ANNEX I

LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTH OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member State	Marketing autorisation Holder	Invented Name	Strength	Pharmaceutical form	Route of administration
Austria	Bayer Austria GmbH (Schering Austria GmbH) Herbststr. 6 - 10 1160 Wien, Austria	Aliane	0.02 mg / 3 mg	film-coated tablets	Oral use
Belgium	Bayer S.A./N.V. 143, Avenue Louise 1050 Brussel, Belgium	Liofora	0.02 mg / 3 mg	film-coated tablets	Oral use
Cyprus	Bayer Hellas AG 18-20 Sorou Str 15125 Amaroussion Athens, Greece	Liofora	0.02 mg / 3 mg	film-coated tablets	Oral use
Czech Republic	Bayer Schering Pharma AG D-13342 Berlin Germany	Belanette	0.02 mg / 3 mg	film-coated tablets	Oral use
Denmark	Bayer Schering Pharma AG D-13342 Berlin Germany	Liofora	0.02 mg / 3 mg	film-coated tablets	Oral use
Estonia	Bayer Schering Pharma AG D-13342 Berlin Germany	Aliane	0.02 mg / 3 mg	film-coated tablets	Oral use
Finland	Bayer Schering Pharma Oy Pansiontie 47, FI-20210 Turku Finland	Liofora	0.02 mg / 3 mg	film-coated tablets	Oral use
France	Bayer Santé 13, Rue Jean Jaurès 92807 Puteaux Cedex France	Belanette	0.02 mg / 3 mg	film-coated tablets	Oral use

Germany	Jenapharm GmbH & Co. KG Otto - Schott - Str. 15 D-07745 Jena Germany	aida	0.02 mg / 3 mg	film-coated tablets	Oral use
Greece	Bayer Hellas AG 18-20 Sorou Str 15125 Amaroussion Athens Greece	Liofora	0.02 mg / 3 mg	film-coated tablets	Oral use
Hungary	Bayer Schering Pharma AG D-13342 Berlin Germany	Aliane	0.02 mg / 3 mg	film-coated tablets	Oral use
Ireland	Bayer Ltd. The Atrium, Blackthorn Road Dublin 18 Ireland	Liofora	0.02 mg / 3 mg	film-coated tablets	Oral use
Italy	Bayer S.P.A. Viale Certosa 130 20156 Milano Italy	Aliane	0.02 mg / 3 mg	film-coated tablets	Oral use
Latvia	Bayer Schering Pharma AG D-13342 Berlin Germany	Aliane	0.02 mg / 3 mg	film-coated tablets	Oral use
Lithuania	Bayer Schering Pharma AG D-13342 Berlin Germany	Aliane	0.02 mg / 3 mg	film-coated tablets	Oral use
Luxembourg	Bayer S.A./N.V. 143, Avenue Louise 1050 Brussel	Liofora	0.02 mg / 3 mg	film-coated tablets	Oral use

	Belgium				
Malta	Bayer Schering Pharma AG D-13342 Berlin Germany	Aliane	0.02 mg / 3 mg	film-coated tablets	Oral use
Netherlands	Bayer B.V. Energieweg 1 3641 RT Mijdrecht The Netherlands	Belanette	0.02 mg / 3 mg	film-coated tablets	Oral use
Norway	Bayer Schering Pharma AG D-13342 Berlin Germany	Liofora	0.02 mg / 3 mg	film-coated tablets	Oral use
Poland	Bayer Schering Pharma AG D-13353 Berlin Germany	Aliane	0.02 mg / 3 mg	film-coated tablets	Oral use
Portugal	Lusal, Produção Químico-Farmacêutica Luso-Alemã, Lda. Estrada Nacional 249, Km 15 2725-397 Mem Martins Portugal	Aliane	0.02 mg / 3 mg	film-coated tablets	Oral use
Slovakia	Bayer Schering Pharma AG D-13342 Berlin Germany	Aliane	0.02 mg / 3 mg	film-coated tablets	Oral use
Slovenia	Bayer Schering Pharma AG D-13342 Berlin Germany	Liofora	0.02 mg / 3 mg	film-coated tablets	Oral use
Spain	Química Farmacéutica Bayer, S.L. Av. Baix Llobregat, 3-5 08970 Sant Joan Despí, Barcelona Spain	Liofora	0.02 mg / 3 mg	film-coated tablets	Oral use

Sweden	Bayer Schering Pharma AG D-13342 Berlin Germany	Liofora	0.02 mg / 3 mg	film-coated tablets	Oral use

ANNEX II

SCIENTIFIC CONCLUSIONS

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The Belanette blister is glued in a carton which is subsequently folded to a wallet configuration. The wallet with the inserted blister is assembled with a package leaflet (PL) and all components are wrapped together with clear, transparent cellophane wrapping to form the unit pack which prevents the loss of individual components. The product is marketed in pack size of 3 x 21 film-coated tablets.

OVERALL SUMMARY OF THE SCIENTIFIC EVALUATION OF BELANETTE AND ASSOCIATED NAMES (see Annex I)

The required basic information (how to use the product, what to do in case of missed dose, etc.), which ensures the safe use of the product is present on the cardboard wallets and visible through the cellophane wrapping. Once the cellophane wrapping is removed the safe use of the product is still ensured as the cardboard wallets contain the required information. In addition it is not possible to separate blisters from cardboard wallets and therefore the users always have access to the required information. Moreover cardboard wallets protect blisters against damage.
The risk resulting from the separation of a package leaflet from cardboard wallets is comparable with the risk resulting from separation of blisters from conventional external packaging (cardboard box).

Although different observations in respect to readability of the Braille text through the cellophane wrapping have been made by blind users, it is assumed that before use of the product the cellophane wrapping will be removed and therefore blind person will be in a position to identify the product. It has also been confirmed by blind persons that the Braille text on the cardboard is palpable and readable.
Since it is a prescription medicine, the name of the product always will be known to the blind user as during the visit the physicians inform patients about medicinal product they are prescribing, including the name of the product. Therefore blind users will be able to double check the information written on the cardboard wallets (Braille text) with the information obtained from a physician (during the visit). Finally taking into account that the medicinal product is intended for long term use, the possible mistakes and misuse are further minimised.

ANNEX III

SUMMARY OF PRODUCT CHARACTERISTICS,
LABELLING AND PACKAGE LEAFLET

The valid Summary of Product Characteristics, labelling and package leaflet are the final versions achieved during the Coordination group procedure.