

ANNEX I

**LIST OF THE PRODUCT NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE
MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION AND MARKETING
AUTHORISATION HOLDERS IN THE MEMBER STATES AND ICELAND**

Member State	MAH name and address	INN	Product Name	Strength	Pharmaceutical Form	Route of administration
Austria	Bayer HealthCare AG 51368 Leverkusen Germany	Moxifloxacin hydrochloride	Actira 400 mg - Filmdabletten	400 mg	Film-coated tablet	Oral use
Austria	Bayer HealthCare AG 51368 Leverkusen Germany	Moxifloxacin hydrochloride	Octegra 400 mg - Filmdabletten	400 mg	Film-coated tablet	Oral use
Austria	Bayer Austria GmbH Herbststraße 6-10 1160 Wien Austria	Moxifloxacin hydrochloride	Avelox 400 mg - Filmdabletten	400 mg	Film-coated tablet	Oral use
Bulgaria	Bayer AG 51368 Leverkusen Germany	Moxifloxacin	Avelox	400mg	Film-coated tablet	Oral use
Belgium	Bayer AG 51368 Leverkusen Germany	Moxifloxacin hydrochloride	Actira 400 mg	400 mg	Film-coated tablet	Oral use
Belgium	Bayer s.a.-n.v. Avenue Louise 143 Louizalaan B-1050 Bruxelles Belgium	Moxifloxacin hydrochloride	Avelox 400 mg	400 mg	Film-coated tablet	Oral use
Belgium	Therabel Pharma S.A. Rue Egide Van Ophem 108 1180 Bruxelles Belgium	Moxifloxacin hydrochloride	Proflox 400 mg	400 mg	Film-coated tablet	Oral use
Cyprus	Bayer Hellas S.A. Sorou 18-20 151 25 Marousi - Athens Greece	Moxifloxacin hydrochloride	AVELOX	400 mg	Film-coated tablet	Oral use
Czech Republic	Bayer HealthCare AG 51368 Leverkusen Germany	Moxifloxacin hydrochloride	Avelox	400 mg	Film-coated tablet	Oral use

Member State	MAH name and address	INN	Product Name	Strength	Pharmaceutical Form	Route of administration
Germany	Bayer Vital GmbH 51368 Leverkusen Germany	Moxifloxacin hydrochloride	Avalox 400 mg Filmtabletten	400 mg	Film-coated tablet	Oral use
Germany	Bayer HealthCare AG 51368 Leverkusen Germany	Moxifloxacin hydrochloride	Octegra 400 mg Filmtabletten	400 mg	Film-coated tablet	Oral use
Germany	Bayer HealthCare AG 51368 Leverkusen Germany	Moxifloxacin hydrochloride	Actira 400 mg Filmtabletten	400 mg	Film-coated tablet	Oral use
Germany	Bayer HealthCare AG 51368 Leverkusen Germany	Moxifloxacin hydrochloride	Actimax 400 mg Filmtabletten	400 mg	Film-coated tablet	Oral use
Denmark	Bayer HealthCare AG 51368 Leverkusen Germany	Moxifloxacin hydrochloride	Actira	400 mg	Film-coated tablet	Oral use
Denmark	Bayer HealthCare AG 51368 Leverkusen Germany	Moxifloxacin hydrochloride	Avelox	400 mg	Film-coated tablet	Oral use
Denmark	Teva Denmark A/S, Parallelvej 10, 2800 Kongens Lyngby Denmark	Moxifloxacin	Infekt	400 mg	Film-coated tablet	Oral use
Denmark	Teva UK Limited Brampton Road BN22 9AG East Sussex United Kingdom	Moxifloxacin	Moxifloxacin "Teva"	400 mg	Film-coated tablet	Oral use
Estonia	Bayer Health Care AG 51368 Leverkusen Germany	Moxifloxacin hydrochloride	Avelox	400 mg	Film-coated tablet	Oral use

Member State	MAH name and address	INN	Product Name	Strength	Pharmaceutical Form	Route of administration
Greece	Elpen SA Pharmaceutical Industry 95, Marathonos Avenue 190-09 Pikermi Greece	Moxifloxacin	Octegra	400 mg	Film-coated tablet	Oral use
Greece	Bayer Hellas Abee Sorou 18-20 15125 Maroussi - Athens Greece	Moxifloxacin	Avelox	400 mg	Film-coated tablet	Oral use
Greece	Bayer plc, Pharmaceutical Bayer House Strawberry Hill Newbury Berkshire RG14 1JA United Kingdom	Moxifloxacin	Proflox	400 mg	Film-coated tablet	Oral use
Spain	QUÍMICA FARMACEUTICA BAYER, S. A. Av. Baix Llobregat, 3 y 5 08970 Sant Joan Despi Barcelona Spain	Moxifloxacin hydrochloride	Actira 400 mg film coated tablets	400 mg	Film-coated tablet	Oral use
Spain	Procter and Gamble Pharmaceuticals Iberia, SL WTC Almeda park, Edif 1, 2º planta 08940 Cornellá de Llobregat Barcelona Spain	Moxifloxacin hydrochloride	Octegra 400 mg film coated tablets	400 mg	Film-coated tablet	Oral use
Spain	RECORDATI ESPAÑA, SL Carretera De Zeneta, 149 30588 Beniel (Murcia) Spain	Moxifloxacin hydrochloride	Havelox 400 mg film coated tablets	400 mg	Film-coated tablet	Oral use
Spain	Laboratorios Dr Esteve, SA Avda. Mare de Déu de Montserrat, 221 08041 Barcelona Spain	Moxifloxacin hydrochloride	Proflox 400 MG film coated tablets	400 mg	Film-coated tablet	Oral use

Member State	MAH name and address	INN	Product Name	Strength	Pharmaceutical Form	Route of administration
Finland	Bayer HealthCare AG 51368 Leverkusen Germany	Moxifloxacin hydrochloride	Actira	400 mg	Film-coated tablet	Oral use
Finland	Bayer HealthCare AG 51368 Leverkusen Germany	Moxifloxacin hydrochloride	Avelox	400 mg	Film-coated tablet	Oral use
France	BAYER SANTE 13, rue Jean Jaures 92807 PUTEAUX CEDEX France	Moxifloxacin hydrochloride	IZILOX 400 mg, comprimé pelliculé	400 mg	Film-coated tablet	Oral use
France	BAYER HEALTHCARE AG 51368 Leverkusen Germany	Moxifloxacin hydrochloride	OCTEGRA 400 mg, comprimé pelliculé	400 mg	Film-coated tablet	Oral use
Hungary	Bayer Hungária Kft Alkotás ut.50 1123 Budapest Hungary	Moxifloxacin hydrochloride	Avelox	400 mg	Film-coated tablet	Oral use
Iceland	Bayer HealthCare AG 51368 Leverkusen Germany	Moxifloxacin hydrochloride	Avelox	400 mg	Film-coated tablet	Oral use
Italy	Bayer S.p.A. Viale Certosa, 130 20156 Milano Italy	Moxifloxacin hydrochloride	Avalox	400 mg	Film-coated tablet	Oral use
Italy	Bayer AG 51368 Leverkusen Germany	Moxifloxacin hydrochloride	Proflox	400 mg	Film-coated tablet	Oral use
Italy	Innova pharma S.p.A. Via M. Civitali, 1 20148 Milano Italy	Moxifloxacin hydrochloride	Octegra	400 mg	Film-coated tablet	Oral use

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Italy	Sigma-Tau Industrie Farmaceutiche Riunite S.p.A. Viale Shakespeare, 47 00144 Roma Italy	Moxifloxacin hydrochloride	Actira	400 mg	Film-coated tablet	Oral use
Ireland	Bayer Limited The Atrium Blackthorn Road, Dublin 18 Ireland	Moxafloxacin hydrochloride	Avelox	400mg	Film-coated tablet	Oral use
Lithuania	Bayer HealthCare AG 51368 Leverkusen Germany	Moxifloxacin hydrochloride	Avelox	400 mg	Film-coated tablet	Oral use
Luxembourg	Bayer Healthcare AG 51368 Leverkusen Germany	Moxifloxacin hydrochloride	Actira	400 mg	Film-coated tablet	Oral use
Luxembourg	Bayer s.a.-n.v. Avenue Louise 143 Louizalaan 1050 Bruxelles Belgium	Moxifloxacin hydrochloride	Avelox	400 mg	Film-coated tablet	Oral use
Luxembourg	Therabel Pharma 110 Rue Egide Van Ochem 1180 Bruxelles Belgium	Moxifloxacin hydrochloride	Proflox	400 mg	Film-coated tablet	Oral use
Latvia	Bayer HealthCare AG 51368 Leverkusen Germany	Moxifloxacin hydrochloride	Avelox	400 mg	Film-coated tablet	Oral use
Malta	Bayer Vital GmbH 51368 Leverkusen Germany	Moxifloxacin hydrochloride	Avalox	400 mg	Film-coated tablet	Oral use

Member State	MAH name and address	INN	Product Name	Strength	Pharmaceutical Form	Route of administration
Netherlands	Bayer BV Energieweg 1 3641 RT Mijdrecht Nederland	Moxifloxacin hydrochloride	Avelox 400 mg tabletten	400 mg	Film-coated tablet	Oral use
Netherlands	Bayer HealthCare AG 51368 Leverkusen Germany	Moxifloxacin hydrochloride	Octegra 400 mg tabletten	400 mg	Film-coated tablet	Oral use
Poland	Bayer HealthCare AG 51368 Leverkusen Germany	Moxifloxacin hydrochloride	Avelox	400 mg	Film-coated tablet	Oral use
Portugal	Bayer AG 51368 Leverkusen Germany	Moxifloxacin hydrochloride	Actira	400 mg	Film-coated tablet	Oral use
Portugal	BayHealth - Comercialização de Produtos Farmacêuticos Unipessoal, Lda. Rua Quinta do Pinheiro, 5 2794-003 Carnaxide Portugal	Moxifloxacin hydrochloride	Avelox	400 mg	Film-coated tablet	Oral use
Portugal	Bialfar - Produtos À Av. da Siderurgia Nacional P.O. Box 56 4745-457 S. Mamede do Coronado Portugal	Moxifloxacin hydrochloride	Proflox	400 mg	Film-coated tablet	Oral use
Romania	Bayer HealthCare AG 51368 Leverkusen Germany	Moxifloxacin hydrochloride	Avelox	400 mg	Film-coated tablet	Oral use
Sweden	Bayer HealthCare AG 51368 Leverkusen Germany	Moxifloxacin hydrochloride	Avelox	400 mg	Film-coated tablet	Oral use

Member State	MAH name and address	INN	Product Name	Strength	Pharmaceutical Form	Route of administration
Sweden	Bayer HealthCare AG 51368 Leverkusen Germany	Moxifloxacin hydrochloride	Actira	400 mg	Film-coated tablet	Oral use
Sweden	Bayer HealthCare AG 51368 Leverkusen Germany	Moxifloxacin hydrochloride	Octegra	400 mg	Film-coated tablet	Oral use
Slovenia	BAYER d.o.o. Bravničarjeva 13 1000 Ljubljana Slovenia	Moxifloxacin hydrochloride	Avelox 400 mg filmsko obložene tablete	400 mg	Film-coated tablet	Oral use
Slovakia	Bayer HealthCare AG 51368 Leverkusen Germany	Moxifloxacin hydrochloride	Avelox 400	400 mg	Film-coated tablet	Oral use
United Kingdom	Bayer plc, Pharmaceutical Bayer House Strawberry Hill Newbury Berkshire RG14 1JA United Kingdom	Moxifloxacin hydrochloride	Avelox 400mg Tablets	400 mg	Film-coated tablet	Oral use