lagos
Tel: 234 1 269 3105
Fax: 234 1 269 3104

Norway*
(letter of 9 April 1976)

The Norwegian Medicines Control
Authority
Sven Oftedals vei 6
N-0950 Oslo
Tel: 47 22 89 7700
Fax: 47 22 89 7799

Oman
(letters of 9 March 1982 and
10 December 1995)

Directorate General of Pharmaceutical
Affairs and Drug Control
Ministry of Health
P.O. Box 393
113, Muscat
Tel: 00968 600016
Fax: 00968 600595

Pakistan*
(letter of 5 May 1979)

Drugs Controller
Ministry of Health, Special Education
and Social Welfare
Islamabad
Tel: 828867

* See also text of reply reproduced in Section III

Panama*
(letter of 29 August 1979)

Director
Departamento de Farmacia y Drogas
Ministerio de Salud
Apartado 2048
Panama
Tel: 507 623 546
Fax: 507 275 276

Papua New Guinea*
(letter of 1 September 1982)

Chief of Pharmaceutical Services
Department of Health
P.O. Box 3991
Boroko, NCD
Tel: 675 248 672
Fax: 675 254 209

Peru
(letters of 7 October 1980 and
24 October 1994)

Direccion General de Medicamentos,
Insumos y Drogas (DIGEMID)
Av. Arenales 1302 Oficina 318
Lima, 11
Tel: 511 472 4419
Fax: 511 472 3332

Philippines
(letters of 3 August 1988 and
9 November 1994)

Bureau of Food and Drugs
Ministry of Health
Alabang, Muntinlupa
Metro Manila 1702
Tel: 632 842 45 83
Fax: 632 842 46 03.

Poland
(letters of 16 October 1976
and 21 August 1995)

Drug Institute
Chelmska Str30/34
00725 Warsaw
Tel: 48 22 41 2940
Fax: 48 22 41 0652

Portugal
(letters of 13 February 1976,
28 November 1989 and 6 September 1994)

INFARMED
Estados Unidos de America 37
1700 Lisbon
Tel: 351 180 4131
Fax: 351 184 8031

Qatar
(letter of 8 June 1982)

Drug Control Department
Ministry of Public Health
Post Box 42
Doha
Tel: 974 468 458
Fax: 974 433 019

Romania
(letter of 29 August 1977)

Ministère de la Santé
Direction pharmaceutique et
de l'Équipement médical
Ilfov
70621 Bucarest

* See also text of reply reproduced in Section III

Rwanda (letter of 6 June 1979)	Directeur de la Pharmacie Ministère de la Santé B.P. 84 Kigali Tel: 250 759 68 Fax: 250 760 98
Saint Lucia (letter of 21 December 1981)	The Medical Supplies Officer Ministry of Health Chaussee Road Castries Tel: 809 452 2673 Fax: 809 452 5655
Sao Tome and Principe* (letter of 16 May 1979)	Direção da Farmácia Ministério da Saude Publica Rua Patricia Lumumba C.P. 23 Sao Tome Tel: 23 21 359 Fax: 23 21 306
Saudi Arabia* (letters of 8 July 1982 and) 20 January 1989)	Department of Medical Licences and Pharmaceutical Affairs Ministry of Health P.O. Box 27278/11417 Riyadh 11484 Tel: 405 9700 Fax: 405 9435
Senegal (letter of 29 August 1977)	Inspection des Pharmacies Ministère de la Santé publique et l'Action sociale 153, rue Mousse Diop Dakar
Seychelles* (letter of 15 September 1981)	Director, Pharmaceutical Services Ministry of Health P.O. Box 52 Victoria Hospital Mahe Tel: 224400 Fax: 224792
Sierra Leone (letter of 26 July 1982)	Chief Pharmacist Government Central Medical Stores Pharmacy Board Box 838 New Englandville Freetown Tel: 232 22 24 05 89 Fax: 232 22 22 56 15

* See also text of reply reproduced in Section III

Singapore*
(letter of 18 April 1994)

The Drug Administration Division
Pharmaceutical Department
Ministry of Health
2 Jalan Bukit Merah
Singapore 169547
Tel: 65 325 5619
Fax: 65 325 5423

Slovak Republic
(letter of 25 March 1991)

Director
State Institute for Drug Control
Gelnicka 12
82508 Bratislava
Tel: 427 566 4127
Fax: 427 566 4127

Slovenia
(letter of 23 June 1993)

Agency for Medicinal Products
Ministry of Health
Stefanova 5
61000 Ljubljana
Tel: 386 61 178 6026
Fax: 386 61 178 6058

Solomon Islands*
(memorandum of 6 February 1986)

Director, Pharmacy Services
Ministry of Health and Medical Services
P.O. Box 349
Honiara
Tel: 677 23 427
Fax: 677 20 420

Somalia
(letter of 13 June 1982)

Department of Pharmacy and
Medical Supplies
Ministry of Health
P.O. Box 1750
Mogadishu

South Africa
(letter of 28 April 1981)

Medicines Control Council
Private Bag X828
Pretoria 0001
Tel: 27 12 312 0322
Fax: 27 12 326 4344

Spain*
(letters of 29 June 1977,
15 July 1983 and 21 April 1986)

Director General de Farmacia y
Productos Sanitarios
Ministerio de Sanidad y Consumo
Paseo del Prado, 18-20
28014 Madrid
Tel: 341 596 4381
Fax: 341 596 1547

Sri Lanka
(letter of 16 June 1980)

Director
Quality Control Laboratory Highways and
Department of Health Services
General Hospital
Colombo 8

* See also text of reply reproduced in Section III

- Sudan*
(letter of 6 April 1981)
- Directorate of Pharmacy
Federal Ministry of Health
P.O. Box 303
Khartoum
Tel: 249 11 775697
Fax: 249 11 772970
- Suriname
(letter of 11 December 1986)
- Ministry of Health
Gravenstraat 64
Paramaribo
- Swaziland
(letter of 9 November 1978)
- Director of Medical Services
Department of Pharmacy
Ministry of Health
P.O. Box 5
Mbabane
- Sweden*
(letter of 1 April 1976)
- Director-General
Medical Products Agency
Box 26
751 03 Uppsala
Tel: 46 18 17 4665
Fax: 46 18 50 1168
- Switzerland*
(letter of 8 July 1980)
- Office intercantonal de Contrôle
des Médicaments
Erlachstrasse 8
3000 Berne 9
Tel: 41 31 302 3651
Fax: 41 31 302 0654
- Syrian Arab Republic
(letter of 12 November 1975)
- Pharmaceutical Services
Ministry of Health
Damascus
Tel: 963 11 331 1114
Fax: 963 11 331 1116
- Tanzania, United Republic of
(letter of 27 June 1978)
- Pharmacy Board
Ministry of Health
P.O. Box 9083
Dar es Salaam
Tel: 255 051 26211
Fax: 255 051 46229
- Thailand
(letter of 30 December 1977)
- Director-General
Food and Drug Administration
Ministry of Public Health
Tiwanond Road
Nonthaburi 11000
Tel: 662 591 8458
Fax: 662 591 8457

* See also text of reply reproduced in Section III

Togo
(letter of 4 July 1983)

Directeur des Pharmacies et Laboratoires
Direction Generale de Santé Publique
B.P. 336
Lomé
Tel: 228 21 45 02
Fax: 228 22 07 99

Trinidad & Tobago*
(letter of 7 November 1984)

Chief Chemist
Director Food and Drugs
Ministry of Health
Duncan Street and Independence Square
Port of Spain
Tel: 809 624 1592
Fax: 809 623 9528

Tunisia
(letter of 8 February 1978)

Direction de la Pharmacie et du Médicament
Ministère de la Santé publique
Bab Sadoun
Tel: 216 253 407
Fax: 216 351 762

Turkey*
(letter of 27 September 1979)

Directorate-General of Drugs and Pharmacy
Ministry of Health
Mithat Pasa Cad
06434 Sihhiye
Ankara
Tel: 90 312 431 4829
Fax: 90 312 434 4518

United Arab Emirates
(letter of 21 June 1977)

Pharmacy and Drug Control
Ministry of Health
P.O. Box 848
Abu Dhabi
Tel: 971 2 211 357-04384159
Fax: 971 2 313 142-04364550

United Kingdom of Great Britain*
and Northern Ireland
(letter of 13 April 1976)

Medicines Control Agency
Department of Health
Market Towers
1 Nine Elms Lane
London SW8 5NQ
Tel: 44 171 273 0100
Fax: 44 171 273 0548

United States of America*
(letters of 5 April 1976 and
9 September 1990)

Food and Drug Administration (FDA)
Room 15
5600 Fishers Lane
Rockville, MD 20857
Tel: 001 301 443 6143
Fax: 001 301 443 1309

* See also text of reply reproduced in Section III

Vanuatu*
(letter of 26 September 1983)

Principal Pharmacist
Department of Health
Private Mail Bag 009
Port Vila
Tel: 678 24 417
Fax: 678 24 420

Venezuela*
(letter of 5 August 1985)

Jefe, Division de Drogas y Cosméticos
Ministerio de Sanidad y Asistencia Social
Centro Simon Bolivar
Edificio Sur piso 3 Oficina 335
Caracas
Tel: 58 2 482 0657
Fax: 58 2 484 9471

Yemen Arab Republic
(letter of 9 June 1982)

Director-General
Supreme Board of Drugs and Medical
Appliances
Ministry of Public Health
P.O. Box 265
Sana'a
Tel: 967 2 252 210
Fax: 967 2 251 632

Zambia
(letter of 31 May 1979)

Pharmaceutical Services
Ministry of Health
P.O. Box 31890
Lusaka
Tel: 260 1 22 9021
Fax: 260 1 22 3435

Zimbabwe
(letter of 28 September 1982)

Director, Pharmacy Services
Ministry of Health and Child Welfare
P.O. Box 8204
Causeway
Harare
Tel: 263 4 730001
Fax: 263 4 795 353

* See also text of reply reproduced in Section III

III. TEXTS OF REPLIES FROM PARTICIPATING COUNTRIES

In order to keep this document as short as possible, straightforward replies declaring participation in the Scheme only, and merely providing the address of the competent authority, have not been included in this section.

On the other hand, any reservations expressed in the letter of participation, such as inability of the authority to issue batch certificates, or intent to participate as importing country only, or any other relevant information, is given below.

Any letter dated prior to May 1988 refers to the original version of the Scheme as adopted in May 1975 (WHA28.65). All letters dated after this date refer to the amended version as adopted in May 1988 (WHA41.18).

Letters referring specifically to implementation of the Guidelines adopted by the Thirty-fourth meeting of the Expert Committee on the Specifications for Pharmaceutical Preparations in 1994 and since endorsed by the World Health Assembly in resolution WHA50.3 in May 1997 are identified with an asterisk (*).

ALGERIA (letter of 14 June 1994)

- (a) The participation of Algeria will only be for the importation of products and pharmaceutical substances.
- (b) The availability of WHO-type product certificates will not replace the normal product registration process.

AUSTRALIA (letters of 26 May 1976, 16 January 1989 and 25 January 1996*)

Australia will participate in the certification scheme and the information requested in your letter is appended.

WHO Product Certification Scheme

1. The Australian Department of Health is the certifying authority within the meaning of the certification scheme.
2. There would appear to be no significant reservations regarding the proposed product certification scheme except in relation to the nomination of persons designated to sign certificates of individual batches of the product to be exported (annex 2, Part II, 1(c) refers). This is considered impracticable for the reason given in 3,2(ii) below.
3. The following are general comments on Annex 2 of the document:
 - (1) **Certification of Pharmaceutical Products (Annex 2A)**
 - (i) Although the definition of a "Drug" (on page 1 of Annex 2) refers to use in man or animal (as does the definition of a therapeutic substance in the Australian Customs Act and Therapeutic Goods Act), it appears from the first item on page 11 of Annex 2, that the certification scheme is to apply, at least at this stage, only to pharmaceutical products intended for human use. However, should certification of veterinary products be introduced in the future the authority is in a position to deal with the matter.
 - (ii) The requirement for "Number of permit and date of issue (if applicable)" will be relevant only when national product registration is introduced.

* See Section III, page 1, paragraph 4.

(iii) Batch certification – certification of individual batches is not generally required prior to distribution of pharmaceutical products marketed in Australia, and it is not considered feasible for the Department to routinely test and certify each batch exported. However, the authority could supply information as to the previous record of the manufacturer's products when tested and even, under very special circumstances, would be prepared to certify a batch of product.

(2) Exchange of Information (annex 2 B Part II)

(i) As noted, some of this information could, at present, be supplied only with the consent of the manufacturer or sponsor company, since such data is held in confidence by the Australian Department of Health.

(ii) Reservations are held as to the practicability of maintaining an up-to-date list of the names of the persons designated to sign certificates of different batches because of:

(a) fluctuations of staff within the industry and also change of position of personnel within a company and their authority to sign such certificates;

(b) the difficulty of policing the above changes in responsibility of personnel within a company;

(c) the problem of forgery of a signature;

(d) the company procedure may require a multiple of signatures or may permit alternative signatures for the release of different products;

(e) the labour which would be required to maintain a current list of persons.

(iii) The requirement for notification to the importer of any serious quality defects is encompassed by action taken under the existing Drug Recall procedure.

(3) Participating Member States (Annex 2 B Part III)

(i) The Australian Department of Health, in cooperation with State Departments of Health where appropriate, already carries out and ensures that:

(a) authorization for sale or distribution of pharmaceutical products is subject to appropriate testing measures by the competent authority, designed to ensure their quality, and that adequate laboratory facilities are available for this purpose;

(b) the pharmaceutical industry is required to conform with requirements for good practices in the manufacture and quality control of drugs;

(c) the competent authority is empowered to conduct appropriate investigations to ensure that manufacturers conform with the requirements referred to in (b);

(d) the inspectors in the services of the authorities have appropriate qualifications and experience.

(ii) Nomenclature: it is noted that the comment in item 3 of Part III requests that the international nonproprietary names be used, whenever available, to describe composition of the product, whereas the footnote on the sample certificate suggests "INN" or national nonproprietary names.

The recently produced list of Australian Approved Names will shortly become standard under the Therapeutic Goods Act, so that these names will be required to be used on the labels of therapeutic goods imported into Australia and on locally manufactured and distributed goods.

It is therefore proposed that the Product Certificates be issued in terms of the Australian Approved Names except that where these differ from the INN the latter be added in brackets.

Letter of 16 January 1989

Australia is in a position to implement the expanded WHO Certification Scheme with the following limitations:

- a national registration scheme has not yet been introduced in Australia and consequently locally-manufactured products may be distributed without prior evaluation by this Department.
- the product information for these products will also not have been approved. Therefore it will only be possible to certify that it is the information currently applicable to the product in Australia.
- Many imported products on the Australian market were "grandfathered", i.e. they were on the market before 1970 when new regulations were introduced which provided for the evaluation of new imported drugs with regard to quality, safety and efficacy prior to their being approved for marketing in Australia.

*Letter of 25 January 1996**

The Australian Therapeutic Goods Administration informed WHO that, from now on, it intended to use the model certificates as included in the final version of the guidelines to be published in the Thirty-fourth Report of the Expert Committee on Specifications for Pharmaceutical Preparations.

AUSTRIA (letter of 5 May 1978)

Part I – Certification of Pharmaceutical Products

2. The certificate does not include that products exported to Austria with certificates can be sold without normal registration procedure.
3. (a) In respect of pharmaceutical products manufactured in Austria for sale only in other countries, the registration procedure is not obligatory at present but according to Austrian regulations a licence is required for the manufacture of pharmaceutical products. In cases of non-registered products it would be possible to certify that the manufacturer is authorized to manufacture drug substances and preparations and conforms to requirements for good practice in manufacture and quality control of drugs as recommended by WHO and that the manufacturing plant is subject to inspections at suitable intervals.
4. The competent authority cannot undertake to issue batch certificates but this would not preclude individual manufacturers from giving such certificates if they so wished.

Part II – Exchange of Information

1. (a) In Austria the regulations concerning requirements for good practices in the manufacture and quality control of drugs as recommended by WHO as well as by the Pharmaceutical Inspection Convention are observed.
1. (c) For reasons of fluctuations of staff within the industry the authority is not in a position to provide the names and functions of the persons designated by individual manufacturers to sign such certificates.

* See Section III, page 1, paragraph 4.

2. This point might cause many practical problems and should be reserved strictly for serious defects.

BAHRAIN (letter of 6 June 1978)

Part I: Certification of pharmaceutical products

It is accepted, however as in No. 2 concerning drug products imported to Bahrain, the authorization for import, sale or distribution of such products is restricted to drugs and pharmaceutical preparations registered in Bahrain only.

BARBADOS (letter of 3 March 1983)

In regard to pharmaceutical products for export, certification by Barbados will depend on the current capability at the time requests for information are received. Batch certificates of authorised independent testing laboratories are available from the manufacturers.

BULGARIA (letter of 13 March 1997*)

The Director of the National Drug Institute (NDI) reconfirmed Bulgaria's participation in the WHO Certification Scheme. As from 1 January 1998 the NDI will issue WHO-type product certificates in accordance with the model included in the guidelines on the WHO Certification scheme as published in the Thirty-fourth Report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations, Technical Report Series 863, Geneva, 1996.

BURKINA FASO (letter of 29 September 1981)

Original: French

As Burkino Faso is not at present an exporting country, our participation in the scheme will be limited to obtaining certified information.

CAMBODIA, KINGDOM OF (letter of 31 December 1993)

For the moment, the Kingdom of Cambodia wishes to limit its participation to the importation of products.

CANADA (letters of 23 February 1983, 11 October 1988 and 6 December 1995*)

Canada agrees to participate in the certification scheme with the following reservations.

Part 1 – Certification of Pharmaceutical Products

The Food and Drugs Act does not apply to any packaged drug (other than a drug or other substance defined as a controlled drug by Part III or as a restricted drug by Part IV) not manufactured for consumption in Canada and not sold for consumption in Canada, if the package is marked in distinct overprinting with the word "EXPORT", and a certificate that the package and its contents do not contravene any known requirement of the law of the country to which it is or is about to be consigned, has been issued in respect thereof in prescribed form and manner.

Notwithstanding the above, the competent authority can certify that:

- (a) the manufacturing plant in which the product is produced is subject to inspections at regular intervals; and :

* See Section III, page 1, paragraph 4.

(b) the manufacturer conforms to requirements for good manufacturing practices, as recommended by the World Health Organization, in respect of products to be sold or distributed within Canada.

The competent authority cannot undertake to issue batch certificates, but this would not preclude individual manufacturers from giving such certificates if they so wished. The competent authority monitors by inspection the control system of the manufacturers.

Part II - Exchange of Information

The competent authority is not in a position to provide the names and functions of the persons designated by individual manufacturers to sign such certificates.

Letter of 11 October 1988

With regard to extension of the Scheme to Raw Materials, I would like to point out that Canadian GMP are not specific to the production of raw materials. However, upon specific requests, we have provided inspection reports of raw material producers based on inspection standards such as that of the USFDA.

*Letter of 6 December 1995**

The Director General of the Drugs Directorate, Health Protection Branch of Health Canada informed WHO of the following:

"After a trial period for certain products exported from Canada, we are in the process of implementing the Scheme for all applicants requesting "export" certificates.

Our certificates and procedures for issuing them will conform as closely as possible to the Scheme and this, of course, includes the standardized text of the certificate".

CHILE (letter of 18 August 1980)

Original: Spanish

1. It is confirmed that Chile agrees to take part in the certification scheme on the quality of pharmaceutical products moving in international commerce.
2. The Institute of Public Health of Chile, through the Department of National Control, is the authority that must be considered competent for the purposes of the certification scheme. This is consequent upon the new health structures established in the country by the promulgation of Decree Law 2.763 of 3 August 1979 and Supreme Decree No. 79 of 25 February 1980 which approved the "Regulations for the Institute of Public Health of Chile".
3. It is necessary to place on record what is set forth hereunder:
 - 3.1 Pharmaceutical manufacturing plants can function only with the authorization of the Institute of Public Health.
 - 3.2 Since 1976, it has been recommended to the pharmaceutical industry that it apply the good manufacturing practices proposed by WHO. The incorporation of those practices into the Health Regulations is under study.
 - 3.3 The Inspectors of manufacturing plants are professional pharmacists or chemists possessing adequate qualifications and experience and perform periodic inspections in accordance with programmes.

* See Section III, page 1, paragraph 4.

3.4 Certification of batches or control of series is a requirement laid down for products termed "biologicals", which include: sera, antitoxins, hormones, enzymes, vaccines, toxins, preparations of bacteria or viruses, and microbial derivatives, whether they be prepared within the country or imported, but only for consumption in the country. This inspection of series or batches is performed by the Sub-Department of Analytical Chemistry, Department of National Control, Institute of Public Health.

3.5 Supreme Decree No. 0346 of November 1961 approved the "Regulations for Pharmaceutical Products intended for Export", which provides:

(a) that these products may be manufactured only in manufacturing plants that comply with the requirements established in the Regulations for the pharmaceutical industry;

(b) that they may not be manufactured without authorization and registration accorded specifically for purposes of export;

(c) that the containers must carry the following minimum indications:

- name and location of manufacturer;
- designation of product;
- identification of the manufacturing series or
- batch;
- expiry date;
- qualitative and quantitative formula of therapeutically active components;
- instructions and precautions for use or administration;

(d) the producing manufacturer is responsible for the quality of the products it exports;

(e) accordingly, the Institute of Public Health does not verify the authenticity of the batch certificates for export unless expressly requested by the exporting manufacturer.

3.6 Pharmaceutical products authorized and registered in Chile must bear labels indicating, in addition to the trade name, the generic names or international nonproprietary names of the active principles.

COSTA RICA (letter of 5 February 1993)

For the time being our country will use the Scheme only as an importer while, with the aid of WHO, we are preparing to be in a position to comply with the Good Manufacturing Practices by 31 December 1994.

CUBA (letter of 18 June 1997)

The Republic of Cuba has agreed to participate in the Scheme without reservations.

DENMARK (letter of 29 November 1979)

Reservation is held as to the batch certification (part B.1.4), as those certificates can normally not be issued by the National Health Service.

The rules for manufacturing and quality control of drugs recommended by WHO are in force in Denmark.

DJIBOUTI (letter of 16 August 1980)

Does not at present export pharmaceutical preparations

DOMINICAN REPUBLIC (letter of 16 October 1992)

Original: Spanish

Our purpose in joining the Scheme is to control imports of pharmaceutical products and we are taking steps so that in the near future we shall be in a position to participate in the entire Scheme, including the certification of exports.

EUROPEAN AGENCY FOR THE EVALUATION OF MEDICINAL PRODUCTS (letters of 8 May and 3 June 1996*)

The European Agency for the Evaluation of Medicinal Products (EMEA, acting on behalf of the European Commission, will start to issue Certificates for Medicinal Products (Certificate of a Pharmaceutical Product) from 3 June 1996.

The format of the Certificate to be issued follows the latest recommendations of the WHO as adopted in the Thirty-fourth meeting of the Expert Committee on Specifications for Pharmaceutical Preparations.

As recommended under the Guidelines we wish to notify you of the following 'significant reservations':

- (a) the EMEA will only issue the 'Certificate of a Pharmaceutical Product' and will not provide either the 'Statement of Licensing Status of Pharmaceutical Products' or 'Batch Certificates of a Pharmaceutical Product'
- (b) the Certificates will be issued for medicinal products intended for administration to non-food producing as well as food-producing animals,
- (c) the certification of active ingredients will not be included for the time being.

EGYPT (letter of 26 July 1977)

We would like to mention the following reservations and comments:

Part I: Certification of Pharmaceutical products

- 1. Accepted.
- 2. Concerning products imported to Egypt the authorization of sale or distribution is restricted in Egypt.
- 3. Accepted.
- 4. Concerning products exported from Egypt the certificate issued for individual batches of products is - for the time being - issued by the competent authority of Egypt according to Egyptian law.

Part II: Exchange of Information

- 1. Accepted.
- 2. All available information will be provided according to the best capacity of the competent authority

* See Section III, page 1, paragraph 4.

EL SALVADOR (letter of 13 October 1993)

Original: Spanish

At the present time the country will adhere to the Scheme as an importer. We hope to conform to the requirements of Good Manufacturing Practices by 31 December 1994.

FIJI (letter of 30 December 1980)

The competent authority intends only to receive information furnished and certificates issued under the scheme. It is not intended to issue export certificates.

FINLAND (letter of 28 June 1977)

Finland wishes to inform of the following regarding the WHO certification scheme on the quality of pharmaceutical products moving in international commerce.

Part I – Certification of pharmaceutical products

Point 2: For pharmaceutical products to be sold in Finland a sales permit issued by the Health authority is always required. The certificate in question does not release the product from undergoing normal registration process.

Point 4: The health authorities cannot give certificates of individual batches as this would necessitate control measures in the factories during the manufacture and control of each batch. The manufacturers can give individual batch certificates for their products. In Finland the health authorities inspect the pharmaceutical factories and their control units at least once annually.

Part II – Exchange of Information

Point 1a: Finland follows the recommendations of WHO and the EFTA Pharmaceutical Inspection Convention regarding the requirements for good practices in the manufacture and quality control of drugs.

FRANCE (letter of 23 February 1984)

Original: French

Pharmaceutical specialties, whether intended for the national market or for export, are manufactured in France by pharmaceutical establishments subject to control by the Pharmacy Inspectorate, which checks that the Good Manufacturing Practices are applied.

GABON (letter of 12 November 1981)

Original: French

As this country does not yet export any medicines, this agreement to participate concerns in particular the part "OBTAINING certified information concerning imported products".

GERMANY (letters of 23 July 1985, 15 October 1986 and 18 August 1993)

The certificates will be issued, upon request, for products intended for human or veterinary use by the health authorities of the Laender. Batch certificates for sera, vaccines and test allergens will be issued by the Paul-Erlich Institute and for veterinary products also by the Federal Health Office and the Federal Research Institute for Animal Virus Diseases.

As far as the issuing of batch certificates is concerned, authorities can only issue batch certificates for sera, vaccines and test allergens. For other drugs the manufacturer can submit a certificate of analysis signed by the person responsible for quality control. If desired the signature can be attested by the competent authority.

In addition to the data provided for in the certificate, the Federal Republic is, upon request, also willing to provide information on the conditions under which the drug in question is on the market in the Federal Republic of Germany, such as mandatory prescription, dosage, fields of application, contraindications and warnings. For veterinary drugs the information on target animals and withdrawal periods will also be provided.

GREECE (letter of 27 January 1987)

Greece agrees to participate in the Scheme and certifies the following:

1. Part I – Certification of pharmaceutical products

The manufacturing plant in which the product is produced is subject to inspections at suitable intervals to verify the manufacturer conforms to requirements for good practices in manufacture and quality control, as recommended by the World Health Organization, in respect of products to be sold or distributed within the country of origin or to be exported.

The competent authority cannot issue certificates of individual batches; these will have to be issued by the manufacturer.

2. Part II – Exchange of Information

(i) The competent authority can:

(a) provide information on the implementation of the Requirement for Good Practices in the Manufacture and Quality Control of Drugs as recommended by the World Health Organization.

(b) certify that it conducts appropriate investigation to ensure that manufacturers conform to the requirements referred to (a), including for example, the examination of records and taking of samples. However, the competent authority cannot provide the names and functions of the persons designated to sign certificates of individual batches of the product to be exported.

In the case of quality defects of products imported under this Certification Scheme the carrying out of inquiries should be reserved to serious defects.

GUYANA (letter of 21 January 1980)

Our reservations are as follows:

(1) Part I – Certification of Pharmaceutical Products

(a) The requirement for "Number of permit and date of issue" (if applicable) will be relevant only when national product registration is introduced;

(b) Batch certification - it is not considered feasible for the competent authority to routinely test and certify each batch of pharmaceutical products exported, but under very special circumstances, the authority would be prepared to certify a batch of product. However, this would not preclude individual manufacturers from issuing batch certificates if they so wished.

(2) Part II – Exchange of Information

Some of this information could, at present, be supplied only with the consent of the manufacturer, since such data is held in confidence by the Food and Drug Department.

Implementation of the scheme in Guyana will depend on the availability of staff.

HONDURAS (letters of 9 September 1991 and 15 December 1992)

Original: Spanish

For the time being our country will only use the system as an importer, but with the help of the Organization we are preparing to meet the requirements for Good Practice in Manufacture by 31 December 1994.

HUNGARY (letters of 8 August 1983 and 22 December 1996*)

Reservation is held, however, on the batch certification, part B.I.4., as such certificates cannot normally be issued by the National Health Authority; it is the manufacturers that provide individual batch certificates for their products. The manufacturing plants and their control units are subject to inspections by the Health Authority at suitable intervals.

*Letter of 22 December 1996**

The National Institute of Pharmacy, competent drug regulatory authority in Hungary, having been participating, by the appointment of the Ministry of Welfare, in the WHO Certification Scheme on Quality of Pharmaceutical Products Moving in International Commerce, informs WHO formally herewith that from now on we would issue WHO type product certificates as included in the Thirty-fourth report of the Expert Committee on Specifications for Pharmaceutical Preparations (TRS 863, WHO Geneva 1996). In practice, the Institute had already started to issue certificates in this form the last two years.

INDIA (letter of 16 May 1978)

So far as "Batch Certificates" are concerned, it is felt that these certificates can be issued by the manufacturers and it is not necessary for any Government authority to issue such certificates.

IRELAND (letter of March 1985)

In respect of pharmaceutical products manufactured in Ireland for sale only in other countries, the domestic pharmaceutical registration procedure is not obligatory. However, the manufacture or all pharmaceutical products, whether for sale in this country or for export, is subject to a statutory licensing system. Manufacturing plants are inspected at regular intervals in the course of which the requirements for Good Practices in the Manufacture and Quality Control of Drugs as recommended by WHO are applied as well as those of the pharmaceutical inspection convention (EFTA).

The competent authority cannot undertake to issue batch certificates but this would not preclude individual manufacturers from giving such certificates if they so wished. The competent authority would on request authenticate the origin of and signatures on these certificates.

IVORY COAST (letter of 24 June 1986)

Original: French

To some extent this certification scheme complements the legal provisions adopted by Côte d'Ivoire in 1965 providing for the prior registration of pharmaceutical products on the basis of a set of criteria, fundamental to which is authorization for sale in the country of origin.

JAMAICA (letter of 12 August 1980)

The Food and Drugs Act 1964, now in force, lays down that all drugs imported into and exported from Jamaica must be registered.

* See Section III, page 1, paragraph 4.

JAPAN (letter of 21 October 1976)

The names and addresses of the competent authorities to make respective certification are as follows:

1. For the purpose of certifying that the subject product (except biologic product and antibiotic preparation) has been authorized to be placed on the market for use in Japan:

Director, Evaluation and Registration Division
Pharmaceutical Affairs Bureau,
Ministry of Health and Welfare

2. For the purpose of certifying that the subject biologic product or antibiotic preparation has been authorized to be placed on the market for use in Japan:

Director, Biologics and Antibiotics division
Pharmaceutical Affairs Bureau,
Ministry of Health and Welfare

3. For the purpose of certifying that the respective manufacturing plant is subject to inspections at suitable intervals and that the manufacturer conforms to requirements for good practices in the manufacture and quality control:

Director, Inspection and Guidance Division
Pharmaceutical Affairs Bureau
Ministry of Health and Welfare

The address of these Divisions is:

1-2-2 Kasumigaseki
Chiyoda-ku
Tokyo 10

In our country, manufacturing plants in which a pharmaceutical product is produced are subject to inspections by the authorities at suitable intervals. As stated in my previous letter, however, it should be noted that it is impossible for the authorities to issue the certificate of individual batches of the pharmaceutical products because of an enormous amount of work. Therefore, the manufacturers concerned are requested to issue such certificate if it is required and to provide relevant information when requested.

KUWAIT (letter of 12 January 1983)

Concerning pharmaceutical products imported to Kuwait - the authorization of sale or distribution is restricted to pharmaceutical products registered with the competent authority. Therefore, the certificate in question does not release the product from undergoing normal registration process.

LAO PEOPLE'S DEMOCRATIC REPUBLIC (8 August 1994)

The participation of Lao People's Democratic Republic will be limited to importation.

LUXEMBOURG (letter of 12 March 1987)

Original: French

Because our country has no pharmaceutical industry, the purpose of our participation in

this scheme is more especially to enable us to obtain the information provided in the application of this certification scheme.

MADAGASCAR (letter of 29 August 1980)

Original: French

Since our country is not an exporting country, the purpose of our participation in this certification scheme is to enable us to obtain information and certificates issued under the scheme. As a Member of the World Health Organization we therefore intend to require exporting countries

to meet all the conditions laid down in the resolution WHA28.65 of the Twenty-eighth World Health Assembly.

MALAYSIA (letters of 16 November 1982 and 26 December 1996*)

Malaysia supports the recommendation of the resolution in the operative paragraphs 2(a) and 2(b) and agrees to participate in the certification scheme subject to the reservations set out below:

- (a) Application of the revised requirements for good practices in the manufacture and quality control of drugs as formulated in the report of the Director-General is subject to adoption and approval of legislation now being drafted in respect of licensing and control of all pharmaceutical manufacturing establishments.
- (b) Malaysia is not a large exporter of pharmaceuticals and only a very small volume of exports are made to a few countries around the region. It is not possible at present for the issue of certificates in full compliance of the terms of the directive in respect of pharmaceutical products manufactured locally for export. In the meantime, if required in respect of such products, it would be possible for the competent authority to certify that the manufacturing plant in which the product is produced is subject to inspections at regular intervals, and the manufacturer conforms to requirements for good practice in the manufacture and quality control, as recommended by the World Health Organization, in respect of products to be sold or distributed, within the country of origin or to be exported.

It should be pointed out that progress with full implementation of the scheme will depend on availability of staff.

*26 December 1996**

This is to inform that henceforth the Malaysian authorities will issue export certificates as recommended by the World Health Organization in the Thirty-fourth Report of the Expert Committee on Specifications for Pharmaceutical Preparations (TRS 863, WHO Geneva 1996). Similarly, the same WH-type product certificates are required at the time of application for marketing authorization for products to be imported.

MALDIVES (letter of 12 September 1982)

We take pleasure in informing you that we would like to participate in the scheme as an importing country and welcome any facilities that may be provided to us under this scheme. As you are aware due to lack of relevant technical facilities in the country our role in this would be mostly that of a recipient.

* See Section III, page 1, paragraph 4.

MALTA (letter of 27 August 1986)

The competent authority cannot undertake to issue batch certificates but this would not preclude individual manufacturers from giving such certificates if they so wished. The competent authority would on request authenticate the origin of and signatures on these certificates.

MAURITIUS (letter of 1 August 1977)

Though Mauritius does not export pharmaceutical products, it is interested in participating in the certification scheme.

MONGOLIA (letter of 14 July 1994)

As Mongolia is not at present an exporting country, participation in the Scheme will be limited to importation of products.

NAMIBIA (letter of 15 January 1992)

For the present, we will only participate in controlling the import of pharmaceutical products and substances.

NICARAGUA (letter of 10 December 1992)**Original: Spanish)**

For the time being our country will use the Scheme solely as an importer; meanwhile, with the help of the Organization, we are preparing to become able to comply with the Good Manufacturing Practices by 31 December 1994.

NORWAY (letter of 9 April 1976)

With reference to B. part I, 4 in the report of the Director-General, batch certificates from Norway normally will be issued by the manufacturer. Referring to part III, 2 in the report, this point is interpreted as reserved strictly to serious defects.

PAKISTAN (letter of 5 May 1979)

Subject to the reservation that batch certificates are not issued by the competent authority, as these can be issued by the manufacturers.

PANAMA (letter of 29 August 1979)**Original: Spanish**

Our country does not at present feature among the exporting countries, and therefore this participation will be for the purpose of receiving information and the certificates issued in accordance with the certification scheme.

PAPUA NEW GUINEA (letter of 1 September 1982)

The competent authority intends only to receive information furnished and certificates issued under the scheme. It is not intended to issue export certificates.

SAO TOME AND PRINCIPE (letter of 16 May 1979)**Original: Portuguese**

We recognize this to be of basic importance for our country which is almost completely dependent on imports of pharmaceuticals, chemico-pharmaceuticals, raw materials, and finished and semi-finished drugs, we agree to the participation of our country in the certification scheme, without reservations. We propose to request the exporting country, as a member of WHO, to fulfil

all the requirements embodied in resolution WHA28.65 approved by the Twenty-eighth World Health Assembly.

SAUDI ARABIA (20 January 1989)

In accordance with the Certification Scheme, free sale certificates in the country of origin is a basic requirement among documents to be provided on application to register any drug in Saudi Arabia. Besides, the Ministry of Health can cooperate closely with WHO in case of obvious doubt in any pharmaceutical product.

SEYCHELLES (letter of 15 September 1981)

As we are supporting the principle of using only drugs of reliable manufacturers, we will apply this scheme to all our imports.

SINGAPORE (letter of 18 April 1994)

- (i) Our participation will be limited to finished dosage forms for pharmaceutical forms intended for administration to human beings only.
- (ii) Batch certificates will be issued by the manufacturer, but the competent authority could on request verify the authenticity of the batch certificate.

SOLOMON ISLANDS (memorandum of 6 February 1986)

We do already require that all bulk purchases of drugs and dressings are accompanied by certificates of analysis, issued by the manufacturers. In some cases the quality and more potency, of preparations is confirmed by provision of suitable samples for analysis to the National Biological Standards Institute in Australia.

SPAIN (letters of 29 June 1977 and 15 July 1983)

Original: Spanish

In principle this Subdirectorate-General sees no objection to participating in the certification scheme on the quality of pharmaceutical products moving in international commerce, subject to the following considerations:

- (a) that at the present time the main provisions of the requirements for good manufacturing practice are binding for Spanish manufacturers, many of whom comply with all the requirements that have been in the recommendations phase for the past two years. For those manufacturers who comply with or are to comply with these requirements, the proposed certification scheme can be put into effect;
- (b) that it is necessary to update the present system for inspection of installations and production batches, adapting the present scheme so as to meet the requirements of the scheme, which will depend to a great extent on the availability of personnel;
- (c) that in the case of batch certificates they would be issued by the manufacturers themselves, once the conditions specified in paragraph (a) are established.

SUDAN (letter of 6 April 1981)

The competent authority will not be in a position to issue a batch certificate, but these could be and are issued by the manufacturers.

SWEDEN (letter of 1 April 1976)**Part I – Certification of pharmaceutical products**

1. No comments.
2. The Certificate does not include that products exported to Sweden with certificates can be sold without normal registration procedure.
3. No comments.
4. The batch certificates from Sweden should be issued by the manufacturer. The control system of the manufacturers is checked by inspection of the Authority.

Part II

- 1(a) In Sweden the requirements for Good Practices in the Manufacture and Quality Control of Drugs are applied to Recommendations from WHO as well as from the Pharmaceutical Inspection convention (EFTA).
- (b) No comments.
- (c) This should normally be that person at a Manufacturer's who is responsible to the National Board of Health and Welfare.
2. This point might cause many practical problems and should be reserved strictly to serious defects.

SWITZERLAND (letter of 8 July 1980 and OICM Bulletin, November 1995*)**Original: French**

The certificates signed by the competent authority and authenticated by the State Chancellory and by the embassy of the importing country will be forwarded by the industry.

The batch certificates will be prepared by the manufacturer. The competent authority simply authenticates the origin and signatures of these certificates. We would point out that a certification system of this kind has already been operating in Switzerland for some years.

*The following information was published in the Monthly Bulletin of the Swiss Intercantonal Office for Drug Control (IKS Monatsbericht/Bulletin mensuel OICM November 1995)**

Information concerning the issue of export certificates.

WHO has been actively pursuing the introduction of a world-wide valid Export certificate for medicines intended for international commerce. Switzerland has provided a considerable contribution to this and will continue to do so in the interest of the exporting industry in its own country.

We would like to inform applicants for export certificates herewith that the WHO-certificate in its form and content will prevail increasingly. It is anticipated, that the form of the WHO- certificate adopted during the meeting 29 November to 3 December 1994 will be declared valid by the Executive Board in spring 1996. For its part, the European Union already declared on 3 May 1989 the eventual final version of the WHO certificate as being the future binding version.

* See Section III, page 1, paragraph 4.

The OICM continues to issue export certificates in the usual manner, but is already now able to issue WHO type certificates. There is not much difference between the contents of the OICM and WHO type certificates. The WHO type certificate always mentions the importing country.

The OICM will likewise give information about further developments in due course."

TRINIDAD AND TOBAGO (letter of 7 November 1984)

The Government of the Republic of Trinidad and Tobago also wishes to make a reservation regarding participation in the scheme as follows:

that it will not be feasible for the Chief Chemist/Director of Food and Drugs to routinely test and certify each batch of pharmaceutical products exported, but under special circumstances, the Authority would be prepared to certify a batch product.

TURKEY (letter of 27 September 1979)

1. The manufacturing plant in which the product is produced is subject to inspection of the M.H.S.A according to the respective regulation of 1955 stating that these places should be inspected at least twice a year or whenever it is necessary. This regulation covers the recommendations of WHO in relation to quality control and inspection of the manufacturing plants. This point has been accepted. If there will be any change your suggestion will surely be asked.

2. There have been some obstacles in the respective law of our country in relation to the certification scheme on the quality of pharmaceutical products moving in international commerce. The respective law relates to the certification and quality control of pharmaceutical products which will be used in the country. Nevertheless, it is possible to give special certification to the pharmaceutical products which will be exported.

The Ministry of Health and Social Assistance will be able to prepare a document and certify that the production system of the manufacturing plant is valid according to the recommendations of WHO and also is inspected at suitable intervals.

Nevertheless, consideration should be given to those countries who do not have the legal right to give certification to the pharmaceutical products which will be exported.

3. Batch certificates should be issued by the manufacturer in Turkey. It is impossible for the competent authority to issue such a certificate, though it will be possible to do it for some series upon request. The competent authority has to inspect the quality system of the manufacturing plant and also inspect at certain intervals the samples from the pharmaceutical market.

UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND (letters of 13 April 1976 and 7 May 1996*)

Reservations are as follows:

1. Part 1 – Certification of pharmaceutical products

(i) Because of the provisions of the Medicines Act 1968 it is not possible at this time for the competent authority, which is also the licensing authority under the Act, to give a certificate fully in the terms of the directive in respect of pharmaceutical products that are manufactured in the United Kingdom for sale only in other countries.

* See Section III, page 1, paragraph 4

In respect of such products it would be necessary for fuller compliance with the terms of the directive to reactivate Section 48 of the Medicines Act in pursuance of an international agreement regarding the control of products moving in international commerce. The reactivation of Section 48 would allow the UK licensing authority to grant licences relating to products that are only for export by reference only to their quality.

The United Kingdom's participation in the certification scheme is therefore subject to the parliamentary adoption of an Order activating Section 48 of the Medicines Act 1969.

(ii) In the meantime in respect of pharmaceutical products to which reference is made in (i) above it would be possible for the competent authority to certify that:

(a) the manufacturing plant in which the product is produced is subject to inspection at regular intervals, and

(b) the manufacturer conforms to requirements for good practice in the manufacture and quality control, as recommended by the World Health Organization, in respect of products to be sold or distributed within the country of origin or to be exported.

(iii) The competent authority cannot undertake to issue batch certificates but this would not preclude individual manufacturers from giving such certificates if they so wished.

2. Part II — Exchange of Information

Since the competent authority cannot undertake to issue batch certificates, and it would be for individual manufacturers to issue them if they so wished, the authority is not in a position to provide the names and functions of the persons designated by individual manufacturers to sign such certificates.

Progress with implementation of the scheme in the United Kingdom will depend on the availability of staff.

*Letter of 7 May 1996**

The Medicines Control Agency has informed WHO that the United Kingdom is in conformance with WHO requirements for the new format of Export Certificates and that they are supportive of the measures that have been taken in this respect.

UNITED STATES OF AMERICA (letter of 5 April 1976)

All drug manufacturing facilities in the United States are subject to regular inspection by the FDA; however, batch certification is only required for certain antibiotic drugs. Therefore, under this scheme the FDA could not verify the authenticity of batch certificates (in the absence of independent examination) except as noted above.

VANUATU (letter of 26 September 1983)

Because we are a developing nation, and we invariably rely on imported pharmaceuticals for our Public Health, we recognize the importance of such Resolution, and it is with sincerity that we fully adopt its content.

* See Section III, page 1, paragraph 4.

VENEZUELA (letter of 5 August 1985)

Original: Spanish

For products exported by Venezuela, the tests on which issuance of the quality certificates is based will be performed by the official laboratories or other quality control laboratories that have been approved by the Ministry of Health and Social Welfare and which are subject to rigorous State inspection.

FORTY-FIFTH WORLD HEALTH ASSEMBLY**WHA45.29 Proposed guidelines for the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce**

The Forty-fifth World Health Assembly,

Taking note of previous resolutions on WHO's Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce, and particularly resolution WHA41.16, which refers to the export, import and smuggling of falsely labelled, spurious, counterfeited or substandard pharmaceutical preparations;

Having reviewed the report on the implementation of WHO's revised drug strategy, and in particular the proposed guidelines for the implementation of the Certification Scheme;¹

Aware of the need for prospective importing countries to obtain explicit assurances regarding the quality of products not registered in the country of provenance;

Believing that the adoption of the proposed guidelines will contribute to deterrence of the export, import and smuggling of falsely labelled, spurious, counterfeited or substandard pharmaceutical preparations;

Recognizing that a comprehensive system of quality assurance including the WHO Certification Scheme must be founded on a reliable national system of licensing, independent analysis of the finished product and independent inspection to verify that all manufacturing operations are carried out in conformity with accepted norms, referred to as "good manufacturing practices",

1. ENDORSES the guidelines for implementation of the WHO Certification Scheme, which will be evaluated and revised, as necessary, in consultation with the Committee on Drug Policies of the Executive Board;
2. URGES Member States to implement these guidelines, and to issue certificates within five years in a form to be agreed in the light of experience gained in preliminary field testing.

May, 1992

¹Document WHA45/1992/REC/1, p.155.

FIFTIETH WORLD HEALTH ASSEMBLY

WHA50.3 Guidelines on the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce

The Fiftieth World Health Assembly,

Taking note of previous resolutions on WHO's Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce, and particularly resolutions WHA45.29 and WHA49.14;

Having reviewed the revised guidelines on implementation of the Certification Scheme which are the result of field trials in a number of WHO Member States and discussions during the sixth and seventh biennial International Conferences of Drug Regulatory Authorities;¹

Believing that the adoption of the revised guidelines will provide an important instrument in support of drug registration in the importing country by ensuring access to transparent information on the regulatory status of the pharmaceutical product in the exporting country and the true origin of products to be imported,

1. ENDORSES the guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce and model certification forms annexed to the guidelines;
2. URGES Member States:
 - (1) to implement these guidelines, to request WHO-type certificates in the form contained in the guidelines and to issue the certificates in the form proposed, as from 1 January 1998;
 - (2) to inform the Director-General of their intent to apply the Scheme and of any significant reservations they intend to express relating to their participation as provided for in article 2.1 of the guidelines.

Hbk Res., Vol. III (3rd ed.), 1.15.3

(Eighth plenary meeting, 12 May 1997 -
Committee A, first report)

¹ WHO Technical Report Series, No. 863, 1996, Annex 10.

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WHO Technical Report Series, No. 863, 1996

Annex 10

Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce

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1. Provisions and objectives

1.1 A comprehensive system of quality assurance must be founded on a reliable system of licensing¹ and independent analysis of the finished product, as well as on an assurance obtained through independent inspection that all manufacturing operations are carried out in conformity with accepted norms referred to as "good manufacturing practices" (GMP).

1.2 In 1969, the Twenty-second World Health Assembly, by resolution WHA22.50, endorsed requirements for "Good practices in the manufacture and quality control of drugs"⁽¹⁾ (referred to henceforth as "GMP as recommended by WHO"). These comprise internationally recognized and respected standards that all Member States are urged to adopt and to apply. These requirements have since been revised twice. The first revision was adopted by the Health Assembly in 1975 in

¹ Throughout this document licensing refers to any statutory system of approval required at national level as a precondition for placing a pharmaceutical product on the market.

resolution WHA28.65 (2), and a second revision of the requirements is included in the thirty-second report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (3).

1.3 These standards are fully consonant with those operative within the countries participating in the Convention for the Mutual Recognition of Inspection in Respect of the Manufacture of Pharmaceutical Products, and other major industrialized countries. They also provide the basis for the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce (referred to henceforth as "the Scheme") recommended initially in resolution WHA22.50 (1). The Scheme is an administrative instrument that requires each participating Member State, upon application by a commercially interested party, to attest to the competent authority of another participating Member State that:

- a specific product is authorized to be placed on the market within its jurisdiction or, if it is not thus authorized, the reason why that authorization has not been accorded;
- the plant in which it is produced is subject to inspections at suitable intervals to establish that the manufacturer conforms to GMP as recommended by WHO; and
- all submitted product information, including labelling, is currently authorized in the certifying country.

1.4 The Scheme, as subsequently amended in 1975 (2) and 1988 (4) by resolutions WHA28.65 and WHA41.18, is applicable to finished dosage forms of pharmaceutical products intended for administration to human beings or to food-producing animals.

1.5 Provision for the certification of active ingredients is also included within the scope of the Scheme. This will be the subject of separate guidelines and certificates.

2. Eligibility for participation

2.1 Any Member State intending to participate in the Scheme may do so by notifying the Director-General of WHO, in writing, of:

- its willingness to participate in the Scheme;
- any significant reservations it intends to observe relating to this participation; and
- the name and address of its national drug authority or other competent authority.

2.2 These notifications are subsequently announced in the monthly *WHO pharmaceuticals newsletter*. An updated consolidated list will be published annually in the newsletter and will be available to governments at other times from the Division of Drug Management and Policies, WHO, 1211 Geneva 27, Switzerland. (See also section 3.3).

2.3 A Member State may opt to participate solely to control the *import* of pharmaceutical products and active substances. This intention should be stated explicitly in its notification to WHO.

2.4 A Member State intending to use the Scheme to support the *export* of pharmaceutical products should first satisfy itself that it possesses:

- An effective national licensing system, not only for pharmaceutical products, but also for the responsible manufacturers and distributors.
- GMP requirements, consonant with those recommended by WHO, to which all manufacturers of finished pharmaceutical products are required to conform.
- Effective controls to monitor the quality of pharmaceutical products registered or manufactured within the country, including access to an independent quality control laboratory.
- A national pharmaceuticals inspectorate, operating as an arm of the national drug regulatory authority, and having the technical competence, experience and resources to assess whether GMP and other controls are being effectively implemented, and the legal power to conduct appropriate investigations to ensure that manufacturers conform to these requirements by, for example, examining premises and records and taking samples.
- The administrative capacity to issue the required certificates, to institute inquiries in the case of complaint, and to notify expeditiously both WHO and the competent authority in any Member State known to have imported a specific product that is subsequently associated with a potentially serious quality defect or other hazard.

2.5 Each Member State assumes the responsibility to determine, through a process of self-evaluation, whether it satisfies these prerequisites. The Scheme contains no provision for external inspection or assessment under any circumstances, either of a competent national authority or of a manufacturing facility. However, should a Member State so wish, it can approach WHO, or a well recognized drug regulatory authority, occasionally to delegate consultants to act as advisers in the course of both national inspections and inspector training activities.

3. Requesting a certificate

3.1 Three documents can be requested within the scope of the Scheme:

- a Certificate of Pharmaceutical Product (product certificate);
- a Statement of Licensing Status of Pharmaceutical Product(s); and
- a Batch Certificate of a Pharmaceutical Product.

3.2 Proposed formats for these documents are provided in Appendices 1, 2 and 3 of these guidelines. To facilitate their use, they are presented in forms suitable for generation by computer. All participating countries are henceforth urged to adopt these formats to facilitate the interpretation of certified information. Requests for the provision of certificates offering

more limited attestations – for instance, that the manufacturer complies with GMP or that the product is authorized for “free sale” within the country of export – are discouraged. Similarly, requests should not be made for the certification of information going beyond the scope of the Scheme. When manufacture takes place in a country other than that where the product certificate is issued, an attestation that such manufacture complies with GMP may still be provided as an attachment to the product certificate on the basis of inspections undertaken for registration purposes. The explanatory notes attached to the three documents referred to above are very important. While they are not part of the documents, they should always be attached to them.

3.3 A list of addresses of competent national regulatory authorities participating in the Scheme that are responsible for the registration of pharmaceutical and/or veterinary products, together with details of any reservations they have declared regarding their participation in the Scheme may be obtained from WHO as indicated in section 2.2.

3.4 The competent authority in each country participating in the Scheme should issue guidelines to all agents responsible for importing pharmaceutical products for human and/or veterinary use that operate under its jurisdiction, including those responsible for public sector purchases, to explain the contribution of certification of the drug regulatory process and the circumstances in which each of the three types of documents will be required.

Certificate of a Pharmaceutical Product

3.5 The Certificate of a Pharmaceutical Product (Appendix 1), issued by the exporting country, is intended for use by the competent authority within an importing country in two situations:

- when the product in question is under consideration for a product licence that will authorize its importation and sale;
- when administrative action is required to renew, extend, vary or review such a licence.

3.6 All requests for certificates should be channelled through the agent in the importing country (see section 3.4) and the product-licence holder or other commercially interested party in the exporting country (“the applicant”). The applicant should submit the following information for each product to the authority issuing the certificate:

- the name and dosage form of the product;
- the name and the amount of active ingredient(s) per unit dose (the International Nonproprietary Name(s), where such exist(s), should be used);
- the name and address of the product-licence holder and/or manufacturing facility;

- the formula (the complete qualitative composition including all excipients); this is particularly important when no product licence exists or when the formulation differs from that of the licensed product;
- product information for health professionals and for the public (patient information leaflets) as approved in the exporting country.

For product information to be attached to the certificate, see section 4.7.

3.7 The certificate is a confidential document. As such, it can be issued by the competent authority in the exporting country ("the certifying authority") only with the permission of the applicant and, if different, of the product-licence holder.

3.8 The certificate is intended to be incorporated into a product-licence application in the importing country. Once prepared, it is transmitted to the requesting authority through the applicant and, when applicable, the agent in the importing country.

3.9 When any doubt arises about the status or validity of a certificate, the competent authority in the importing country should request a copy directly from the certifying authority, as provided for in section 4.9 of these guidelines.

3.10 In the absence of any specific agreement, each certificate will be prepared exclusively in the working language(s) of the certifying authority. The applicant will be responsible for providing any notarized translation that may be required by the requesting authority.

3.11 Since the preparation of certificates imposes a significant administrative load on certifying authorities, the service may need to be financed by charges levied upon applicants.

3.12 Supplementary attestations are obtainable only at the discretion of the certifying authority and with the permission of the applicant. The certifying authority is under no obligation to supply additional information. Requests for supplementary information should consequently be referred to the applicant, and only in exceptional circumstances to the certifying authority.

Statement of Licensing Status

3.13 The Statement of Licensing Status of Pharmaceutical Product(s) (Appendix 2) attests only that a licence has been issued for a specified product, or products, for use in the exporting country. It is intended for use by importing agents when considering bids made in response to an international tender, in which case it should be requested by the agent as a condition of bidding. It is intended only to facilitate the screening and preparation of information. The importation of any product that is provisionally selected through this procedure should be determined on the basis of a Certificate of a Pharmaceutical Product.

Batch Certificate

3.14 A Batch Certificate of a Pharmaceutical Product (Appendix 3) refers to an individual batch of a pharmaceutical product, and is a vital instrument in drug procurement. The provision of a Batch Certificate is usually a mandatory requirement in tender and procurement documents.

3.15 A Batch Certificate is normally issued by the manufacturer and only *exceptionally*, as in the case of vaccines, sera and some other biological products, by the competent authority of the exporting country. The Batch Certificate is intended to accompany and provide an attestation concerning the quality and expiry date of a specific batch or consignment of a product that has already been licensed in the importing country. The Batch Certificate should include the specifications of the final product at the time of batch release and the results of a full analysis undertaken on the batch in question. In most circumstances these certificates are issued by the manufacturer to the importing agent (i.e. the product-licence holder in the importing country), but they must be made available at the request of – or in the course of any inspection made on behalf of – the competent national authority.

4. Issuing a certificate

4.1 The certifying authority is responsible for assuring the authenticity of the certified data. Certificates should not bear the WHO emblem, but a statement should always be included to confirm whether or not the document is issued in the format recommended by WHO.

4.2 When the applicant is the manufacturer of the finished dosage form, the certifying authority should satisfy itself, before attesting compliance with GMP, that the applicant:

- (a) applies identical GMP standards to the production of *all* batches of pharmaceutical products manufactured within the facility, *including those destined exclusively for export*;
- (b) consents, in the event of identification of a quality defect consonant with the criteria set out in section 5.1, to relevant inspection reports being released, in confidence, to the competent authority in the country of import, should the latter so require.

4.3 When the applicant is not the manufacturer of the finished dosage form, the certifying authority should similarly satisfy itself – in so far as it has authority to inspect the records and relevant activities of the applicant – that it has the applicant's consent to release relevant reports on the same basis as described in section 4.2 (b) above.

4.4 GMP as recommended by WHO assigns to the manufacturer of the finished dosage form responsibility for assuring the quality of active ingredients. National regulations may require that suppliers of active ingredients be identified in the product licence, but the competent authority may have no power to inspect them.

4.5 Notwithstanding this situation, a certifying authority may agree, on a discretionary and voluntary basis, and at the request of a manufacturer, to undertake an inspection of a manufacturer of active ingredients to satisfy specific requirements of a requesting authority. Alternatively, pending the development of specific guidelines for active pharmaceutical ingredients, the certifying authority may be able to attest that the manufacturer is an established supplier of the substance in question to manufacturers of finished dosage forms licensed for marketing under its jurisdiction.

4.6 Whenever a product is purchased through a broker or another intermediary, or when more than one set of premises has been involved in the manufacture and packaging of a product, the certifying authority should consider whether it has received sufficient information to satisfy itself that those aspects of the manufacture of the product for which the applicant is not directly responsible have been undertaken in compliance with GMP as recommended by WHO.

4.7 The certifying authority should officially stamp and date all copies of product information submitted to it in support of an application for a certificate and intended to be appended to the certificate. Every effort should be made to ensure that certificates and all annexed documentation are consonant with the version of the product licence operative on the date of issue. When available, the certifying authority will add a summary basis of approval or any other material that it may deem relevant. Translation by an applicant of these materials into a widely used language, preferably English, shall be deemed to satisfy the provisions of section 3.10.

4.8 Any additional attachment to a certificate submitted by the applicant, such as price lists of products for which bids are offered, should be clearly identified as not forming part of the attestation made by the certifying authority.

4.9 To avert potential abuse of the Scheme, to frustrate attempts at falsification, to render routine authentication of certificates by an independent authority superfluous, and to enable the certifying authority to maintain comprehensive records of countries to which specific products have been exported, each certificate should identify the importing country and be stamped on each page with the official seal of the certifying authority. If requested by the importing country, an identical copy, clearly marked as duplicate, should be forwarded by the certifying authority directly to that country's authority.

5. Notifying and investigating a quality defect

5.1 Each certifying authority undertakes to institute enquiries into any quality defect reported in a product exported in accordance with the provisions of the Scheme, on the understanding that:

- the complaint is transmitted, together with the relevant facts, through the competent authority in the importing country;

- the complaint is considered to be of a serious nature by the latter authority; and
- the defect, if it appeared after delivery of the product into the importing country, is not attributable to local conditions.

5.2 In the case of obvious doubt, a participating national authority may request WHO to assist in identifying an independent quality control laboratory to carry out tests for the purposes of quality control.

5.3 Each certifying authority undertakes to inform WHO and, as far as is possible, all competent national authorities, of any serious hazard newly associated with a product exported under the provisions of the Scheme or of any criminal abuse of the Scheme directed, in particular, to the export of falsely labelled, spurious, counterfeited or substandard pharmaceutical products. On receipt of such notification, WHO will transmit the message immediately to the competent national authority in each Member State.

5.4 WHO stands prepared to offer advice should difficulty arise in implementing any aspect of the Scheme or in resolving a complaint, but it cannot be a party to any resulting litigation or arbitration.

References

1. Quality control of drugs. In: *Twenty-second World Health Assembly, Boston, Massachusetts, 8-25 July 1969. Part I: Resolutions and decisions, annexes.* Geneva, World Health Organization, 1969: 99-105 (Official Records of the World Health Organization, No. 176).
2. Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. In: *Twenty-eighth World Health Assembly, Geneva, 13-30 May 1975. Part 1: Resolutions and decisions, annexes.* Geneva, World Health Organization, 1975: 94-95 (Official Records of the World Health Organization, No. 226).
3. Good manufacturing practices for pharmaceutical products. In: *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-second Report.* Geneva, World Health Organization, 1992: 14-79 (WHO Technical Report Series, No. 823).
4. WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. In: *Forty-first World Health Assembly, Geneva, 2-13 May 1988. Resolutions and decisions, annexes.* Geneva, World Health Organization, 1988: 53-55 (document WHA41/1988/REC/1).

Appendix 1
Model Certificate of a Pharmaceutical Product

Certificate of a Pharmaceutical Product¹

This certificate conforms to the format recommended by the World Health Organization (*general instructions and explanatory notes attached*).

No. of Certificate: _____

Exporting (certifying) country: _____

Importing (requesting) country: _____

1. Name and dosage form of product:

1.1 Active ingredient(s)² and amount(s) per unit dose:³

For complete qualitative composition including excipients, see attached.⁴

1.2 Is this product licensed to be placed on the market for use in the exporting country?⁵ yes/no (*key in as appropriate*)

1.3 Is this product actually on the market in the exporting country? yes/no/unknown (*key in as appropriate*)

If the answer to 1.2 is yes, continue with section 2A and omit section 2B.

If the answer to 1.2 is no, omit section 2A and continue with section 2B.⁶

2A.1 Number of product licence⁷ and date of issue:

2A.2 Product-licence holder (name and address):

2A.3 Status of product-licence holder.⁸ a/b/c (*key in appropriate category as defined in note 8*)

2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are:⁹

2A.4 Is Summary Basis of Approval appended?¹⁰ yes/no
(key in as appropriate)

2A.5 Is the attached, officially approved product information complete and consonant with the licence?¹¹ yes/no/not provided
(key in as appropriate)

2A.6 Applicant for certificate, if different from licence holder (name and address):¹²

2B.1 Applicant for certificate (name and address):

2B.2 Status of applicant: a/b/c (key in appropriate category as defined in note 8)

2B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form are:⁹

2B.3 Why is marketing authorization lacking?
not required/not requested/under consideration/refused
(key in as appropriate)

2B.4 Remarks:¹³ _____

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?
yes/no/not applicable¹⁴ (key in as appropriate)

If no or not applicable proceed to question 4.

3.1 Periodicity of routine inspections (years): _____

- 3.2 Has the manufacture of this type of dosage form been inspected?
yes/no (*key in as appropriate*)
- 3.3 Do the facilities and operations conform to GMP as recommended
by the World Health Organization?¹⁵
yes/no/not applicable¹⁴ (*key in as appropriate*)
4. Does the information submitted by the applicant satisfy the
certifying authority on all aspects of the manufacture of the
product?¹⁶
yes/no (*key in as appropriate*)

If no, explain: _____

Address of certifying authority:

Telephone number: _____ Fax number: _____

Name of authorized person:

Signature:

Stamp and date:

General instructions

Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the Scheme.

The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten.

Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

Explanatory notes

- ¹ This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.
- ² Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.
- ³ The formula (complete composition) of the dosage form should be given on the certificate or be appended.
- ⁴ Details of quantitative composition are preferred, but their provision is subject to the agreement of the product-licence holder.
- ⁵ When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.
- ⁶ Sections 2A and 2B are mutually exclusive.
- ⁷ Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.
- ⁸ Specify whether the person responsible for placing the product on the market:
 - (a) manufactures the dosage form;
 - (b) packages and/or labels a dosage form manufactured by an independent company; or
 - (c) is involved in none of the above.
- ⁹ This information can be provided only with the consent of the product-licence holder or, in the case of non-registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information.

It should be noted that information concerning the site of production is part of the product licence. If the production site is changed, the licence must be updated or it will cease to be valid.
- ¹⁰ This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.
- ¹¹ This refers to product information approved by the competent national regulatory authority, such as a Summary of Product Characteristics (SPC).
- ¹² In this circumstance, permission for issuing the certificate is required from the product-licence holder. This permission must be provided to the authority by the applicant.
- ¹³ Please indicate the reason that the applicant has provided for not requesting registration:
 - (a) the product has been developed exclusively for the treatment of conditions – particularly tropical diseases – not endemic in the country of export;
 - (b) the product has been reformulated with a view to improving its stability under tropical conditions;

- (c) the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;
 - (d) the product has been reformulated to meet a different maximum dosage limit for an active ingredient;
 - (e) any other reason, please specify.
- ¹⁴ Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.
- ¹⁵ The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations (WHO Technical Report Series, No. 823, 1992, Annex 1). Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).
- ¹⁶ This section is to be completed when the product-licence holder or applicant conforms to status (b) or (c) as described in note 7 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.

The layout for this Model Certificate is available on diskette in WordPerfect from the Division of Drug Management and Policies, World Health Organization, 1211 Geneva 27, Switzerland.

Appendix 2
Model Statement of Licensing Status of Pharmaceutical Product(s)

No. of Statement _____

Exporting (certifying) country:

Importing (requesting) country:

Statement of Licensing Status of Pharmaceutical Product(s)¹

This statement indicates only whether or not the following products are licensed to be put on the market in the exporting country.
 Applicant (name/address):

Name of product	Dosage form	Active ingredient(s) ² and amount(s) per unit dose	Product-licence no. and date of issue ³

The certifying authority undertakes to provide, at the request of the applicant (or, if different, the product-licence holder), a separate and complete Certificate of a Pharmaceutical Product in the format recommended by WHO, for each of the products listed above.

Address of certifying authority:

Telephone/fax numbers:

Name of authorized person:

Signature:

Stamp and date:

This statement conforms to the format recommended by the World Health Organization (general instructions and explanatory notes below).

General instructions

Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the Scheme.

The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten.

Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

Explanatory notes

¹ This statement is intended for use by importing agents who are required to screen bids made in response to an international tender and should be requested by the agent as a condition of bidding. The statement indicates that the listed products are authorized to be placed on the market for use in the exporting country. A Certificate of a Pharmaceutical Product in the format recommended by WHO will be provided, at the request of the applicant and, if different, the product-licence holder, for each of the listed products.

² Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.

³ If no product licence has been granted, enter "not required", "not requested", "under consideration" or "refused" as appropriate.

The layout for this Model Statement is available on diskette in WordPerfect from the Division of Drug Management and Policies, World Health Organization, 1211 Geneva 27, Switzerland.

Appendix 3

Model Batch Certificate of a Pharmaceutical Product

Manufacturer's/Official¹ Batch Certificate of a Pharmaceutical Product

This certificate conforms to the format recommended by the World Health Organization (*general instructions and explanatory notes attached*).

1. No. of Certificate: _____
2. Importing (requesting) authority: _____
3. Name of product: _____
- 3.1 Dosage form: _____
- 3.2 Active ingredient(s)² and amount(s) per unit dose: _____

- 3.2.1 Is the composition of the product identical to that registered in the country of export? yes/no/not applicable³ (*key in as appropriate*)
If no, please attach formula (including excipients) of both products.
4. Product-licence holder⁴ (name and address):

- 4.1 Product-licence number:⁴ _____
- 4.2 Date of issue:⁴ _____
- 4.3 Product licence issued by:⁴ _____
- 4.4 Product-certificate number :^{4,5} _____
- 5.1 Batch number: _____
- 5.2 Date of manufacture: _____
- 5.3 Shelf-life (years): _____
- 5.4 Contents of container: _____
- 5.5 Nature of primary container: _____
- 5.6 Nature of secondary container/wrapping: _____

- 5.7 Specific storage conditions: _____

5.8 Temperature range: _____

6. Remarks:⁶

7. Quality analysis

7.1 What specifications apply to this dosage form? Either specify the pharmacopoeia or append company specifications.⁷

7.1.1 In the case of a product registered in the exporting country, have the company specifications⁷ been accepted by the competent authority? yes/no (*key in as appropriate*)

7.2 Does the batch comply with all parts of the above specifications? yes/no (*key in as appropriate*)

7.3 Append certificate of analysis.⁸

It is hereby certified that the above declarations are correct and that the results of the analyses and assays on which they are based will be provided on request to the competent authorities in both the importing and the exporting countries.

Name and address of authorized person:

Telephone number: _____ Fax number: _____

Signature of authorized person: _____

Stamp and date: _____

General instructions

Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the Scheme.

These forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten.

Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

Explanatory notes

Certification of individual batches of a pharmaceutical product is only undertaken exceptionally by the competent authority of the exporting country. Even then, it is rarely applied other than to vaccines, sera and biologicals. For other products, the

responsibility for any requirement to provide batch certificates rests with the product-licence holder in the exporting country. The responsibility to forward certificates to the competent authority in the importing country is most conveniently assigned to the importing agent.

Any inquiries or complaints regarding a batch certificate should always be addressed to the competent authority in the exporting country. A copy should be sent to the product-licence holder.

- ¹ Strike out whichever does not apply.
- ² Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.
- ³ "Not applicable" means that the product is not registered in the country of export.
- ⁴ All items under 4 refer to the product licence or the Certificate of a Pharmaceutical Product issued in the exporting country.
- ⁵ This refers to the Certificate of a Pharmaceutical Product as recommended by the World Health Organization.
- ⁶ Indicate any special storage conditions recommended for the product as supplied.
- ⁷ For each of the parameters to be measured, the specifications give the values that have been accepted for batch release at the time of product registration.
- ⁸ Identify and explain any discrepancies from specifications. Government batch release certificates issued by certain governmental authorities for specific biological products provide additional confirmation that a given batch has been released, without necessarily giving the results of testing. The latter are contained in the manufacturer's certificate of analysis.

The layout for this Model Certificate is available on diskette in WordPerfect from the Division of Drug Management and Policies, World Health Organization, 1211 Geneva 27, Switzerland.

Appendix 4

Glossary and index

In order to facilitate understanding, terms used in the guidelines are explained here and/or reference is made to relevant sections. This appendix provides supplementary information and is not a formal part of the Scheme.

For the sake of clarity, all definitions taken from the glossary of "Good manufacturing practices for pharmaceutical products" (1) are preceded by an asterisk.

abuse of Scheme

See sections 4.9 and 5.2 of the guidelines.

active ingredients

See sections 1.5, 4.4 and 4.5 of the guidelines.

addresses of competent authorities

See sections 2.2 and 3.3 of the guidelines.

applicant

The party applying for a Product Certificate. This is normally the product-licence holder. Because certain data are confidential for commercial reasons, the competent authority in the exporting country must always obtain permission to release these data from the product-licence holder or, in the absence of a product licence, from the manufacturer.

authentication of certificates

See section 4.9 of the guidelines.

* *batch (or lot)*

A defined quantity of a starting material, packaging material, or product processed in a single process or series of processes so that it can be expected to be homogeneous. In the case of continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity. It may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to form a final homogeneous batch.

batch certificate

A document containing information, as set out in Appendix 3 of the guidelines, will normally be issued for each batch by the manufacturer. Furthermore, a batch certificate may exceptionally be validated or issued by the competent authority of the exporting country, particularly for vaccines, sera and other biological products. The batch certificate accompanies every major consignment (see also section 3.14 of the guidelines).

** batch number*

A distinctive combination of numbers and/or letters which specifically identifies a batch on the labels, the batch records, and the certificates of analysis, etc.

** bulk product*

A product that has completed all processing stages up to, but not including, final packaging.

certifying authority

The competent authority that issues product certificates. It must ensure that it possesses the capacities listed in section 2.4 of the guidelines.

charges for product certificates

See section 3.11 of the guidelines.

competent authority

The national authority as identified in the formal letter of acceptance in which each Member State informs WHO of its intention to participate in the Scheme. The extent of its participation should be indicated in the letter of acceptance (see section 2.1 of the guidelines). The competent authority can issue or receive certificates.

WHO makes available on request a continuously updated list of addresses of competent authorities and, when applicable, the specific conditions for participation.

competence and evaluation of national authority

See sections 2.4, 2.5 and 4.2 of the guidelines.

dosage form

The form of the completed pharmaceutical preparation, e.g. tablet, capsule, elixir, suppository.

drug regulatory authority

An authority appointed by the government of a Member State to administer the granting of marketing authorizations for pharmaceutical products in that country.

** finished product*

A product that has undergone all stages of production, including packaging in its final container and labelling.

free sale certificate

See section 3.2 of the guidelines.

GMP certificate

See section 3.2 of the guidelines.

importing agents, guidelines for
See section 3.4 of the guidelines.

language of product certificate
See section 3.10 of the guidelines.

licence holder
An individual or a corporate entity possessing a marketing authorization for a pharmaceutical product.

licensee
An individual or corporate entity responsible for the information and publicity on, and the pharmacovigilance and surveillance of batches of, a pharmaceutical product and, if applicable, for their withdrawal, whether or not that individual or corporate entity is the holder of the marketing authorization.

limits of certificate by competent authority
See sections 3.12 and 4.8 of the guidelines.

lot
See *batch*.

** manufacture*
All operations of purchase of materials and products, production, quality control, release, storage, shipment of finished products, and related controls.

** manufacturer*
A company that carries out at least one step of manufacture. (For the different categories of manufacturer, see Appendix 1, explanatory note no. 7.)

marketing authorization
See *product licence*.

pharmaceutical product
Any medicine intended for human use or administered to food-producing animals, presented in its finished dosage form or as an active ingredient for use in such dosage form, that is subject to control by pharmaceutical legislation in both the exporting state and the importing state.

product
See *pharmaceutical product*.

product certificate
A document containing the information as set out in Appendix 1 of the guidelines that is validated and issued for a specific product by the competent authority of the exporting country and intended for use by the

competent authority in the importing country or – in the absence of such an authority – by the drug procurement authority (see also section 3.5 of the guidelines).

Transmission of product certificate: see sections 3.8 and 4.9 of the guidelines.

Validity of product certificate: see section 3.9 of the guidelines.

When to request a product certificate: see section 3.5 of the guidelines.

product information

The approved product information referred to in section 4.7 of the guidelines and item 2A.5 of the Product Certificate. It normally consists of information for health professionals and the public (patient information leaflets), as approved in the exporting country and, when available, a data sheet or a Summary of Product Characteristics (SPC) approved by the regulatory authority.

product licence

An official document issued by the competent drug regulatory authority for the purpose of the marketing or free distribution of a product. It must set out, *inter alia*, the name of the product, the pharmaceutical dosage form, the quantitative formula (including excipients) per unit dose (using International Nonproprietary Names or national generic names, where they exist), the shelf-life and storage conditions, and packaging characteristics. It also contains all the information approved for health professionals and the public (except promotional information), the sales category, the name and address of the licence holder, and the period of validity of the licence.

product-licence holder

See *licence holder*.

** production*

All operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing and packaging, to completion of the finished product.

registration

Any statutory system of approval required at national level as a precondition for introducing a pharmaceutical product on to the market.

registration certificate

See *product licence*.

specifications

See Appendix 3, explanatory note 7.

statement of licensing status

See section 3.13 of the guidelines and Appendix 2.

Summary Basis of Approval

The document prepared by some national regulatory authorities that summarizes the technical basis on which the product has been licensed (see section 4.7 of the guidelines and explanatory note 9 of the Product Certificate contained in Appendix 1).

Summary of Product Characteristics (SPC)

Product information as approved by the regulatory authority. The SPC serves as the basis for production of information for health personnel as well as for consumer information on labels and leaflets of medicinal products and for control of advertising (see also *Product information*).

tenders and brokers

See section 4.6 of the guidelines.

WHO responsibility

See section 5.4 of the guidelines.

Reference

1. WHO Expert Committee on Specifications for Pharmaceutical Preparations. *Thirty-second report*. Geneva, World Health Organization, 1992:18-22 (WHO Technical Report Series, No. 823).