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SCHWEIZERISCHER BUNDESRAT
CONSEIL FÉDÉRAL SUISSE
CONSIGLIO FEDERALE SVIZZERO

Beschluss
Décision 28 SEP. 1992
Decisione

Adhésion des Pays-Bas à la Convention du 8 octobre 1970 pour la reconnaissance mutuelle des inspections concernant la fabrication des produits pharmaceutiques (PIC)

Vu la proposition du DFEP du 11 SEP. 1992

Vu les résultats de la procédure de co-rapport, il est

décidé:

1. L'invitation aux Pays-Bas d'adhérer à la Convention du 8 octobre 1970 pour la reconnaissance mutuelle des inspections concernant la fabrication des produits pharmaceutiques est approuvée.

2. Le cas échéant, l'entrée en vigueur de la Convention pour les Pays-Bas, 90 jours après le dépôt de son instrument d'adhésion, est approuvée.

3. Le DFEP est chargé de communiquer la présente décision au Gouvernement suédois, dépositaire de la Convention.

Protokollauszug an: ☒ ohne / ☐ mit Beilage				
z.V.	z.K.	Dep.	Anz.	Akten
	X	EDA	10	–
	X	EDI	5	–
	X	EJPD	5	–
		EMD		
		EFD		
X		EVD	5	–
		EVED		
	X	BK	3	–
		EFK		
		Fin.Del.		

Pour extrait conforme:

6.89 10000 49000/1

EIDGENÖSSISCHES VOLKSWIRTSCHAFTSDEPARTEMENT
DÉPARTEMENT FÉDÉRAL DE L'ÉCONOMIE PUBLIQUE
DIPARTIMENTO FEDERALE DELL'ECONOMIA PUBBLICA
DEPARTAMENT FEDERAL DA L'ECONOMIA PUBLICA

2310.1

Berne, le 11 septembre 1992

Au Conseil fédéral

Adhésion des Pays-Bas à la Convention du 8 octobre 1970 pour la reconnaissance mutuelle des inspections concernant la fabrication des produits pharmaceutiques (PIC)

En 1990, les autorités néerlandaises ont fait part de leur intérêt à adhérer à la PIC (RS 0.812.101). Selon l'art. 11 PIC, l'adhésion d'un nouveau membre ne peut intervenir que sur invitation des Parties contractantes et qu'à condition que l'Etat candidat dispose, sur le plan interne, des arrangements nécessaires pour garantir l'application de la Convention.

Les Pays-Bas ont fourni aux autorités compétentes des Parties contractantes toutes indications nécessaires sur leur législation en matière de produits pharmaceutiques et sur leur système d'inspection. Depuis 1987, des inspecteurs néerlandais ont suivi les séminaires PIC. En novembre 1991, une délégation PIC a été invitée par le ministère néerlandais compétent afin qu'elle puisse observer sur place le fonctionnement du système d'inspection.

Au terme de la procédure, le comité de la PIC en charge de l'examen de la candidature néerlandaise est parvenu à la conclusion que cet Etat remplit les conditions stipulées par la Convention.

Du point de vue de la politique suisse d'intégration, la participation des Pays-Bas à la PIC sera positive puisqu'elle portera à neuf le nombre des Etats membres de la Communauté européenne (Allemagne, Belgique, Danemark, France, Irlande, Italie, Portugal et Royaume-Uni) parties à la PIC. Cet élargissement accentue encore l'importance que revêt la PIC qui, à l'origine, a été conclue entre pays de l'AELE, dans le cadre de l'intégration européenne en matière de produits pharmaceutiques. La PIC a déjà vu son champ d'application géographique s'élargir de manière considérable, notamment de part l'invitation à l'adhésion adressée à

3.89 10000 48082/3

l'Australie. Cet Etat, tout comme la France, pourrait bien déposer sa demande formelle d'adhésion encore au courant de cette année.

En ce qui concerne les perspectives futures, la Turquie et le Luxembourg, mais aussi le Canada et le Japon ont entrepris des démarches en vue d'une adhésion éventuelle. Au terme de l'examen de chacune de ces candidatures, le DFEP soumettra une proposition au Conseil fédéral relative à l'invitation des Etats candidats qui satisfont aux exigences posées par la PIC.

Il est proposé que pour l'Etat néerlandais, la Convention entre en vigueur 90 jours après le dépôt de son instrument d'adhésion. Cette proposition peut être acceptée dès lors qu'elle correspond à la pratique suivie à ce jour en cas d'adhésions.

Consultés, la Chancellerie fédérale, l'Office fédéral de la santé publique/DFI, la Direction du droit international public/DFAE et l'Office fédéral de la justice/DFJP sont d'accord avec cette proposition.

Nous vous proposons de prendre la décision ci-jointe.

DEPARTEMENT FEDERAL DE L'ECONOMIE PUBLIQUE

Annexes: - Projet de décision du Conseil fédéral
- Recommandations du comité PIC chargé de l'examen des Pays-Bas du 11 mai 1992

Pour co-rapport à:

- ChF
- DFJP
- DFAE
- DFI

Extrait du procès-verbal à:

- ChF (2)
- DFI (5)
- DFAE (2)
- DFJP (2)
- DFEP (5)

Adhésion des Pays-Bas à la Convention du 8 octobre 1970 pour la reconnaissance mutuelle des inspections concernant la fabrication des produits pharmaceutiques (PIC)

Vu la proposition du DFEP du 11 septembre 1992

Vu les résultats de la procédure de co-rapport, il est

décidé:

1. L'invitation aux Pays-Bas d'adhérer à la Convention du 8 octobre 1970 pour la reconnaissance mutuelle des inspections concernant la fabrication des produits pharmaceutiques est approuvée.

2. Le cas échéant, l'entrée en vigueur de la Convention pour les Pays-Bas, 90 jours après le dépôt de son instrument d'adhésion, est approuvée.

3. Le DFEP est chargé de communiquer la présente décision au Gouvernement suédois, dépositaire de la Convention.

Pour extrait conforme:

PHARMACEUTICAL INSPECTION

CONVENTION

PH 2/92
11 May, 1992

RECOMMENDATION BY THE COMMITTEE OF OFFICIALS CONCERNING THE ACCESSION OF THE NETHERLANDS TO THE Pharmaceutical Inspection Convention

1. In July 1990, a letter from the Head of Inspectorate of Public Health for Drugs in the Netherlands to the Secretariat of the Pharmaceutical Inspection Convention announced the interest of the Netherlands in acceding to the Convention.

2. Information on the Dutch legislation regulating the manufacture and control of pharmaceutical products, and on the Dutch inspection system was provided and circulated by the Secretariat to all competent authorities as document PH/MISC 1/90. The information was discussed on the occasion of an informal exchange of views which took place in Geneva in December 1990 between the members of the PIC Committee of Officials and an Dutch pharmaceutical officials. Some clarification on the Dutch inspection system was provided at this meeting and additional information was later circulated as PH/MISC 1/91.

3. In conformity with the provisions contained in paragraph 31 of the Convention's Explanatory Notes, Dutch inspectors attended PIC Seminars (there have been Dutch participants to all Seminars having taken place since 1987).

4. In November 1991 a delegation of the PIC Committee of Officials was invited by the Dutch competent authority to come to the Netherlands in order to get better acquainted with the Dutch inspection system and to observe, during the visit to three pharmaceutical companies, the methods of GMP inspection applied by the Dutch inspectors in such companies. A report on the visit was made by the delegation and circulated to competent authorities (PH/W 5/91).

(continued)

Conclusions

5. The Committee of Officials, having duly studied the information on the control and production of pharmaceutical products in the Netherlands and on the basis of the report made on the visit by a delegation of its members, reached the conclusion that the Netherlands had the national arrangements necessary to apply an inspection system comparable to that referred to in the Pharmaceutical Inspection Convention and otherwise complied with the conditions laid down in the provisions of Convention. The Committee also took note of the confirmation given by the Dutch authority that additional staff would be appointed (two additional GMP inspectors and one administrative assistant) in order to satisfy the requirements concerning the frequency of inspections (once every two years). Confirmation was also given that imported pharmaceutical products manufactured in PIC Contracting States would not be submitted to re-analysis (cf. attached copies of the letter PIC 68/91 and of the answer received).

6. The Committee therefore recommends that steps be now taken in order to enable the depositary government to extend an invitation to the Netherlands to accede to the Convention.

7. In order to avoid delays in the consultation procedure, the Committee suggested to the Depositary Government that a deadline be set (four months) for answers by the Contracting States.

8. As to the entry into force of the Convention in relation to the Netherlands, a period of 90 days after the deposit of the instrument of accession could be suggested if no other proposal is made in this respect by the Netherlands.

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Note: All documents and information on the Dutch inspection system have been circulated to the competent authorities of the PIC Contracting States. Spare copies can be obtained on request from the Secretariat.

MINISTRY FOR
FOREIGN AFFAIRS
Trade Department

The Ministry for Foreign Affairs presents its compliments to the Embassy of Switzerland and has the honour to inform the Embassy that the Government of Sweden, as depositary for the Convention for the Mutual Recognition of Inspections in respect of the Manufacture of Pharmaceutical Products, done in Geneva on 8 October 1970 has received a Recommendation by the Committee of Officials set up under the Convention concerning the accession of the Netherlands to the Convention.

According to Article 11 of the Convention it is open to accession by such other States referred to in Article 11 as have the national arrangements necessary to apply an inspection system comparable to that referred to in the Convention. Any such State may accede to the Convention upon invitation of the Contracting States. Such invitation shall according to the Convention normally be preceded by contacts at expert level between the competent authorities in the State in question and the Contracting States.

Information on the Dutch legislation regulating the manufacture and control of pharmaceutical products, and on the Dutch inspection system was provided and circulated to all competent authorities in the Contracting States. Those documents were discussed on the occasion of two informal exchanges of views which took place in December 1990 between the members of the PIC Committee of Officials and pharmaceutical officials from the Dutch competent authority. Some clarification and additional information on the Dutch inspection system was provided and subsequently circulated.

In conformity with the provisions contained in paragraph 31 of the Convention's Explanatory Notes, Dutch inspectors attended PIC seminars since 1987.

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In November 1991, a delegation of the Committee of Officials was invited by the Dutch competent authority to come to the Netherlands in order to get better acquainted with the Dutch inspection system and to observe, during the visit to three pharmaceutical companies, the method of GMP inspection applied by the Dutch inspectors. A report on the visit was made by the delegation and circulated to competent authorities.

The Committee of Officials, having duly studied the information on the control and production of pharmaceutical products in the Netherlands and on the basis of the report made on the visit by a delegation of its members, reached the conclusion that the Netherlands had the national arrangements necessary to apply an inspection system comparable to that referred to in the Pharmaceutical Inspection Convention and otherwise complied with the reqirements laid down in the provisions of the Convention.

For this reason the Ministry for Foreign Affairs requests the Embassy of Switzerland to inform it whether the Swiss Government agrees that an invitation, to accede to the Convention, be extended to the Netherlands. In order to avoid unnecessary delays, a reply within four months from the date of this Note would be appreciated.

It would be appreciated if the contents of this note could be forwarded to the Government of the Principality of Liechtenstein through the good offices of the Swiss Government.

The Ministry for Foreign Affairs would also appreciate being informed of whether the Swiss Government accepts the proposal that the Convention shall enter into force in relation to the Netherlands 90 days after the date of deposit of the Dutch instrument of accession.

The Ministry for Foreign Affairs avails itself of this opportunity to renew to the Embassy of Switzerland the assurance of its highest consideration.

Stockholm 9 July 1992

MINISTRY FOR FOREIGN AFFAIRS

EMBASSY OF SWITZERLAND

Stockholm