Text consolidated by Valsts valodas centrs (State Language Centre) with amending regulations of:

10 April 2012 [shall come into force on 13 April 2012];

25 November 2014 [shall come into force on 1 January 2015];

22 May 2018 [shall come into force on 25 May 2018];

31 August 2021 [shall come into force on 7 September 2021].

If a whole or part of a paragraph has been amended, the date of the amending regulation appears in square brackets at the end of the paragraph. If a whole paragraph or sub-paragraph has been deleted, the date of the deletion appears in square brackets beside the deleted paragraph or sub-paragraph.

Republic of Latvia

Cabinet

Regulation No. 378

Adopted 17 May 2011

**Procedures for Advertising Medicinal Products and Procedures by Which a Medicinal Product Manufacturer is Entitled to Distribute Free Samples of Medicinal Products to Physicians**

*Issued pursuant to*

*Section 5, Clause 5 and Section 56 of the Pharmaceutical Law and Section 7, Paragraph two of the Advertising Law*

**I. General Provisions**

1. This Regulation prescribes:

1.1. the procedures for the advertising of medicinal products (except for veterinary medicinal products);

1.2. the procedures by which a medicinal product manufacturer or importer is entitled to distribute free samples of medicinal products to physicians. Medicinal products which are not labelled as free samples but which are delivered free of charge to medical treatment institutions (as a gift or donation), as well as free samples of medicinal products to medical education and scientific institutions (investigational medicinal products), shall be distributed in accordance with the laws and regulations regarding the procedures for the distribution and quality control of medicinal products.

[*25 November 2014*]

2. This Regulation shall apply to any form of notification, activity, and measure if the purpose thereof is to promote the prescription, distribution, or use of medicinal products, including:

2.1. the advertising of medicinal products to the general public;

2.2. the advertising of medicinal products to those persons who have the right to prescribe or distribute medicinal products (hereinafter – the specialist), including:

2.2.1. the provision of information on medicinal products by a person authorised by an advertiser (hereinafter – the medical sales representative);

2.2.2. the visits of medical sales representatives at specialists;

2.2.3. the distribution of the free samples of medicinal products;

2.2.4. the incitation to prescribe or distribute specific medicinal products by offering gifts or any other material or other kind of benefit;

2.2.5. the organisation and sponsorship of promotional and scientific events attended by specialists, in particular payment for their travel and accommodation expenses related thereto;

2.2.6. material or other support to associations and foundations which bring together specialists, medical treatment institutions, and subjects of pharmaceutical activity for participation in scientifically and professionally oriented events;

2.2.7. any visual, written, or oral advertisement which is used in the cases referred to in Paragraph 35 of this Regulation;

2.2.8. information on the studies of the marketing authorisation holders or their authorised representatives and financing used thereby for development, and information on the payment for the publications of specialists.

[*25 November 2014; 31 August 2021*]

3. The Regulation shall not apply to:

3.1. the labelling and package leaflet of medicinal products which conform to the requirements specified in the laws and regulations regarding the labelling of medicinal products if they are not used separately from the medicinal products in order to advertise them;

3.2. correspondence if it is of non-promotional nature and it is needed to answer a specific question regarding the particular medicinal products;

3.3. informative announcements containing data and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general precautions for the use of medicinal products, and also trade catalogues and price lists in which the therapeutic indications of preparations are not indicated or which do not contain an advertising of medicinal products;

3.4. statements relating to human health or diseases, provided there is no reference, even indirect, to medicinal products;

3.5. information provided to an individual patient by the specialist on the specific medicinal products which the patient needs;

3.6. [22 May 2018].

4. It is prohibited to advertise medicinal products which are not registered in the Republic of Latvia and are not entered in the Medicinal Product Register of Latvia or which have not been registered according to the centralised registration procedure of medicinal products of the European Medicines Agency, and the registration or re-registration of which is not valid.

5. Such advertising of medicinal products is prohibited in which:

5.1. medicinal products are offered as a gift or compensation for the purchase of any goods or receipt of a service;

5.2. a gift is offered for the purchase of medicinal products;

5.3. the public is offered to purchase specific medicinal products with a discount or free of charge;

5.4. in advertising medicinal products, a competition, game, or other similar event is organised the participants or winners of which receive benefits – gifts for participation or awards for winning;

5.5. claims are made regarding medicinal products that they are safe without a corresponding qualitative assessment, they are not toxic, or do not cause addiction.

[*25 November 2014*]

6. The medicinal products which have been included on the list of reimbursable medicinal products in accordance with the laws and regulations regarding the reimbursement of expenditures for the acquisition of medicinal products intended for outpatient medical treatment shall be distributed only for the pharmacy price specified by the National Health Service, and they may not be offered and distributed in pharmacies with additional discount.

[*10 April 2012*]

7. The general requirements for the advertising of medicinal products shall be as follows:

7.1. the information provided in the advertisement conforms to the particulars listed in the summary of the product characteristics;

7.2. the information provided in the advertisement encourages rational use of the medicinal product, is objective, and does not exaggerate the properties of the medicinal product;

7.3. the advertisement is not misleading;

7.4. the comparative advertisement of the medicinal product conforms to the requirements specified in this Regulation and the Advertising Law.

8. In advertisements of homeopathic medicinal products registered according to the simplified registration procedure, only the information included in the labelling or in the package leaflet may be used.

9. When advertising medicinal products that are registered as traditional herbal medicinal products, the statement “*Tradicionālas augu izcelsmes zāles, ko lieto norādītajām indikācijām, pamatojoties vienīgi uz ilgstošā laikā iegūtiem rezultātiem*” [Traditional herbal medicinal products that are used for specific indications based exclusively on the results acquired over a long period of time] shall be included in the advertisement.

**II. Advertising of Medicinal Products to the General Public**

10. Medicinal products which have been specified as non-prescription medicinal products in accordance with the laws and regulations regarding classification of medicinal products may be advertised.

11. It is prohibited to advertise the following to the public:

11.1. medicinal products which, in accordance with the laws and regulations regarding classification of medicinal products, have been specified as medicinal products for the use of which a written indication drawn up by a medical practitioner is required (hereinafter – the prescription medicinal products);

11.2. medicinal products which contain the narcotic and psychotropic substances to be controlled in Latvia, doping substances, medicinal products which have been recognised as narcotic analgesic agents by the State Agency of Medicines, and medicinal products which contain active substances with high pharmacovigilance risk, in accordance with the laws and regulations regarding the regulations for the production and storage of prescription forms, and also for the writing out and storage of prescriptions;

11.3. medicinal products the purchase costs of which are partly or fully covered from State budget funds.

[*22 May 2018*]

12. The prohibitions specified in Paragraph 11 of this Regulation shall not apply to the vaccines which are advertised by an advertiser during a vaccination campaign. The issue of a vaccination campaign shall, on the basis of a submission of the advertiser and the available epidemiological data, be examined by the Centre for Disease Prevention and Control within 15 days after receipt of the submission. If the Centre for Disease Prevention and Control takes the decision to approve a vaccination campaign, it shall determine the term for the vaccination campaign and inform the Health Inspectorate and the advertiser thereof.

[*10 April 2012*]

13. It is prohibited to distribute medicinal products to the public for advertising purposes.

14. Advertisements for medicinal products to the general public shall be designed so that there could be no doubt that the information distributed is an advertisement and the product being advertised is a medicinal product.

15. If the advertisement for the medicinal products referred to in Paragraph 11 of this Regulation which are intended for specialists is distributed in electronic mass media, the advertiser and distributor of advertising shall ensure that the information is not accessible to the public.

16. An advertisement for medicinal products to the public shall include at least the following information if particular medicinal products are advertised:

16.1. the name of the medicinal product and also the general name specified in the laws and regulations regarding the procedures for the labelling of medicinal products and the requirements to be met for the package leaflet of medicinal products if the medicinal product contains only one active substance;

16.2. information that is necessary for the correct use of the medicinal product;

16.3. a clear and legible invitation to carefully read the package leaflet or the relevant information on the packaging;

16.4. an invitation to consult with a physician or pharmacist on the use of the medicinal product;

16.5. the warning “*Zāļu nepamatota lietošana ir kaitīga veselībai*” [Unreasonable use of medicinal products is harmful to your health]. Such warning shall take up not less than 10 per cent of the visual amount of the advertisement. The size of letters must be such that the title would take up the largest technically available part of the area intended for a warning text. In video advertisements, such warning shall be retained throughout advertisement, whereas in audio advertisements, the warning shall be expressed at the end of the advertisement text;

16.6. the advertiser.

[*25 November 2014*]

17. An advertisement for medicinal products to the general public may indicate only the name of the medicinal product or the international non-proprietary name thereof, or trade mark if the advertisement is intended as a reminder of a previously distributed advertisement.

18. In an advertisement for medicinal products to the general public, it is prohibited to include information which:

18.1. suggests treatment by mail or providing advice in another similar way and which gives the impression that the diagnosis may be determined without involving a medical practitioner;

18.2. suggests that the effects of the medicinal product are guaranteed, use of the medicinal product is unaccompanied by adverse reactions, and the effects of the medicinal product are equivalent to or better than those of another method of medical treatment or another medicinal product;

18.3. suggests that the overall health condition of the patient will significantly improve by taking the medicinal product;

18.4. suggests that the health of the patient may deteriorate by not taking the relevant medicinal product. This condition shall not apply to the advertising of the vaccines referred to in Paragraph 12 of this Regulation;

18.5. is directed exclusively or principally at children;

18.6. refers to recommendations by scientists, health care professionals, or such persons who are not part of any of the abovementioned categories, but could encourage the consumption of medicinal products because of their celebrity;

18.7. suggests that the medicinal product is a foodstuff, cosmetic, or other consumer product;

18.8. suggests that the safety and efficacy of the medicinal product is guaranteed due to the fact that it is natural;

18.9. could, by a description or detailed representation of a medical history, lead to erroneous diagnosis;

18.10. refers, in improper, alarming, or misleading terms, to claims of recovery;

18.11. uses, in improper, alarming, or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the effect of the medicinal product on the human body or parts thereof;

18.12. promotes the purchase of the medicinal product, justifying the necessity of the purchase of the medicinal product with the price of the medicinal product by announcing a special clearance sale or providing a notification that the medicinal product is sold together with another medicinal product (including for a lowered price) or goods.

[*25 November 2014*]

**III. Advertising of Medicinal Products to Specialists**

19. Advertisements for medicinal products to specialists shall include at least the following information:

19.1. the most essential information which conforms to the summary of the product characteristics;

19.2. whether the medicinal product belongs to the group of prescription or non-prescription medicinal products;

19.3. the date when the advertising was developed or reviewed the last time;

19.4. the advertiser.

[*25 November 2014*]

20. An advertisement for medicinal products to specialists may indicate only the name of the medicinal product or the international non-proprietary name thereof, or trade mark if the advertisement is intended as a reminder of a previously distributed advertisement.

21. Information included in the advertisement for medicinal products to specialists shall be:

21.1. accurate, up-to-date, verifiable, and complete so that the recipient could evaluate the therapeutic value of the relevant medicinal product;

21.2. quoted verbatim from medical journals or other scientific publications with references to the source of quotations, tables, and other illustrative material.

22. Advertisements for medicinal products to specialists shall be placed only in scientific and informative press publications intended for specialists or in specially prepared advertising materials, or in websites intended only for specialists, ensuring that there is a warning prior to opening the advertisement that the content of the site is intended only for specialists. The warning must appear every time when the relevant website is opened.

[*25 November 2014*]

23. The marketing authorisation holder or a representative authorised thereby, or another person who is the advertiser or distributor of advertising may not, directly or indirectly, offer, promise, or supply to specialists any material benefit or benefit of another kind. When advertising medicinal products, the advertiser and distributor of advertising may supply and the specialist may accept only educational materials which are intended directly for the education of specialists and the value of which does not exceed EUR 10 (excluding value added tax).

[*22 May 2018*]

24. In scientific conferences, congresses, seminars, and other scientifically or professionally oriented events which also provide for the advertising of medicinal products to specialists, the representation expenses of the advertiser shall be subordinated to the professional or scientific objective of the event and they may only pertain to specialists in accordance with the restrictions specified in Paragraph 32.1 of this Regulation.

[*22 May 2018*]

25. Specialists may not solicit, request, or accept any material benefit or benefit of another kind that is prohibited in accordance with Paragraph 23 of this Regulation or is contrary to Paragraph 24 of this Regulation.

26. Specialists in medical treatment institutions may be informed of medicinal products only outside office hours for accepting patients, agreeing upon the time of the visit with the specialist beforehand and complying with the procedures stipulated by the head of the medical treatment institution. In pharmacies, specialists may be informed of medicinal products, agreeing upon the time of the visit with the head of the pharmacy beforehand.

[*25 November 2014*]

27. Free samples of medicinal products may be distributed by a manufacturer or importer of medicinal products, a representative authorised thereby, or by a wholesaler of medicinal products with which the manufacturer or importer of medicinal products has entered into an agreement for the distribution of free samples of medicinal products (hereinafter – the distributor of free samples of medicinal products) in conformity with the following conditions:

27.1. the packaging of the free sample of the medicinal product is the smallest trade unit of the relevant medicinal product;

27.2. the labelling of the free sample of the medicinal product conforms to the laws and regulations regarding the procedures for the labelling of medicinal products and the requirements specified for the package leaflet of medicinal products;

27.3. a copy of the summary of the product characteristics is appended to each free sample of the medicinal product;

27.4. the storage regime specified in the labelling and package leaflet of the medicinal product and the term of validity of the medicinal product is conformed to;

27.5. free samples of medicinal products, for the purpose of introduction, are supplied only to persons who have the right to prescribe the particular medicinal products;

27.6. free samples of medicinal products may be distributed only according to a written request signed and dated by a medical practitioner or the head of the medical treatment institution in which the name, strength, or concentration of the medicinal products, the pharmaceutical form and number of packages are indicated;

27.7. the distributor of free samples of medicinal products, when distributing free samples of medicinal products, appends an accompanying document thereto in which at least the following information is indicated:

27.7.1. the date of supply;

27.7.2. the name, pharmaceutical form, and strength or concentration of the medicinal product;

27.7.3. the term of validity of the medicinal product;

27.7.4. the serial number of manufacture of the medicinal product;

27.7.5. the number of free samples of the medicinal product;

27.7.6. the manufacturer of the medicinal product;

27.7.7. the name, address of the medical treatment institution and given names, surnames, specialities of medical practitioners;

27.7.8. the name and address of the distributor of free samples of medicinal products;

27.7.9. information shall be appended to the medicinal products the use of which may result in increased risk to health that the measures for reducing the risk developed by the marketing authorisation holder and agreed upon with the State Agency of Medicines must be conformed to for the safe and efficient use of the particular medicinal products;

27.8. not more than four free samples of prescription medicinal product of the same name may be distributed within a year to each person who has the right to prescribe the particular medicinal product, and to all persons together – not more than 1000 free samples of prescription medicinal products of the same name within a year;

27.9. free samples of medicinal products may be distributed to a person who has the right to prescribe the particular medicinal product not more than two years after the relevant person or head of the medical treatment institution has requested free samples of the particular medicinal products for the first time;

27.10. the distributor of free samples of medicinal products shall establish a system for the accounting and control of the supplied free samples of medicinal products in which the information indicated in the accompanying document referred to in Sub-paragraph 27.7 of this Regulation has been included.

[*25 November 2014*]

27.1 Distribution of free samples of medicinal products to only use them for the medical treatment of patients or as the incitation to prescribe, recommend, purchase, sell, or use specific medicinal products is prohibited.

[*25 November 2014*]

27.2 Distribution of free samples of medicinal products is prohibited if:

27.21. the medicinal product contains the narcotic and psychotropic substances to be controlled in Latvia;

27.22. the medicinal product contains doping substances;

27.23. the State Agency of Medicines has recognised the medicinal product as narcotic analgesic preparation;

27.24. the medicinal product contains active substances with high pharmacovigilance risk, in accordance with the laws and regulations regarding the regulations for the production and storage of prescription forms, and also for the writing out and storage of prescriptions.

[*25 November 2014; 22 May 2018*]

28. The distributor of free samples of medicinal products shall, each year (by 31 January), notify to the State Agency of Medicines the data on the free samples of medicinal products distributed in the previous calendar year, indicating:

28.1. the registration number of the medicinal product;

28.2. the name, pharmaceutical form, strength, or concentration of the medicinal product;

28.3. the number of distributed samples;

28.4. the date of supply;

28.5. the recipient.

[*25 November 2014*]

**IV. Requirements for the Marketing Authorisation Holder of the Medicinal Products to be Advertised, the Representatives Authorised Thereby, Advertisers, Distributors of Advertising, and Medical Sales Representatives**

[*25 November 2014*]

29. The marketing authorisation holder shall establish a scientific service which prepares information on the medicinal products represented thereby and compile the information provided by medical sales representatives on the results of the use of medicinal products.

[*25 November 2014*]

30. The marketing authorisation holder or a representative authorised thereby, or another person who is an advertiser or distributor of advertising shall ensure that:

30.1. the requested information that is necessary for monitoring on the advertising material of the medicinal product (text, image, audio recording or video recording, advertising media), the method for distributing the advertising, the distribution commencement date, and the target audience to whom the advertising is addressed as well as advertising materials of the medicinal product in electronic form is provided, without delay, to officials of the Health Inspectorate;

30.2. advertisements of the medicinal product conform to this Regulation and other laws and regulations governing advertising and commercial practice;

30.3. the medical sales representatives under its supervision are trained appropriately, with sufficient knowledge to be able to provide as accurate and complete information as possible on the medicinal products being advertised, and to perform their obligations in accordance with this Regulation.

[*25 November 2014*]

31. When advertising medicinal products to the specialist, a medical sales representative shall also issue a summary of the product characteristics being advertised.

32. A medical sales representative shall provide to the scientific service referred to in Paragraph 29 of this Regulation all information on the results of the use of the medicinal products being advertised with particular reference to the observed adverse reactions in accordance with the information provided by specialists.

32.1 When organising and sponsoring the professionally and scientifically oriented events referred to in Paragraph 24 of this Regulation and also providing material or other support to associations, foundations, medical treatment institutions, and subjects of pharmaceutical activity for the participation of specialists in such events, the marketing authorisation holder or a representative authorised thereby, or another person who is the advertiser or distributor of advertising shall ensure the storage of documents and information in accordance with Paragraph 35.1 of this Regulation and shall comply with the following conditions:

32.11. it is not a sports, tourism, recreational event or an entertainment event of another kind;

32.12. the event is directly related to a benefit to the development of science and medicine and improvement of health care;

32.13. if the event is organised outside Latvia, a justification of the association, foundation, or medical treatment institution for the participation of the specialist in the event has been received;

32.14. for specialists who are registered for participation in an event (also in an event where medicinal products are not advertised), only the registration fee, training materials, travel and accommodation expenses, including catering expenses within the scope of the event programme, may be paid;

32.15. material or other support does not promote the prescribing or use of the medicinal product with the specific name.

[*25 November 2014; 31 August 2021*]

32.2 The person referred to in Paragraph 32.1 of this Regulation shall, once a year (by 30 May) by using the form available on the website of the Health Inspectorate, electronically submit to the Inspectorate a notification on the previous year. The following shall be indicated in the notification:

32.21. name, registration number, and legal address of the submitter of the notification;

32.22. information on the recipient of the material or other support (including a donation or gift):

32.22.1. name, registration number, and legal address of the association, foundation, medical treatment institution or subject of pharmaceutical activity;

32.22.2. given name, surname, and speciality of the specialist who participated in the event;

32.22.3. amount of the material or other support in monetary terms (if there are several recipients of the material or other support, the amount of the material or other support shall be indicated for each recipient individually);

32.22.4. objective of the material or other support (shall be indicated for each recipient of the material or other support individually);

32.22.5. name, place, and time of the event;

32.23. information on each event organised or sponsored by the submitter of the notification:

32.23.1. name, place, and time of the event;

32.23.2. information on the consideration to the specialists involved in the organisation and course of the event (lecturers and consultants), indicating the given name, surname, and speciality of each specialist and the consideration received thereby;

32.23.3. summarised information on the costs of the organising and implementation of the event, except for that referred to in Sub-paragraph 32.23.2 of this Regulation, by including expenditures of catering, lease of premises, and technical equipment, fee of a third party (if such is involved), fee for the examination of the event application, expenditures of the preparation of the documents confirming participation, lease fee of the space for a stand at an event of another organiser;

32.24. information on the amount spent on studies and development;

32.25. information on the payment for publications of specialists, indicating the given name, surname, and speciality of each specialist and the consideration received thereby.

[*22 May 2018; 31 August 2021*]

32.3 If the person referred to in Paragraph 32.1 of this Regulation has not provided material or other support to associations, foundations, and medical treatment institutions and also has not organised or sponsored events in the previous year, it shall be indicated in the notification to the Health Inspectorate.

[*22 May 2018 / Paragraph shall come into force on 1 January 2019. See Paragraph 2 of Amendments*]

32.4 The information specified in Paragraphs 32.2 and 32.3 of this Regulation shall be published by the Health Inspectorate on its website by 31 July.

[*22 May 2018 / Paragraph shall come into force on 1 January 2019. See Paragraph 2 of Amendments*]

**V. Monitoring of Advertisements for Medicinal Products**

33. The advertiser shall, 15 days prior to the commencement of the vaccination campaign referred to in Paragraph 12 of this Regulation, submit to the Health Inspectorate the advertising material of vaccine which has been prepared in accordance with the requirements of this Regulation if an approval of the Centre for Disease Prevention and Control has been received for the relevant vaccination campaign.

[*10 April 2012*]

34. If amendments have been approved to the registration documentation of a medicinal product or the data of clinical trials which are in contradiction with the advertising material of medicinal products have been published, the advertiser or distributor of advertising shall, without delay, suspend the distribution of the advertisement.

35. If seminars, conferences, congresses, competitions, exhibitions, and other events where medicinal products are advertised are organised, the organiser of the event or the advertiser, if the advertiser is not the organiser of the event, shall submit information in writing to the Health Inspectorate not later than seven days before the relevant event, including through the website www.latvija.lv, indicating the organiser and sponsor of the event, the advertiser of medicinal products, the persons responsible for the advertising of medicinal products, the range of participants invited, the place and time of the event, and also providing a description of the event programme.

[*25 November 2014*]

35.1 The organisers and advertisers of the events referred to in Paragraphs 32.1 and 35 of this Regulation shall, in accordance with the laws and regulations regarding the conducting and organisation of accounting, ensure the storage of the documentation related to the organising of events, including the storage of source documents on the financing of events and provision of support, and also the storage of advertising materials according to the record-keeping procedures stipulated in the institution or undertaking, but for not less than two years.

[*25 November 2014*]

36. Non-governmental organisations that are related to the field of pharmacy may develop and approve a joint code of ethics for the advertising of medicinal products which conforms to the Advertising Law, this Regulation, and the international ethical standards for the advertising of medicinal products.

37. Conformity with this Regulation shall be monitored by the Health Inspectorate. The Health Inspectorate shall commence an inspection regarding the possible violations in the field of the advertising of medicinal products on the basis of a submission or complaint or upon its own initiative. The Health Inspectorate has the right to request and receive documents and information on the preparation and distribution of advertisements and also on the financing of the events referred to in Paragraphs 32.1 and 35 of this Regulation and payment of the participation fee for specialists in order to ensure the monitoring of conformity with this Regulation.

[*25 November 2014*]

**VI. Closing Provisions**

38. Cabinet Regulation No. 167 of 6 March 2007, Procedures for Advertising of Medicinal Products and the Procedures by Which a Medicinal Product Manufacturer is Entitled to Give Free Samples of Medicinal Products to Physicians (*Latvijas Vēstnesis*, 2007, No. 41, 63; 2008, No. 53; 2009, No. 126), is repealed.

39. The advertising materials the distribution of which has been commenced until the day of coming into force of this Regulation shall be revised according to the requirements of this Regulation by 1 July 2011.

40. The advertising materials the distribution of which has been commenced until 1 January 2015 shall be revised according to the requirements provided for in Sub-paragraphs 16.6 and 19.4 of this Regulation by 30 June 2015.

[*25 November 2014*]

41. The notification referred to in Paragraph 32.2 of this Regulation on 2015 shall be submitted for the first time by 31 March 2016.

[*25 November 2014*]

**Informative Reference to European Union Directives**

This Regulation contains legal norms arising from:

1) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use;

2) Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use;

3) Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.

Prime Minister V. Dombrovskis

Acting for the Minister for Health, Minister for Education and Science R. Broks