Medicines Evaluation Board

Policy document

Parallel import: marketing authorisation and maintenance

MEB 14
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Contents

1. New applications

1.1 Introduction

The parallel import of medicinal products is the import and subsequent marketing in the Netherlands of a medicinal product that has been authorised elsewhere in the EU by an importer who has not been designated by the original marketing authorisation holder, whilst an identical or virtually identical version of this medicinal product is already authorised in the Netherlands, the so- called Dutch reference product.

The parallel product may not be authorised by means of the central procedure, since this would otherwise result in parallel distribution instead of parallel import. Applications for parallel distribution are handled by the EMA, not the MEB.

Section 48(1) of the Medicines Act states that the Dutch reference product must have a marketing authorisation issued by the MEB. This means that the Dutch reference product must not have been authorised through the central procedure, since the MEB does not issue authorisations for central products; these are handled by the EMA.

An application for awarding a parallel marketing authorisation is processed in accordance with Section 48 of the Medicines Act (*Geneesmiddelenwet*) and according to the policy set out in this document.

A parallel marketing authorisation is valid for the same indications, contra-indications, adverse reactions, dosage and method of use and administration as for the reference medicinal product (Section 48(2) of the Medicines Act). The Dutch reference product must have a valid marketing authorisation at the time of submission of the application for the parallel product.

The parallel product will be given the legal status of supply as it was awarded to the Dutch reference product. If the legal status of supply of the Dutch reference product changes following authorisation of the parallel product, the parallel product must adopt this new status of supply.

The MEB will assess whether the product to be parallel imported does not differ from the Dutch reference product in terms of safety and efficacy and whether the requested parallel product can therefore be considered identical or virtually identical to the Dutch reference product. When assessing an application for awarding a parallel marketing authorisation, the starting point is that the product already has a valid marketing authorisation elsewhere in the EU and that trade barriers may not be created, unless there is a risk to public health.

1.2 Assessment criteria for parallel application

1.2.1 Identical or virtually identical

A. General

The assessment will determine whether the product to be parallel imported does not differ from the reference product in terms of safety and efficacy; the parallel product must be identical or virtually identical to the reference product (Section 48(1) of the Medicines Act). The following assessment criteria are important in this case:

- A reference product must be designated that is authorised in the Netherlands. This reference product must have a valid marketing authorisation at the time of submission of the application for the parallel import product (see §1.2.5).
- The dosage to be administered must be identical or virtually identical (see §1.2.1-B and §1.3.11-B).
- The qualitative and quantitative composition of the active ingredient or active ingredients of the product to be parallel imported must be identical to that of the reference product.
- The qualitative composition of the excipients must be identical or virtually identical. In the case of products with a local effect or products with controlled release, this requirement also applies to the quantitative composition. An exception to these conditions can only be made if it can be assumed that the difference in excipients does not lead to a difference in efficacy and safety between the requested parallel product and the Dutch reference product (see §1.2.1-C).
- The pharmaceutical form of the product to be parallel imported must be identical to that of the reference product. The various oral immediate release forms are considered to be the same pharmaceutical form in this respect.
- The method of administration, preparation and supplied devices (including dosage accuracy) must be identical to those of the Dutch reference product. A difference is only acceptable if it can be assumed that this will not result in possible incorrect use and, consequently, pose a risk to public health (see §1.2.1-D).
- The storage conditions of the parallel import product (before and after opening, after further preparation) and, if relevant, its in-use shelf life as approved in the country of origin must be identical to those of the Dutch reference product. A difference in storage conditions and/or storage period compared to those approved for the reference product is only acceptable if it is not expected to result in problems with use and subsequent risk to public health (see §1.2.1-E).
- The packaging size to be imported should be identical or virtually identical to the packaging size approved for the Dutch reference product. A difference in packaging size is only acceptable if this falls within the same legal status of supply and if the same dosage
  schedule (treatment duration) can be followed as has been approved for the Dutch reference product (see §1.2.1-F). In such cases, different packaging sizes must have the same origin. An additional packaging size that falls under a different marketing authorisation, or originates from a different Member State, must be submitted as a new application and will be fully assessed.
- If the finished product manufacturer of the parallel product is not the same as the finished product manufacturer of the Dutch reference product, an agreement between the parallel marketing authorisation holder and the marketing authorisation holder of the parallel product in the country of origin,

or an agreement between the parallel marketing authorisation holder and the wholesaler in the country of origin, must be submitted. This agreement must state that, in the event of a quality defect, recall or pharmacovigilance issues, the marketing authorisation holder of the parallel product must be informed accordingly by the marketing authorisation holder or the wholesaler in the country of origin. This agreement must be signed by the marketing authorisation holder or the wholesaler in the country of origin of the parallel product, and the relevant product must be referred to in the agreement. As it is usually impossible for the parallel applicant to identify the finished product manufacturer of the parallel product and of the Dutch reference product, respectively, the MEB will request such an agreement when it is found that the finished product manufacturer of the parallel product is not identical to that of the Dutch reference product. If the parallel marketing authorisation holder receives a report on a quality defect, recall or pharmacovigilance issue, he must pass on this information to the MEB immediately.

- For parallel products with an active substance containing a complex biological active ingredient, the MEB will check whether the product derives from the same production location. If the origin (production location/finished product manufacturer) is different from that of the Dutch reference product, the parallel product cannot, generally speaking, be regarded as identical or virtually identical to the Dutch reference product. According to the EU legislation governing biological medicines, a biological medicinal product has a specific production process (Annex 1 of Directive 2001/83/EC). Medicinal products that are manufactured according to a parallel but not identical production process can therefore not be regarded as identical or virtually identical.

B. Difference in (function of) a break line

If there is a difference between (the function of) a break line of the parallel product and the Dutch reference product, it may be that the dosage instruction is not entirely feasible. If the difference concerns the function (to divide the tablet into equal halves/to make it easier to break the tablet) or absence of a break line in the parallel product, the parallel applicant must substantiate that the parallel product is identical or virtually identical to the Dutch reference product. To this end, it must also be assessed whether the entire dosage instruction and all indications are still feasible. If a break line has been added for the parallel product while this is missing from the Dutch reference product, it must be checked whether the foreign package leaflet includes information about the function of the break line. If so, this information must be included in the Dutch package leaflet for the parallel product.

C. Difference in excipients

The composition of a parallel product and the Dutch reference product in terms of excipients should be virtually identical in this case. In the case of products with a local effect and products with controlled release, even a quantitative difference in excipients can result in differences in biological availability and subsequent differences in efficacy and/or safety.

A difference in excipients is only acceptable if this does not result in a difference in safety and/or efficacy.

D. Difference in method of administration and/or preparation

If the method of administration differs from that of the Dutch reference product, for example due to a difference in (the dosage accuracy of) supplied devices and/or preparation of the parallel product (this also includes a difference in compatibility with various solvents/diluents or a difference in final concentration or concentration range), this can endanger the patient's safety. There is a risk that the medical professional or the user is not used to or not familiar with the method of preparation and/or administration of the parallel product, which could result in incorrect use. The parallel application cannot be accepted in such cases.
See also §1.2.2, §1.3.6. and §1.3.8.

E. Difference in storage conditions and in-use shelf life

The product to be parallel imported must be kept under the storage conditions approved by the regulatory authority in the country of origin. This relates both to the storage conditions before opening and the storage conditions that apply after first use of the product (after opening and, if relevant, further preparation). In addition, the product to be parallel imported must be kept in accordance with its in-use shelf life as approved in the country of origin, if such a shelf life has been set. The reason for this is that the regulatory authority in the country of origin has used the data in the dossier to stipulate the conditions that guarantee the quality of the product.
The storage conditions and, if relevant, in-use shelf life of the product to be parallel imported can sometimes differ (slightly) compared to those of the Dutch reference product. If the difference is such that switching from the Dutch reference product to the parallel product or vice versa in daily practice could result in errors in storage that could result in a risk to the user, the parallel application cannot be accepted.
If a difference in storage conditions exists, the comparison form (see §1.3.4) must be used to argue whether or not this can result in a risk to the user.
If the Dutch reference product has more stringent storage conditions, these should not be adopted for the product to be parallel imported.

In the case of OTC medicinal products, the shelf life and storage conditions after opening should always be stated. See also MEB 6.

F. Packaging size and legal status of supply

The packaging size of medicinal products should be identical or virtually identical to the packaging size approved for the Dutch reference product. If this is not the case, the MEB will assess whether the packaging size matches the treatment duration as stated in the SmPC of the reference product. The MEB also assesses whether the packaging size to be imported falls within scope of the channelling of the reference product. The packaging size can determine whether a product is awarded the 'Pharmacy only' (PH), 'Pharmacy and Drugstore only' (PDO) or 'General Sales' (GS) status. The packaging size that will be imported must fall under the same legal status of supply as has been approved for the reference product. If this is not the case and/or the treatment duration approved for the reference product cannot be performed with the packaging size that is to be imported, the parallel application cannot be accepted. In such cases, different packaging sizes must have the same origin. An additional packaging size that falls under a different marketing authorisation, or originates from a different Member State, must be submitted as a new application and will be fully assessed.
See also §1.2.2.

1.2.2 Change in packaging contents

The contents of the packaging (e.g. a medical device) of the product to be parallel imported may only be changed if this change is essential to ensure that the parallel product is identical or virtually identical to the reference product, e.g. in order to eliminate a difference in use. A proposal for a change in the contents of the packaging must be clearly described and substantiated in the application for a parallel marketing authorisation. It is up to the MEB to determine whether the change in the contents of the packaging will result in both products being identical or virtually identical and whether this is acceptable. If necessary, the MEB will also assess any additional items for quality, for example. The parallel applicant may need to submit additional data for this assessment. See also §1.3.8.

Changes to the packaging size are subject to the conditions described in §1.3.15-B.

1.2.3 Product is a medical device in the country of origin

If the product to be parallel imported is not authorised as a medicinal product in the country of origin, but as a medical device (as denoted by a CE marking on the packaging), the application is not acceptable. The quality requirements for medicinal products are more stringent than for medical devices. Furthermore, medical devices are not assessed by a regulatory authority for medicinal products such as the MEB, but by a Notified Body. As a result, the dossier does not meet the requirement of Directive 2001/83/EC. Legal entities intending to import a medical device should contact the competent authority about this.

1.2.4 Parallel import of a product from a European sister company

The marketing authorisation holder in the country of origin of the product to be parallel imported may not be the same company as and may not be affiliated[1] to the legal entity that intends to market the product in the Netherlands (the importer/future parallel marketing authorisation holder). The parallel import is not permitted if they are the same entity or if they are affiliated to each other. The Mutual Recognition Procedure (MRP) should be followed instead. For more information about the MRP, please refer to the HMA website.

An exception to this is made in the case of parallel import of an 'own' medicinal product, meaning the importer for the product to be imported is already in possession of a valid marketing authorisation in both the country of export and the country of import. In that case, the importer in the Netherlands has two authorisations for the same product, a 'normal' marketing authorisation and a parallel marketing authorisation.

[1] As stated in Commission Communication No. 98C 229/03, companies are considered to be the same entity if they belong to the same parent company or group of parent companies, or if they have 'concluded agreements' (e.g. 'licensees') or 'concerted practices' exist for the marketing of medicinal products.

1.2.5 Ongoing suspension or withdrawal of authorisation or a GMP/GCP problem for the Dutch reference product

If the MEB intends to suspend or withdraw the marketing authorisation of the Dutch reference product due to problems regarding the efficacy, safety or quality, the MEB will place a clock-stop on the parallel application until a decision has been made regarding the suspension or withdrawal. The parallel application cannot be accepted if the suspension or withdrawal is enforced.

If there is a report pending for the Dutch reference product in relation to the GMP or GCP status and this applies or could also apply to the parallel product, the parallel application cannot be accepted before the GMP or GCP problem is resolved.

1.3 Data and documentation to be submitted

1.3.1 Introduction

A. Documentation

This must demonstrate that the parallel product is identical or virtually identical to the Dutch reference product. The applicant must submit the following documents to underpin the parallel application:

1. application letter (§1.3.2);
2. application for the granting of a parallel import authorisation (§1.3.3);
3. comparison form (§1.3.4);
4. comparison photo (colour) of the parallel import product and the Dutch reference product and of any included medical device (§1.3.5);
5. photograph (colour) of all sides of the foreign inner and outer packaging (§1.3.5);
6. foreign package leaflet;
7. proposed package leaflet for the parallel product (Word file) (§1.3.11);
8. package leaflet declaration (§1.3.11);
9. proposed label text (Word file) or new outer packaging (PDF file) (§1.3.15);
10. manufacturing authorisation, with or without wholesale distribution authorisation, or parallel wholesale distribution authorisation: copy or EudraGMP reference (§1.3.18).

Depending on the situation, the following documentation may also be needed:

11. authorised translation of all or parts of the foreign package leaflet (§1.3.13);
12. proof that the parallel product and the Dutch reference product have completed the same MRP/DCP (§1.3.4);
13. declaration regarding the connection between the proposed parallel marketing authorisation holder and the marketing authorisation holder in country of origin (§1.3.4);
14. declaration from the Member State of origin of the parallel import and copy of notification to the patent holder, or a declaration that the parallel product is no longer subject to a patent or supplementary protection certificate (§1.3.19);
15. package leaflet for medical professionals (§1.3.12);
16. declaration regarding the package leaflet for medical professionals (§1.3.12);
17. additional educational material and a declaration that the material is and will

remain verbatim identical to the Dutch reference product (§1.3.16);
18. Controlled Access Program (CAP)/Controlled distribution system and a declaration that the material is verbatim identical to the Dutch reference product and will remain so (see §1.3.17);
19. declaration about making certain information invisible on the foreign packaging (§1.3.15);
20. foreign SmPC (§1.3.6);
21. authorised translation of parts of the foreign SmPC (§1.3.6 and §1.3.13);
22. additional data to substantiate that the parallel import product and the Dutch reference product are identical or virtually identical (§1.3.7);
23. supporting evidence for a change in the content of the packaging of the parallel import product (§1.3.8);
24. sample of the parallel product (§1.3.9);
25. braille declaration (§1.3.20);
26. declaration regarding the batch release of blood products and vaccines (§1.3.21);
27. mock-up in colour of the new outer packaging (secondary packaging) and separate document with packaging text;
28. a declaration that the proposed packaging size is not available on the market in the country of origin and that the proposed packaging size has been approved for the Dutch reference product

The sections below provide a further explanation of the requirements for a parallel application dossier.

B. Structure of submission

The MEB has established an electronic format for parallel applications. It has been obligatory to use this as of 12 August 2015. Parallel applications submitted after this date that do not conform to the electronic format for parallel marketing authorisations will not be processed. More information about this format is available on the MEB website.

1.3.2 Application letter

The application letter must at least contain the following information:
- that this is a request for awarding of a marketing authorisation for a product to be parallel imported;
- the proposed product name;
- the country of origin;
- the RVG (Register of Packaged Medicinal Products) number of the Dutch reference product;
- the legal entity or natural person submitting the application (the future parallel marketing authorisation holder);
- the name and full address of the manufacturer(s) responsible for the repackaging and release of the parallel product that is the subject of the application;
- the name, telephone number and email address of the person who is handling the application on behalf of the submitting legal entity or natural person (contact person). This person must sign and date the application letter.

1.3.3 Application for a parallel import marketing authorisation

The template for the application for awarding of a parallel marketing authorisation is available on the MEB website.

The application for awarding of a parallel marketing authorisation must at least contain the following details:

1. the proposed product name;
2. the legal entity or natural person submitting the application (the future parallel marketing authorisation holder);
3. the name of the person who is handling the application on behalf of the submitting legal entity or natural person. This person must sign and date the application.

1.3.4 Comparison form

The template for the comparison form is available on the MEB website.

The comparison form clearly states which data must be completed. The following points are important:

1. The comparison form must be signed and dated by the Qualified Person who will release the parallel import product once it has been labelled in Dutch or following complete repackaging and replacement of the foreign package leaflet by a Dutch package leaflet.
2. If the parallel product and the Dutch reference product have completed the same MRP/DCP, the comparison form does not have to be completed in its entirety. The reason for this is that – in this case – the parallel product and the Dutch reference product are exactly the same product (the same authorisation dossier). The comparison form clearly describes which minimum information must be provided in this situation.
3. If the parallel product and the Dutch reference product have not completed the same MRP/DCP, the 'Declaration regarding the connection between the proposed parallel marketing authorisation holder and the marketing authorisation holder in country of origin' must be completed and submitted. A model declaration can be found on the MEB website. See also §1.2.4.

Re 2: If the parallel importer claims that the parallel product and the Dutch reference product have completed the same MRP or DCP, a copy of the MRI product index must be added to the application dossier. This can be added as an annex to the comparison form.

1.3.5 Comparison photograph and photograph of the parallel product

The application dossier must include a comparison photograph, depicting both the Dutch reference product and the parallel product, as well as all sides, including the inside, if this features information, of the inner and outer packaging and, if relevant, the further contents (e.g. applicators, measuring cups and injection needles) of both products. For included medical devices, the CE marking, manufacturer and dimensions must be visible. Based on this information, the MEB will assess whether the products differ in appearance, method of preparation and/or administration and/or (contents of) the packaging in such a way that it could result in the parallel product and reference product not being considered identical or virtually identical.
However, it is possible that the Dutch reference product is not available on the market, meaning that the parallel applicant is unable to submit the required comparison photograph. The parallel importer should state this clearly in the application dossier. The MEB will then consult other sources to assess whether both products are identical

or virtually identical.

A colour photograph of the parallel product should always be submitted, with all sides of the inner and outer packaging and the entire contents clearly visible. See also §1.3.14.

1.3.6 Foreign SmPC

If the product to be parallel imported needs to be dissolved or diluted before use, the comparison form must state which solvents or diluents the parallel and reference products are compatible with. This also applies to the final concentration or concentration range after dilution, if relevant.
This information must be obtained from the SmPC for the product. This means that the foreign SmPC must be consulted for the parallel product. This foreign SmPC, as well as an authorised translation of the relevant section, must form part of the application dossier.
The foreign SmPC does not have to be included only if a complete description of the compatibility with certain solvents or diluents and the final concentration or concentration range are included in the foreign package leaflet. After all, the foreign package leaflet always has to be included in the application dossier. It remains essential to submit an authorised translation of the relevant section(s) of the foreign package leaflet (see §1.3.13).

The requirement to submit information relating to compatibility with certain solvents or diluents and the final concentration or concentration range does not apply if the parallel and reference products form part of the same MRP or DCP.

The foreign SmPC must also be added to the application dossier, including an authorised translation of the sections that are referred to, if it was used as a source for other information in the comparison form.

1.3.7 Additional information about being identical or virtually identical

If there are one or more differences between the parallel product and the reference product (particularly differences in the characteristics listed under §1.2.1), an underpinning of why both products can nevertheless be considered identical or virtually identical must be included.

1.3.8 Change in packaging contents

If the parallel importer wishes to change the contents of the packaging of the product to be parallel imported in order to ensure that the parallel product is identical or virtually identical to the reference product, this change and the reason underpinning it must be included in the application dossier. If the parallel applicant wishes to add or replace a device, data (including data on quality) for the device (e.g. details of the manufacturer and the CE marking, and proof of dosage accuracy) must also be submitted so that the MEB can assess whether the device is comparable in use and quality to the approved device for the reference medicinal product. See also §1.2.2.

Changes to the packaging size are subject to the conditions described in §1.3.15-B.

1.3.9 Sample of the parallel product

There is no standard requirement to submit samples of the product to be parallel imported. However, the parallel importer must have a sample available and submit this sample if requested to do so by the MEB.

1.3.10 Nomenclature of parallel product

The MEB strongly prefers that the parallel importer selects the name used for the Dutch reference product. This reduces the risk of confusing the user.
If the Dutch reference product has a name that is no longer permitted according to the current nomenclature policy ('Nomenclature of pharmaceutical products', MEB 13), the MEB will accept the use of a name in the 'old style' for the parallel product.
If the applicant suggests a product name that is not identical to that of the reference product, this will only be accepted if the name meets the requirements of the current MEB nomenclature policy.

1.3.11 Proposed package leaflet

A. Verbatim identical/identical

The package leaflet for the parallel product must be verbatim identical to the Dutch reference product as regards the sections on indications, contra-indications, adverse events, dosage, method of use and method of administration. The other sections of the parallel package leaflet must be identical, preferably verbatim identical, to the reference package leaflet, with the exception of those sections of the package leaflet that contain parallel-specific information; see §1.3.11-B. A declaration to this effect must accompany all applications. The template for this package leaflet declaration is available on the MEB website.

In addition, the package leaflet for the parallel product is generally subject to the same requirements as the package leaflet for the Dutch reference product as described in the policy document 'Package leaflet of pharmaceutical products' (MEB 5). Annex 1 'Information on sections of package leaflet sections in the QRD template' in MEB 5 contains an upside down triangle (▼) as a symbol for products 'subject to additional monitoring'. This symbol is used in the SmPC, the package leaflet and any educational materials. If this symbol is shown in the package leaflet (and any educational materials) of the reference product, it must also be included in the package leaflet (and any educational materials) of the parallel product; see also §1.3.16.

If the reference product is a medicinal product that has been authorised without Dutch translations, the MEB will request the marketing authorisation holder of the reference product with English product information to submit a high-quality Dutch translation of the product information within 1 month. See also Policy Document MEB 41 'MEB policy concerning marketing authorisations without Dutch translations of the product information and/or mock-ups'. The parallel package leaflet should be based on this Dutch version of the package leaflet (see also § 1.6).

B. Stating parallel-specific information

Attention must be paid to the correct stating of the parallel-specific information in the

proposed package leaflet, i.e. the characteristics where the parallel product may differ from the reference product, namely:

1. Product name:
   This must be stated completely and clearly recognisably at the top of the package leaflet, even in the case of a combined package leaflet.
   If the product name in the country of origin differs from that of the parallel product, section 6 of the package leaflet must state the product name in the country of origin by means of the following standard sentence: *'The product mentioned in this package leaflet is marketed in the country of origin under the name <foreign product name>'.*
   NB: given that a parallel marketing authorisation concerns a national authorisation, it is not permitted to include the text '*This medicinal product is authorised in Member States of the EEA under the following names: The Netherlands + country of origin*' in the package leaflet.
2. Excipients:
   The excipients of the parallel product must be stated in the package leaflet as they are in the foreign package leaflet.
3. Warning for excipients:
   Warnings for certain excipients as stipulated in the 'Guideline on the excipients' (MEB 08) must be included, if applicable. (Please note that the relevant excipient must also be listed on the label, followed by a reference to the package leaflet, such as: '*Please read the package leaflet for further information*').
4. Method of preparation and/or administration:
   The method of preparation and/or administration (this includes the compatibility with certain solvents/diluents and the final concentration or concentration range, if relevant for the product) must be included where applicable to the parallel import product.
5. Instructions for correct use on the immediate packaging:
   If the foreign immediate packaging contains instructions for correct use, these instructions must be placed in Dutch on the parallel labelling (see also §1.3.15-B). However, if relabelling of the immediate packaging is not possible (see §1.3.15-A), a translation of these instructions must be included in the parallel package leaflet. This applies, for example, to calendar packaging where the abbreviations of the days of the week are stated in a language other than Dutch on the foreign strip or blister packaging. These abbreviations must then be translated in the package leaflet.
   Please note: if the contents of the packaging (e.g. addition/removal of device) are amended because this is essential to ensure that the parallel product is identical or virtually identical to the Dutch reference product, the foreign instructions for use may no longer apply or no longer apply completely. The instructions for use then need to be amended. If changes to the contents of the packaging ensure that the use and administration are exactly identical to the reference product, the text included in the reference package leaflet may be copied verbatim.
6. Contents of the packaging:
   The contents of the packaging must be stated exactly as the parallel importer wishes to market it in the Netherlands.
7. Packaging size:
   The packaging size listed in the package leaflet must correspond to the packaging size that will actually be imported. If the packaging size has been changed, the new packaging size must be stated (see also §1.3.15-B).
8. Storage conditions (before and after opening and further preparation) and in-use shelf life: The storage conditions (before and after opening and further preparation) of the parallel product and, if relevant, its in-use shelf life as

approved in the country of origin must be stated in the proposed package leaflet. (See §1.2.1-E.)

9. Dosage schedule (more pharmaceutical forms and strengths):
   If the package leaflet of the Dutch reference product contains more strengths than the package leaflet of the parallel product, this can have consequences for the feasibility of the dosage instructions and even the indication(s):
   a. If not all the dosages are feasible with the requested parallel product, this must be stated using the following standard sentence in the parallel package leaflet: *'The recommended dosages cannot all be achieved with <this product> <these products>. However, other products with a lower strength than <strength> are also available'.*
   b. If it transpires that a patient needs to use a lot of tablets, capsules, etc. of a product to achieve the recommended dosage, the following sentence can be included:
      'The recommended doses are possible with this product. However, products with a higher strength than <strength> are also available, which means that fewer tablets are needed at a time'.
   c. If certain indications are not feasible with the requested parallel product, this indication and any information related to this indication must be removed from the parallel package leaflet.
10. Description of appearance of parallel product:
    If the package leaflet of the Dutch reference product states the appearance (such as the shape, colour and presence and function of the break line) of the product, such information must also be included in the package leaflet of the parallel product. Of course, this information must refer to the details of the product to be parallel imported.
11. RVG number:
    The complete RVG number of the parallel product must be stated on the package leaflet (and on the label). At the time of submission of the application, the parallel importer only knows the RVG2 (the RVG number of the reference product). Therefore, the MEB will complete the RVG1 on the package leaflet and on the label. The parallel applicant must do the same for the printed versions of the package leaflet and the label.
12. Country of origin:
    The country of origin must be stated, preferably after the RVG number (e.g. as follows: 'L.v.h.: Griekenland').
13. Batch release manufacturer:
    The batch release manufacturer(s) of the product to be imported must be stated in the package leaflet. Even if no manufacturers are listed in the Dutch reference package leaflet, the batch release manufacturers of the product to be imported must still be added to the parallel package leaflet. If multiple batches are brought in parallel from the country of origin, with different package leaflets listing different batch release manufacturers, the manufacturers mentioned in both foreign package leaflets may be listed in the parallel package leaflet. However, it must clearly be explained why the batch release manufacturers from the different package leaflets are listed in the parallel package leaflet and also both foreign package leaflets must be submitted.
14. The date of approval and version management:
    The date of approval will be entered by the MEB. This is the date on which the package leaflet is adopted by the MEB. In this regard, the following QRD text must be used: '*This package leaflet was last approved in [Month Year]*'.

In connection with a possible infringement of trademark law, the parallel applicant may

also include the following information in the package leaflet and/or the label/new outer packaging:

15. Origin of included accessory:
    If the parallel applicant has added an item to the packaging, the origin of this item may be stated in the package leaflet and/or on the label/new outer packaging.
16. Name of original marketing authorisation holder:
    The name of the original marketing authorisation holder in the country of origin *may* be included in the package leaflet and/or on the label/new outer packaging. However, this must be done in such a manner that it does not result in confusion for the user as to who is responsible for placing the parallel product on the Dutch market.

(See §1.3.15-B and -C).

Combined package leaflet

A 'combined package leaflet' refers both to the combining of different strengths or pharmaceutical forms of a certain product in a single package leaflet and to the inclusion in one package leaflet of several products with the same strengths and pharmaceutical form that have been imported from different countries. In general, both situations are permitted for parallel package leaflets. The various products in the combined package leaflet can differ in product name, strength, packaging size, storage conditions, etc. The combined package leaflet must clearly state which data applies to which product. This must be achieved by at least stating the RVG number after the (product- specific) information that applies to that product. More distinguishing characteristics are permitted. However, if there are numerous differences between the parallel-specific information of the various products in the combined package leaflet, this can result in the package leaflet becoming unclear or confusing. In that case, separate package leaflets must be drawn up for the various products.

1.3.12 Information for medical professionals

As stated in the document 'Package leaflet of pharmaceutical products' (MEB 5), for parenterals and other pharmaceutical products that are usually used in hospitals, information for medical professionals must be added in addition to a package leaflet containing information for the patient. The information intended for the patient and for the medical professionals must be clearly separated from each other. This can be achieved in the form of two separate package leaflets (patient package leaflet and information for the medical professionals) or by including the information for medical professionals under a perforated line at the bottom of the package leaflet.

If the reference product contains information for medical professionals, this information must also be included for the parallel product. The information for medical professionals must be verbatim identical to the information for the reference product, except for the parallel-specific information (as stated under §1.3.11-B). The information for medical professionals, as well as a signed declaration that this information is verbatim identical for the parallel and reference products, should be added to the application dossier. The template for the declaration is available on the MEB website. In addition, the following sentence should be included at the bottom of the patient package leaflet:
<The following information is only for doctors or other healthcare professionals>.

If the information for medical professionals for the reference product consists of the entire SmPC, the product-specific information for the parallel product must be adopted correctly when copying this SmPC for the parallel product (see also above under §1.3.11-B). The information in section 6.3 of the SmPC of the reference product, the

shelf life, must not be copied. Instead, a reference must be made to the expiry date stated on the label, as is also required in section 5 of the package leaflet for the patient. The reason for this is that, if the two products have not completed the same MRP/DCP, the shelf life as approved by the foreign authority for the product to be parallel imported can differ from the shelf life of the Dutch reference product.

See also the policy document 'Package leaflet of pharmaceutical products' (MEB 5).

1.3.13 Authorised translation of the foreign package leaflet and, if relevant, the SmPC

The applicant must submit a Dutch or English authorised translation of the package leaflet valid in the country of origin for the parallel import product if (1) the package leaflet is drawn up in a language other than Dutch, English, French or German and (2) the Dutch reference product and the product to be parallel imported have not completed the same MRP/DCP.
At the time of the application, a translation only needs to be submitted for the passages that contain the following information:

1. qualitative and quantitative composition of the active ingredient(s) and the qualitative composition of the excipients;
2. pharmaceutical form;
3. storage temperature and conditions, also (if relevant) after opening or reconstitution;
4. processing instructions (method of reconstitution, the solvents used and whether or not these are included/the use of listed devices, such as nebulisers and spacers, and whether or not these devices are included);
5. the legal entities listed in the package leaflet and their capacity (marketing authorisation holder, manufacturer, licensor/licensee, where applicable, etc.);
6. if relevant: information pertaining to the compatibility with certain solvents/diluents and final concentration or concentration range (see §1.3.6).

The rest of the package leaflet does not need to be translated at the time of the application. A complete translation is only required in the event of withdrawal of the reference product, where the parallel marketing authorisation holder wishes to continue the parallel marketing authorisation (see Section 3).

If the information listed under point 6 is not or not fully included in the foreign package leaflet, this information must be obtained from the foreign SmPC. An authorised translation of the relevant section(s) of the foreign SmPC must then be submitted, unless the SmPC is drawn up in Dutch, English, French or German. This also applies if the SmPC is used as a source for other information in the comparison form (see §1.3.6.).

1.3.14 Foreign packaging

Information on the foreign packaging that contradicts (1) the Dutch SmPC and/or (2) the Dutch labelling policy 'Labelling of pharmaceutical products' (MEB 6) must be made illegible, and a declaration stating that this information will be made illegible and the method by which this will be done (e.g. by taping it over or blotting it out) must be included in the application. Whether or not the method for making this information illegible is acceptable will be assessed by the MEB on a case- by-case basis.

The foreign package leaflet must be replaced by the Dutch package leaflet; see also

§1.3.11.

Opening the immediate labelling is not permitted, as this would have adverse consequences for the quality, safety and/or efficacy of the product.

Re 1: In the case of **OTC medicinal products**, the indications, contra-indications and dosages stated on the packaging must be rendered illegible if they differ from those approved for the Dutch reference product.
The following applies to both prescription and OTC medicinal products: information about a **route of administration** that is not (or no longer) approved in the Netherlands must be rendered illegible. Furthermore, **QR codes** on the foreign packaging must be rendered illegible. QR codes refer to a foreign website that does not fall under the responsibility of the parallel marketing authorisation holder, and the content of this website could cause confusion if it does not match the SmPC of the Dutch reference product. The parallel marketing authorisation holder is allowed to place its own QR code on the label. The rules as drawn up in the MEB's QR policy apply, as stated on the MEB website.

Re 2: Logos, signs and/or pictograms on the foreign packaging that contradict the policy document MEB 6 and that have previously been rejected for the Dutch reference product must be rendered illegible.

Exception:
The text '*Teil einer Klinikpackung – Einzelverkauf unzulässig'* does not need to be rendered illegible, in accordance with a previous ruling by the MEB.

1.3.15 Proposed labelling text and replacing outer packaging

A. Obligation to relabel/replace outer packaging

According to the Medicines Act, the inner and outer packaging of a medicinal product that is marketed in the Netherlands must be in Dutch. This also applies to parallel products. The parallel importer must therefore either relabel both sets of packaging or relabel the immediate packaging and then repackage the product in a new outer packaging (see also under D and E).
It is important to note that the relabelling/repackaging should not result in a change or deterioration in the condition of the medicinal product (Article 7 of the Trade Marks Directive (Directive 2008/95/EC), repealing the First Trade Marks Directive (Directive 89/104/EEC)). The MEB will therefore not insist on the requirement of relabelling the immediate packaging if this would be detrimental to the patient. Examples of this include being able to remove tablets from a blister. If the parallel applicant is of the opinion that the relabelling of the immediate packaging will change/worsen the condition of the product, a substantiation for this must be submitted as part of the application dossier. Furthermore, if the parallel applicant wishes to fully repackage the product, the MEB will assess whether this is detrimental to the original condition of the product.

B. Requirements and conditions for the Dutch label/new outer packaging

In the Joined Cases C-427/93, C-429/93 and C-436/93, the Court of Justice of the European Union has set five conditions that apply to both the repackaged and relabelled

product. These conditions are:

I. Repackaging is essential to allow marketing of the product in the country of import.
II. Repackaging does not impair the original condition of the product in the packaging.
III. The new packaging clearly states who is responsible for the repackaging and also states the original marketing authorisation holder in the country of origin. This also applies to the origin of items added to the packaging by the importer (see also under C and D).
IV. The presentation of the repackaged product may not result in damage to the reputation of the trademark and the trademark owner (for example, the packaging may not be defective, of poor quality or shoddy).
V. The parallel importer should inform the trademark owner about the repackaging before marketing the product. In addition, if requested, the importer should supply the trademark owner with a sample of the repackaged product.

If one or more of the above-mentioned conditions are not met, the trademark owner can object to the relabelling/repackaging.
The MEB is not a party to matters relating to trademark law, but in the case of a parallel application, for other reasons as set out in this policy document, will carry out a partial check for the first three conditions based on the following criteria:

1. Is repackaging (which includes making changes to the contents of the packaging; see §1.3.8) necessary to make the parallel product identical or virtually identical to the reference product or is repacking necessary because of the Falsified Medicines Directive (FMD)? (Directive 2011/62/EU; for more information, see the European Commission's Q&A on the implementation of Delegated Regulation 2016/161 (https://ec.europa.eu/health/human- use/falsified_medicines_en#).)
2. Is relabelling/repackaging in no way detrimental to the user? (See also under A.)
3. Is the party responsible for relabelling/repackaging stated on the label/new outer packaging? (See also under C and D).

In addition, the MEB has the following requirements regarding the new label or new outer packaging:

4. Information specific to the parallel product must be stated correctly; see below under C.
5. Important warnings or restrictions on the packaging of the Dutch reference product must be copied; see below.
6. Instructions for correct use on the foreign immediate and other packaging (e.g. the days of the week or abbreviations thereof in the case of calendar packaging) must be copied correctly in Dutch on the label.
7. If relabelling of the primary packaging is not possible (see under A), a translation of these instructions must be included in the package leaflet (see also §1.3.11-B).
8. The labelling text/outer packaging must meet the requirements of the policy document 'Labelling of pharmaceutical products' (MEB 6). Accordingly, in the case of repackaging, the sets of packaging for the different pharmaceutical forms and strengths of products from the same marketing authorisation holder must be clearly distinguishable from each other.
9. The labelling text/outer packaging must meet the requirements of the 'Guideline on readability' (particularly font size). This entails that the font size of the packaging text must be at least 7 Didot points. (For more information, see the policy document 'Labelling of pharmaceutical products' (MEB 6).)
10. The information must be stated clearly on the label/packaging.

In addition, the following applies to **OTC medicinal products**:

11. <u>Indications and contra-indications</u>:

The indication(s) and contra-indication(s) must be stated on the label; the information must be verbatim identical to the indication(s)/contra-indication(s) as stated on the packaging of the Dutch reference product.

12. Dosage, method of use and method of administration:
    If the packaging of the Dutch reference product states the dosage, the method of use and/or the method of administration, this information must be copied verbatim in the labelling text of the product to be parallel imported.

In addition, the **packaging size** may only be changed provided that:

13. as long as the desired new packaging size is not available on the market in the country of origin;
14. by changing the packaging size, this is made identical or virtually identical to a packaging size registered for the Dutch reference product (as stated in the SmPC/package leaflet).
    It is not permitted to change the packaging size of the product to be imported to a packaging size that differs significantly from the packaging size(s) registered for the Dutch reference product. See also §1.2.1-A and F.

Re 6: Important warnings or restrictions on the packaging of the Dutch reference product (e.g. 'to be used by men only') must also be copied on the label of the parallel product. This is because it has been decided for the reference product that this warning is essential to ensure correct use of the product. The information that is included must be identical to the information on the packaging of the reference product. (See also the policy document 'Labelling of pharmaceutical products' (MEB 6).)

Re 13 and 14: The parallel applicant must include a declaration that products are only repackaged as long as the proposed packaging size is not available on the market in the country of origin and that the proposed packaging size has been approved for the Dutch reference product.

Re 13: If foreign individual packaging in a multipack features a statement regarding separate sale (for example: 'Part of a multipack; may not be sold separately') and the multipack is split up, the statement must be made illegible (e.g. by taping it over or blotting it out; see also §1.3.14) to avoid confusion for the user and/or medical professionals. However, splitting up a multipack and making such a statement illegible remains the responsibility of the parallel applicant. To avoid any conflict, the MEB advises informing the trademark owner about this intended course of action. See also §1.3.15.B.

In addition, the parallel applicant is allowed to place its own QR code on the packaging (see §1.3.14).

C. Stating parallel-specific information

The information that must be included on the labelling text/new outer packaging of the parallel product is described in the policy document 'Labelling of pharmaceutical products' (MEB 6). In addition, attention must be paid to the correct listing of the parallel-specific information, namely:

1. Product name:
   The product name must be the same as the product name stated on the application document and in the proposed package leaflet.
2. Excipients:

If the product contains an excipient listed in the 'Guideline on the excipients' (MEB 8), this excipient must be listed on the label followed by '*Read the package leaflet for further information*'. This also applies if the packaging of the reference product does not contain such information.
In the case of products for **parenteral administration**, for **local use** and for **the eye**, the primary and secondary label must also state all excipients. If the composition of the parallel product differs from that of the reference product, it is important to ensure that the composition of the parallel product is stated.

3. Storage conditions (before and after opening and further preparation) and in-use shelf life: The storage conditions of the parallel import product (before and after opening, after further preparation) and, if relevant, its in-use shelf life as approved in the country of origin must be stated. (See §1.2.1-E.)
4. Packaging size:
   The stated packaging size must correspond to the size stated in the comparison document and in the comparison or other photograph. If the packaging size has been changed, the new packaging size must be stated (see also §1.3.15-B).
5. Repackager and batch release manufacturer:
   Please refer to D for information on the separate requirements for stating the repackager and the batch release manufacturer.
6. Country of origin:
   It is preferable, but not mandatory, to state the country of origin (or the abbreviation thereof).

In connection with a possible infringement of trademark law, the parallel applicant may also include the following information in the package leaflet and/or the label/new outer packaging:

17. Origin of included accessory:
    If the parallel applicant has added an item to the packaging, the origin of this item may be stated in the package leaflet and/or on the label/new outer packaging.
18. Name of original marketing authorisation holder:
    The name of the original marketing authorisation holder in the country of origin may also be included in the package leaflet and/or on the label/new outer packaging. However, this must be done in such a manner that it does not result in confusion for the user as to who is responsible for placing the parallel product on the Dutch market. This can be done, for example, by using the text: 'Marketing authorisation holder in the country of origin: [name of marketing authorisation holder]'.
19. Batch release manufacturer:
    The name of the batch release manufacturer in the country of origin must be included in the package leaflet and *can* also be included on the label/new outer packaging. However, this must be done in such a manner that it does not result in confusion for the user as to who is responsible for releasing the batches of the parallel product in the Netherlands. Therefore, this information must be stated as follows: 'Manufacturer in the country of origin: [name of manufacturer]'. The manufacturer that must be included here is the batch release manufacturer listed in the foreign package leaflet of the imported packaging. If several batch release manufacturers are listed in the foreign package leaflet, all of these can be listed, or the parallel applicant can choose to list only one of these.

D. Party responsible for repackaging and the batch release manufacturer

Stating the repackager

The repackager is the company that relabels the parallel product or gives it an entirely new outer packaging.
Stating the name and address of the legal entity responsible for the repackaging on the packaging of the parallel product is required under trademark law, in accordance with Article 7 of Directive 2008/95/EC, and is therefore mandatory. This means that both the actual repackager and the marketing authorisation holder on whose instructions the product was repackaged and who assumes responsibility for the repackaging must be listed as repackager on the label. (This in accordance with the ruling by the Court of Justice of the European Union, dated 28 July 2011, regarding cases C-400/09 and C-207/10).

Article 7 of Directive 2008/95/EC must be interpreted as allowing the original marketing authorisation holder to oppose the further marketing of its product by a parallel importer if the repackager is not listed on the new packaging. After all, the repackaging/relabelling is not performed on the instructions or under the responsibility of the original marketing authorisation holder, and any change or impairment of the condition of the product is therefore not the responsibility of the original marketing authorisation holder.

If the repackager and the parallel marketing authorisation holder are the same party, or if the latter assumes responsibility for the repackaging, this is usually indicated by referring to this party on the label as 'marketing authorisation holder/repackager'.

Stating the batch release manufacturer
In the case of radiopharmaceuticals, stating the batch release manufacturer on the label is mandatory (see 'Labelling of pharmaceutical products' (MEB 6)). This obligation does not apply for all other products (see §1.3.15.C.19).

E. Complete repackaging

Instead of relabelling the secondary packaging, the parallel importer can also completely repackage the product. The following requirements apply with regard to the parallel application dossier:

- The application must not only include a flat label text, but also a full-colour mock-up of the new outer packaging (secondary packaging).
- The printed text on the new outer packaging must meet the same requirements as a Dutch label; see under A and B.
- The new outer packaging must include braille text, and the accompanying braille declaration must be submitted; see under §1.3.20.

For the other conditions relating to repackaging, please refer to B.
If the product is going to be repackaged, the immediate packaging must obviously still be given a new label; see under A.

1.3.16 Additional risk minimisation measures (aRMM)

For some products, there are additional requirements regarding information for the user and/or medical professionals, known as the additional risk minimisation measures (aRMM). For a parallel product, in practice, this will mainly boil down to educational material. An example of this is the patient card. This card contains important instructions for use of the product. If this educational material is available for the Dutch reference product, this must also be submitted for the parallel product. This educational material must be drawn up in Dutch. The educational material must be verbatim

identical to that of the Dutch reference product, including the upside-down triangle (▼) as a symbol for products 'subject to additional monitoring' (see §1.3.11-A). The parallel applicant must submit a declaration to this effect or include it in the application letter. The parallel authorisation holder must have all the established material, both online and on paper, in its possession to provide this upon request.

The name of the Dutch reference product must be replaced(*) by the name of the active ingredient (* unless this creates confusion). The name of the marketing authorisation holder of the Dutch reference product must be removed if mentioned in the educational material.
Only in the standard phrase (or part thereof):
'Additional material can be obtained from the [department name] department of [marketing authorisation holder], which can be reached on phone number [phone number] or at [email address that does not contain any personal data]. The material can be found online on <URL linking to online material> by scanning <QR code>. should the details of the marketing authorisation holder of the Dutch reference product be changed to the details of the marketing authorisation holder of the parallel product. The link to the web address of the parallel marketing authorisation holder must link directly to the relevant material. Creating an own QR code is not mandatory. However, a reference to the material on the website of the parallel marketing authorisation holder *is* mandatory.

The Medicines Information Bank on the MEB website can be consulted to check whether educational material has been drawn up for a certain product. The parallel applicant must check this before submitting an application for awarding of a parallel marketing authorisation. The proposed educational material must form part of the application dossier. It may be the case that the reference product has not been placed on the market but educational material has nonetheless been adopted within the EU. In that case, the educational material is not included in the Medicines Information Bank and will still need to be translated and implemented. In that case, a distribution plan must be submitted. The MEB will determine during the assessment of these parallel applications and the educational material whether active distribution is required and, if so, to which target groups.

If the educational material also includes an instructional video, the parallel marketing authorisation holder must have this video in its possession. The parallel applicant must contact the marketing authorisation holder of the reference product to gain possession of the video (source material) and post it on its own website (not subject to copyright). The product featured in the video must have the same appearance as the parallel product. If this is different, the parallel applicant itself must replicate the video.

The educational material has been drawn up based on the active ingredient and is sometimes combined for multiple products. The parallel applicant must ensure that the material for all relevant parallel products is the same and continues to be the same and that the most recently approved material is posted on the website of the parallel marketing authorisation holder.

See also the policy document for marketing authorisation holders: National implementation of additional risk minimisation measures (MEB 45).

1.3.17 Controlled Access Program (CAP)/Controlled distribution

system

A CAP or a Controlled distribution system is imposed if, for example, the product is known to cause very serious or fatal adverse reactions, which makes it necessary for the product to be made available in a controlled way. Examples include: distribution solely from within a hospital setting, restricted packaging size or a prohibition on repeat prescriptions. A CAP or a Controlled distribution system follows from the RMP.

Whether a CAP or a Controlled distribution system is recorded for a certain product, can be found in the Medicines Information Bank (GIB) on the MEB website. Information about the CAP or the Controlled distribution system and the accompanying documents are given in the PAR of the reference product. The parallel applicant must ascertain before submitting an application for the granting of a parallel marketing authorisation whether a CAP or a Controlled distribution system has been recorded. The proposed CAP or the proposed Controlled distribution system must be part of the application dossier. If necessary, you may contact the authorisation holder of the reference product.
The CAP or the Controlled distribution system must be verbatim identical to that of the Dutch reference product and remain so. The parallel applicant must attach a declaration for this purpose or include it in the application letter. The name of the Dutch reference product must be replaced(*) by the name of the active substance (* unless this creates confusion). The name of the marketing authorisation holder of the Dutch reference product must be removed, if it is mentioned in the CAP or the Controlled distribution system.

1.3.18 Authorisations

A copy of the required authorisation(s) or a reference to EudraGMP must be included in the parallel dossier.

The following authorisations are relevant for parallel marketing:

A. Manufacturing authorisation (supplemented if necessary by a GMP certificate):
   - A valid manufacturing authorisation is required to be allowed to repackage/relabel, release and/or supply parallel imported products. A valid manufacturing authorisation not older than three years must be submitted for all legal entities involved in one or more of the listed actions.
   - If the manufacturing authorisation is older than three years, it must be supplemented by a valid GMP certificate.

B. Wholesale distribution authorisation:
   - Usually, a manufacturing authorisation will suffice for parallel marketing. Although the importer is obtaining medicinal products from within the EEA, these are 'self-prepared medicinal products' due to repackaging/relabelling. A wholesale distribution authorisation is only required for legal entities that resell or supply the purchased medicinal products without performing any preparation steps or without themselves releasing the products. In that case, the legal entity is selling/supplying third-party medicinal products.
   - A wholesale distribution authorisation issued by another EU country is only valid in the Netherlands if the wholesale distribution activities take place exclusively in other countries. If wholesale distribution activities take place in the Netherlands, a Dutch wholesale distribution authorisation is required.
   - The wholesale distribution authorisation is granted for an indefinite period.

C. Parallel wholesale distribution authorisation:
   - Before the Medicines Act came into effect (1 July 2007), there was the parallel

wholesale distribution authorisation. These authorisations were awarded for an indefinite period and are still legally valid, but they are no longer awarded. Under the Medicines Act, a parallel wholesale distribution authorisation is equal to a limited manufacturing authorisation in combination with a wholesale distribution authorisation.

Authorisation is not required for merely purchasing medicinal products.

Please contact the Central Information Point for Healthcare Professions (CIBG) for more information regarding the authorisations required for parallel import.

1.3.19 Addendum on expansion of the European Union ('specific mechanism')

New rules for parallel import came into effect with the admission of ten new Member States to the European Union on 1 May 2004. These rules were updated in 2007, following the admission of Romania and Bulgaria. The rules concern agreements made between the EU and the new Member States to prevent the import of products from a new Member State to an 'old' Member State where such products are subject to a patent or a supplementary protection certificate. This concerns the so-called 'specific mechanism' included in the accession treaties. The reason for this is that, prior to their admission to the EU, the new Member States offered more limited protection than the 'old' Member States. If a medicinal product from Bulgaria, Estonia, Hungary, Croatia, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia or Czechia is imported to an 'old' Member State where that product is still subject to a patent or a supplementary protection certificate, the holder of the patent or supplementary protection certificate, or its beneficiary, can object to the parallel import due to infringement of patent rights. Therefore, the legal entity that wishes to parallel import a medicinal product from a new Member State to an 'old' Member State where that product is subject to a patent or supplementary protection certificate must inform the patent holder about this intention one month prior to submitting an application to the MEB. This will inform the patent holder of this intention and provides adequate time to submit a legal objection to the parallel import.

The parallel importer must demonstrate with the parallel application that the holder of the patent or supplementary protection certificate, or its beneficiary, was notified about the proposed parallel import at least one month prior to the parallel marketing authorisation being awarded. To this effect, a completed and signed 'Declaration on Member State of origin of parallel import' and a copy of the notification to the holder of the patent or supplementary protection certificate must be added to the application dossier. The template for the declaration is available on the MEB website.
If the parallel product is no longer subject to a patent or supplementary protection certificate, the parallel importer must submit a declaration to this effect, instead of the above-mentioned documents, as part of the application dossier.

The above-mentioned requirements are also described in Section 48(7) of the Medicines Act.

1.3.20 Braille

The European legislation (Article 65(a) of Directive 2001/83/EC) stipulates that the product name must also be stated in braille on the packaging. However, the braille requirements for parallel import products differ from those for non-parallel import

products:

1. There is no braille present on the foreign packaging:
   - The parallel applicant is not required to place braille on the packaging.
   - If the parallel importer itself decides that it wants to use braille, the same requirements apply as for a non-parallel import product.
2. There is braille present on the foreign packaging:
   If the product name in the country of origin differs from the name in the Netherlands, the product name in the country of origin may still be written in braille. The Dutch product name does not need to be added in braille. However, the braille must remain legible after relabelling. The braille may be written through the printed text.
3. The parallel importer will repackage the product:
   In that case, the parallel importer must place braille on the new packaging.

The parallel applicant only needs to submit a braille declaration if the applicant is responsible for adding braille to the packaging. This declaration is not required if the braille already formed part of the foreign packaging before import.

1.3.21 Declaration regarding batch release of blood products and vaccines

If the product to be parallel imported concerns a blood product or vaccine, one of the following declarations must be submitted:

- a declaration that the product was imported from a country where additional release in accordance with Article 114 of Directive 2001/81/EC, as amended via Directive 2004/27/EC, is mandatory;

or, if this declaration cannot be made,

- information about how the applicant will ensure that the batches have been released by a government authority appointed for this task. (An acceptable answer would be that the applicant declares that they have reached an agreement with the National Institute for Public Health and the Environment (RIVM) that the latter will check whether the batches have undergone additional release for the European market or whether RIVM will be notified per batch concerning the blood product or vaccine).

The parallel applicant can include this declaration in the application letter. There is no template available on the MEB website.
For more information, please refer to section 1.5.

1.4 Common origin

In the past, a requirement for parallel applications was that the parallel product and the Dutch reference product were produced by the same manufacturer or by manufacturers belonging to the same group of companies (common origin). The reason for this was that this effectively ensured that only a product that was identical to a product already approved in the country of import (the reference product) was imported into that country. However, due to a ruling by the European Court in the Kohlpharma case (case C-112/02, dated 1 April 2004), this requirement of common origin no longer applies. The ruling by the Court means that a foreign, generic product can now also be imported to another country, provided that the innovator for which therapeutic equivalence has been demonstrated also has a marketing authorisation in the country of import.
In the case of a parallel application without common origin, the MEB will assess whether the product is therapeutically equivalent to the Dutch reference product (i.e. that the

products are identical or virtually identical). The application can only be accepted if therapeutic equivalence is confirmed. This is in line with Section 48(1) of the Medicines Act.
(See also §1.2.1).

1.5 Parallel import of blood products and vaccines

Batches of blood products and vaccines, including parallel import products, must be released by an appointed government authority, the Official Medicines Control Laboratories (OMCL), before being marketed. The OMCL in the Netherlands is the National Institute for Public Health and the Environment (RIVM). The OMCL determines whether the batch meets the approved specifications before being released to the market. A certificate is awarded in the case of a positive result.
The requirements for the batch release (Official Control Authority Batch Release (OCABR)) of vaccines and blood products are included in Article 114 of Directive 2001/81/EC, as amended by Directive 2004/27/EC, and incorporated in the Dutch legislation. The basis for the OCABR is set out in Section 28(6) of the Medicines Act and in Section 6.2 of the Medicines Act Regulations. Section 6.3(1) of the Medicines Act Regulations also stipulates that a blood product or vaccine that has already been released in a Member State does not need to undergo further batch release; OMCLs in the EU recognise each other's approval for release. This means that, for a batch of a blood product or vaccine that will be imported to the Netherlands, the OCABR procedure does not have to be repeated, provided that additional release by another EU OMCL has already taken place. In that case, it suffices to provide RIVM with the release certificate awarded by the foreign OMCL.
However, batch release of blood products or vaccines by an OMCL is not mandatory or fully implemented in a number of EU countries. Therefore, for parallel imported batches of blood products or vaccines from such countries, it cannot be assumed that they have been released by an OMCL. However, this can be assumed for parallel imported batches of blood products and vaccines originating from the regular channels of EU Member States with an obligation to perform additional release procedures.

What does this mean for the parallel application?
One of the declarations listed under §1.3.21 must be included in the application for a parallel marketing authorisation for a vaccine or blood product. If neither of these declarations is included in the parallel dossier, the OCABR will not be sufficiently guaranteed. In that case, the parallel marketing authorisation cannot be awarded.

Following the awarding of the parallel marketing authorisation by the MEB, the parallel importer must also report each batch of vaccines or blood products to RIVM.

The MEB will inform RIVM of the awarding of a parallel marketing authorisation for a blood product or vaccine by providing a copy of the authorisation letter.

1.6 Use of clock-stop

A parallel application can be placed in clock-stop if:
- the parallel applicant has been asked to provide additional information;
- the MEB needs to obtain information from the regulatory authority in the country of origin to determine whether the parallel product and Dutch reference product are identical or virtually identical;

- the reference product is a medicinal product that has been authorised without Dutch translations. The MEB must ask the marketing authorisation holder of the reference product to submit a high-quality Dutch translation of the product information within one month. The parallel package leaflet must be based on this Dutch-language version of the package leaflet (see also § 1.3.11-A);
- an intention of refusal has been sent out, if the MEB has concluded that the applicant has failed to demonstrate that the parallel product and the Dutch reference product are identical or virtually identical. The policy document 'Written and oral opinion procedure for a proposed primary judgement by the MEB' (MEB 18) contains more information about this procedure.

In the second case, the MEB will inform the applicant about the clock-stop and the reason for this clock-stop.

The clock will be restarted as soon as additional information has been received from the Member State of export or a response has been received from the parallel applicant.

1.7 Authorisation

When the product to be parallel imported is authorised by the MEB, the same indications, contra- indications, adverse reactions, dosage, method of use and administration will apply to this authorisation as for the Dutch reference product. The SmPC approved for the Dutch reference product will also apply to the linked parallel product. The SmPC of the Dutch reference product will be sent along with the awarded parallel marketing authorisation.

In the case of a combined package leaflet, where one or more products have already been authorised, the following request will be included in the notification of authorisation:
'This is a combined package leaflet that includes one or more previously authorised parallel products. The MEB has replaced the package leaflet of these previously authorised parallel products with the version of the package leaflet approved in this procedure. Please update your file accordingly.'

If educational material (aRMM) has been drawn up and there is a combined package leaflet with one or multiple products already having been authorised, the aRMM of the already authorised products may have to be replaced. The notification of authorisation will therefore include the following request:
The aRMM drawn up also applies to other, already authorised parallel products from the package leaflet. TheMEB has replaced the aRMM of thesealready authorised parallel products (where necessary) with the version of the aRMM approved in this procedure. You are requested to adapt your dossiers of these medicinal products and your website accordingly. If the aRMM also applies to products other than those listed in the package leaflet, you have to submit a variation to that end (where necessary).

The parallel import product will be registered under RVG1/RVG2, with RVG2 being the registration number of the reference product.

2. Maintenance

2.1 Introduction

The parallel marketing authorisation holder is responsible for keeping the package leaflet up to date. Certain variations in the dossier in the country of origin or in the dossier of the Dutch reference product can affect the package leaflet and/or the label for the parallel product. The parallel marketing authorisation holder may also wish to implement variations in the parallel dossier.

All variations, regardless of the origin or the type of variation, should be submitted a priori to the MEB for approval. The Variation Regulation does not apply to parallel products.

Since 12 August 2015, variations must be submitted via the prescribed electronic standard structure for parallel products, otherwise the request cannot be accepted for processing (see also §1.3.1-B).

Several variations can be submitted for the same parallel product under one submission (one application letter).

Depending on the type of variation, the following documents must be submitted:

1. application letter describing the variation;
2. amended comparison form (annotated version);
3. signed package leaflet declaration (not necessary if the reference product has been withdrawn and a new reference SmPC has been linked);
4. foreign package leaflet;
5. translation of the relevant section of the foreign package leaflet with certificate from a recognised translation agency, if the package leaflet was not drawn up in English, German, French or Dutch;
6. amended package leaflet for the parallel product (clean and track changes version);
7. amended label for the parallel product (clean and track changes version);
8. amended educational material (clean and track changes version);
9. Adjusted Controlled Access Program (CAP)/Controlled distribution system (clean and track changes version);
10. photograph of all sides of the foreign packaging;
11. new comparison photograph of the parallel product and the Dutch reference product;
12. signed declaration that the new image/new logo or sign will be made illegible on the packaging if it contradicts the Dutch labelling policy;
13. a declaration from the current parallel marketing authorisation holder that it agrees to the transfer of the parallel marketing authorisation;
14. a declaration from the prospective parallel marketing authorisation holder that they will adopt all rights and obligations relating to the authorisation;
15. manufacturing authorisation and/or wholesale distribution authorisation, parallel wholesale distribution authorisation: copy or reference to EudraGMP;
16. additional information about the parallel product and the Dutch reference product remaining identical or virtually identical;

17. mock-up in colour of the new outer packaging (secondary packaging) and separate document with packaging text;
18. braille declaration (see under §1.3.20);
19. a declaration that the proposed packaging size is not available on the market in the country of origin and that the proposed packaging size has been approved for the Dutch reference product;
20. Declaration regarding the connection between the proposed parallel marketing authorisation holder and the marketing authorisation holder in country of origin.

Re 2: It is preferable that the latest version of the comparison form is used.

Re 16: In exceptional cases, variations in the parallel dossier can result in the parallel product and the Dutch reference product no longer being identical or virtually identical. Therefore, for each requested variation not approved for the Dutch reference product, it must be substantiated that this is not the case.

The following sections describe which documentation must be submitted for a certain type of variation. However, if deemed necessary, the MEB can always ask for more information than stated below.

2.2 Variation in original dossier in the country of origin

This section summarises the variations in the original dossier in the country of origin that affect the parallel dossier.

Variation in packaging size

- origin of variation: the original marketing authorisation holder in the country of origin has altered the packaging size via a variation. As a result, the parallel marketing authorisation holder no longer has access to the packaging size that it previously imported. Therefore, the marketing authorisation holder wishes to import a different packaging size. See also §1.2.1-A and F.
  If the new packaging comes from a different Member State than the already registered packaging, this can be implemented by means of a variation. This will require a new application to be submitted by the parallel marketing authorisation holder;
- documentation to be submitted: 1, 2, 6, 7, 10 (and 16, if the new packaging size is not yet approved for the Dutch reference product).

If the size of the new packaging is also to be changed, documentation must be submitted as described under 'Changing packaging size (contents) of product to be imported' (see §2.4).

NB: the application letter must also include a declaration that, other than with respect to the information regarding the packaging size, no changes will be made to the package leaflet and label. It is important that the new packaging size to be imported falls within the same legal status of supply and treatment duration as has been approved for the Dutch reference product (see also §1.2.1-F).

Variation in batch release manufacturer

- origin of variation: the marketing authorisation holder in the country of origin has added/removed a batch release manufacturer to/from the original dossier;

- documentation to be submitted: 1, 2, 4, 5, 6 (and 7, for radiopharmaceuticals and other products if the batch release manufacturer is stated on the packaging; see §1.3.15-D).

NB: the application letter must also include a declaration that, other than with respect to the information regarding the batch release manufacturer(s), no changes will be made to the package leaflet and label.

Variation in storage conditions and/or shelf life

- origin of variation: the storage conditions and/or shelf life (before/after opening and/or further preparation) have changed in the country of origin;
- documentation to be submitted: 1, 2, 4, 5, 6, 7 (and 16, if the new storage conditions and/or shelf life differ from those approved for the Dutch reference product).

NB: the application letter must also include a declaration that, other than with respect to the information regarding the storage conditions and/or shelf life, no changes will be made to the package leaflet and label
(see also §1.2.1-E).

Variation in excipients

- origin of variation: the composition of excipients has changed;
- documentation to be submitted: 1, 2, 4, 5, 6 (and 7, if relevant; for the rules for stating excipients on the label, see the 'Guideline on the excipients' (MEB 8)) (and 16, if the new composition differs from that approved for the Dutch reference product).

NB: the application letter must also include a declaration that, other than with respect to the information regarding the excipients, no changes will be made to the package leaflet and, if relevant, to the label
(see also §1.2.1-C).

Variation in external appearance of the product

- origin of variation: the marketing authorisation holder in the country of origin has, for example, decided to change the colour, printing or dimensions of the medicinal product;
- documentation to be submitted: 1, 2, 4, 5, 6, 11 (and 16, if the new appearance differs from that of the Dutch reference product).

NB: the application letter must also include a declaration that, other than with respect to the information regarding the appearance of the product, no changes will be made to the package leaflet and label.
If the variation involves the removal of a break line, it must be checked whether the entire dosage instruction and all indications are still feasible. If a break line has been added, it must be checked whether the function of the break line is included in the foreign package leaflet; this information must then also be included in the Dutch package leaflet for the parallel product.

Variation in external appearance of the packaging

- origin of variation: the original marketing authorisation holder has, for example, decided to change the dimensions or the image/colours of the packaging;
- documentation to be submitted: 1, 10, 11 (and 12, if relevant).

NB: it is important to check that no logos or images are added to the new packaging that are not acceptable under the labelling policy. If that is the case, the logo/image must be made invisible and a declaration to this effect must be submitted (see §1.3.14).

Change in packaging contents

- origin of variation: the contents of the packaging have changed, e.g. as a result of the addition or removal of devices in the packaging;
- documentation to be submitted: 1, 2, 4, 5, 6, 7, 10, 11 (16, if the new contents differ from those approved for the Dutch reference product).

NB: the application letter must also include a declaration that, other than with respect to the information regarding the contents of the packaging, no changes will be made to the package leaflet and label
(see also §1.2.1-D and §1.2.2).

Variation in foreign product name

- origin of variation: the name of the product in the country of origin has changed;
- documentation to be submitted: 1, 2, 4, 6.

NB: the application letter must also include a declaration that no changes will take place in the package leaflet, other than the information pertaining to the foreign product name.

2.3 Variation in dossier of Dutch reference product

Variations that are reflected in the SmPC and/or package leaflet of the reference product

- origin of variation: variations in the dossier of the Dutch reference product will be reflected in the SmPC and the package leaflet. The parallel marketing authorisation holder is responsible for keeping the package leaflet up to date and must therefore regularly check the product information of the reference product for relevant variations. The Medicines Information Bank (*Geneesmiddeleninformatiebank*, GIB) on the MEB website can be consulted for this purpose. If no response is received from the MEB, the new version of the package leaflet may be implemented after 30 days. At the bottom of the package leaflet, the date corresponding to day 30 of the procedure must be indicated by stating the month and year;

- documentation to be submitted: a request for amendment of the parallel package leaflet must be submitted within three months after amendment of the reference text, including the following documentation: 1, 2 (when there are variations in product-specific information (SmPC section 2, 3 and/or 6, package leaflet section 5 and/or 6)), 3, 6 (and 7, if relevant).

NB: in the event that the amended SmPC results, for example, from a variation in the composition of excipients, the administration form or a change in or the addition/removal of a device, the parallel product and the reference product being identical or virtually identical may be threatened if this same variation is not or not yet

incorporated into the original dossier of the product to be parallel imported or if the imported product is an old batch. Such a situation can have consequences for the parallel marketing authorisation if the co-existence of two different versions of the product poses a danger to public health (see also §1.2.1 and §2.1.).

Variation in the educational material

- origin of variation: if the educational material for the Dutch reference product changes, a request for amendment of the educational material for the parallel product must be submitted within three months after this variation. The parallel marketing authorisation holder is responsible for keeping the educational material up to date and must therefore regularly check the educational material of the reference product for relevant variations. The Medicines Information Bank (*Geneesmiddeleninformatiebank*, GIB) on the MEB website can be consulted for this purpose;
- documentation to be submitted: a request for amendment of the educational material must be submitted within three months after amendment of the reference text, including the following documentation: 1, 8. The parallel applicant must declare (in the application letter) that the educational material is verbatim identical to that of the Dutch reference product.

NB: the MEB will assess whether the updated material must be actively distributed, and if so, to which target groups. See also §1.3.16.

Variation in the Controlled Access Program (CAP)/Controlled distribution system

- origin of variation: if the CAP or the Controlled distribution system of the Dutch reference product changes, a request for amendment of the CAP or the Controlled distribution system for the parallel product must be submitted within three months after this variation. The parallel marketing authorisation holder is responsible for keeping the CAP or the Controlled distribution system up to date, and must therefore regularly check the CAP or theControlled distribution system of the reference product for relevant variations. The Medicines Information Bank (*Geneesmiddeleninformatiebank*, GIB) on the MEB website may be consulted for this purpose.
- documentation to be submitted: a request for amendment of the CAP or yhe Controlled distribution system must be submitted within three months after amendment of the reference text, including the following documentation: 1, 9. The parallel applicant must declare (in the application letter) that the CAP or the Controlled distribution system is verbatim identical to that of the Dutch reference product.

Variation in the legal status of supply

- origin of variation: if the legal status of supply of the Dutch reference product changes, the parallel product must adopt this new legal status of supply.
- documentation to be submitted: a request to amend the label of the parallel product must be submitted within three months of the change to the legal status of supply of the Dutch reference product, including the following documentation: 1 and 7.

2.4 Variation only in the parallel dossier

A parallel marketing authorisation holder can also decide to implement variations in the parallel dossier. The following situations are possible:

Importing different packaging size

- origin of variation: the parallel marketing authorisation holder decides to import an additional or different packaging size. See also §1.2.1-A and -F;
- documentation to be submitted: 1, 2, 6, 7, 10 (16, if the new packaging size is not yet approved for the Dutch reference product).

NB 1: the application letter must also include a declaration that, other than with respect to the information regarding the packaging size, no changes will be made to the package leaflet and label. It is important that the new packaging size to be imported falls within the same legal status of supply and treatment duration as has been approved for the Dutch reference product (see also §1.2.1-F).

NB 2: the different packaging sizes must have the same origin. An additional packaging size that falls under a different marketing authorisation, or originates from a different Member State, must be submitted as a new application and will be fully assessed.

Changing packaging size (contents) of the product to be imported

- origin of variation: the parallel marketing authorisation holder changes the packaging size of the product to be imported. See 1.3.15-B;
- documentation to be submitted: 1, 2, 6, 7, 10 and 19 (16, if the new packaging size is not yet approved for the Dutch reference product; 17 and 18 in case of a new outer packaging).

NB 1: it is important that the new packaging size to be imported falls within the same legal status of supply and treatment duration as has been approved for the Dutch reference product (see also §1.2.1-F).

NB 2: the different packaging sizes must have the same origin. An additional packaging size that falls under a different marketing authorisation, or originates from a different Member State, must be submitted as a new application and will be fully assessed.

Repackaging in relation to the Falsified Medicines Directive (FMD)

- origin of variation: the parallel marketing authorisation holder wishes to repack due to an anti- tampering device on the original foreign packaging;
- documentation to be submitted: 1, 17 and 18.
  If the size of the new packaging is also to be changed, documentation must be submitted as described under 'Changing packaging size (contents) of the product to be imported'.

NB: the printed text on the new outer packaging must meet the same requirements as a Dutch label; see under §1.3.15 B–E.

Variation in parallel marketing authorisation holder

- origin of variation: the parallel marketing authorisation holder transfers the marketing authorisation to another legal entity;
- documentation to be submitted: 1, 6, 7, 13, 14, 15, 20 (if the parallel product and

Dutch reference product have not followed the same MRP).

NB: the application letter must also include the following: (a) name, business address, telephone, fax and email address of the current and the new marketing authorisation holder and (b) a declaration that, other than with respect to the information regarding the marketing authorisation holder and (if applicable) the product name, no changes will be made to the package leaflet and label.
Furthermore, if the variation in marketing authorisation holder results in a variation in product name, both variations can be submitted as one case.

Variation in name and/or address of the parallel marketing authorisation holder

- origin of variation: the parallel marketing authorisation holder has changed its name and/or address but is still the same legal entity;
- documentation to be submitted: 1, 6, 7.

NB: the application letter must also include a declaration that, other than with respect to the name and/or address of the parallel marketing authorisation holder, no changes will be made to the package leaflet and label.

Variation in name of parallel product

- origin of variation: the parallel marketing authorisation holder wishes to change the product name, for example due to commercial reasons, or the name change is the result of a change in marketing authorisation holder;
- documentation to be submitted: 1, 6, 7.

NB: the application letter must also include a declaration that, other than with respect to the product name, no changes will be made to the package leaflet and label.
The new product name must meet the regulations described in §1.3.10.
If the variation in product name is the result of a variation in marketing authorisation holder, both variations can be submitted as one case.

Addition of a new legal entity in the parallel marketing chain

- origin of variation: the parallel marketing authorisation holder wishes to add a legal entity responsible for the repackaging/relabelling, release and/or supply of the parallel import product;
- documentation to be submitted: 7, 15.

NB: the application letter must also include a declaration that, other than with respect to the listed repackager, no changes will be made to the package leaflet and label.
See §1.3.15-D and §1.3.18.

2.5 Change to the package leaflet shortly after submission of year-end withdrawal

If a request for withdrawal of the marketing authorisation effective 31 December has been sent that involves a combined package leaflet, a variation (change to package leaflet) can subsequently be submitted, with the combined package leaflet containing only the products for which the marketing authorisation is maintained.
The MEB will process this variation within the normal deadline (1 month).
The letter accompanying the change must set out that a request for withdrawal of one or

more products from the package leaflet effective 31 December 20xx has already been submitted.
The MEB will then take up the change to the package leaflet from the withdrawal request and process both cases together (within 1 month of receipt of the variation).
However, a situation where a new batch of products to be withdrawn is marketed with a package leaflet from which the new safety information from the change is missing is not desirable. In that case, the change must be submitted for all products from the package leaflet, including the products to be withdrawn effective 31 December.

3. Withdrawal of marketing authorisation for parallel or reference product

3.1 Introduction

This section describes the situation where the parallel importer decides to request the withdrawal of the parallel marketing authorisation (§3.2) or where the marketing authorisation for the Dutch reference product is withdrawn (§3.3).

3.2 Withdrawal of parallel marketing authorisation at the request of the parallel marketing authorisation holder

A request for withdrawal should be accompanied by a completed and signed application form 'Withdrawal of parallel marketing authorisation at the request of the parallel marketing authorisation holder', which can be found on the MEB website.
In the case of a combined package leaflet, an amended package leaflet (clean and track changes version) and the 'Declaration for a package leaflet of a parallel imported product' must also be submitted. In the event that, as a result of the removal of one or more products from the combined package:

(1) not all dosages are achievable any more, then this must be stated in the package leaflet by means of the relevant standard sentence; or
(2) not all indications are feasible any more, then the relevant indication(s) and all related information must be deleted from the package leaflet.

(See the 'Withdrawal of parallel marketing authorisation' form on the MEB website.)

3.3 Withdrawal of marketing authorisation for the Dutch reference product

3.3.1 Introduction

If the marketing authorisation for the Dutch reference product is withdrawn, the linked parallel marketing authorisation(s) will continue(s) to exist, unless the MEB deems there are valid grounds to withdraw the parallel marketing authorisation(s) due to public health concerns (Section 48(6) of the Medicines Act).
If such grounds exist, the MEB will notify the parallel marketing authorisation holder of the intention to withdraw the authorisation on the instructions of the MEB. In this notice of the intention to withdraw the authorisation, the parallel marketing authorisation holder will be asked to submit substantiating arguments and/or data to demonstrate that keeping the parallel import product on the market does not pose a risk to public health. If no (convincing) arguments are submitted, the marketing authorisation will be withdrawn.

3.3.2 Parallel marketing authorisation continues to exist

If the MEB concludes that the parallel marketing authorisation can continue and the parallel importer does not indicate that it wishes to withdraw the parallel marketing

authorisation(s), the parallel product will remain linked to the withdrawn reference product. The parallel marketing authorisation holder must then submit a proposal for a new reference SmPC, which will from that point serve as a guideline for keeping the parallel package leaflet up to date. The SmPC of the withdrawn reference product (RVG2) will be 'frozen' from the moment of withdrawal, meaning that the package leaflet for the parallel product can no longer be updated with new insights and therefore will, over time, no longer reflect the current scientific knowledge. Therefore, a source of information other than the 'frozen' SmPC of RVG2, which the parallel marketing authorisation holder will have to use to keep the package leaflet of the parallel product up to date, will have to be designated.

There are then two options:

1. The parallel product can be linked to the SmPC of another product authorised in the Netherlands with the same qualitative and quantitative composition of active ingredient(s) and a similar pharmaceutical form (i.e. an improved product, a copy dossier of the reference product, a 'second innovator' or a generic).
2. No suitable reference SmPC is found to link the parallel product to. The parallel product will then continue without a Dutch reference SmPC.

In addition, the parallel marketing authorisation holder must submit an agreement between the parallel marketing authorisation holder and the marketing authorisation holder of the parallel product in the country of origin, or an agreement between the parallel marketing authorisation holder and the wholesaler in the country of origin. This agreement must state that, in the event of a quality defect, recall or pharmacovigilance issues, the marketing authorisation holder of the parallel product must be informed accordingly by the marketing authorisation holder or the wholesaler in the country of origin. This agreement must be signed by the marketing authorisation holder or the wholesaler in the country of origin of the parallel product, and the relevant product must be referred to in the agreement. If the parallel marketing authorisation holder receives a report on a quality defect, recall or pharmacovigilance issue, he must pass on this information to the MEB immediately.

If the reference product of a parallel product is withdrawn, the SmPC of the reference product will no longer appear with the parallel product in the Medicines Information Bank. The new reference SmPC for the parallel product will not appear either.

3.3.3 Link to a new reference SmPC

The parallel marketing authorisation holder must submit a proposal for a new reference SmPC. The MEB will then assess whether this is indeed (the most) suitable.
If the parallel product is linked to a new reference SmPC, the parallel marketing authorisation holder must from then on focus on this new reference SmPC in order to keep the package leaflet up to date. From that time on, the new reference SmPC will serve as the basis for keeping the parallel package leaflet up to date. This means that only new safety information (new contraindications, warnings, interactions, adverse reactions, etc.) must be included in the parallel package leaflet. It is not the intention that the entire parallel package leaflet should be made identical to the package leaflet accompanying the new reference SmPC. Consequently, no package leaflet declaration should be submitted, but a justification must be provided of why the additional safety information is also applicable to the parallel product. The MEB will then assess whether this additional information is in fact applicable to the parallel product.

3.3.4 No link to a new reference SmPC

If the parallel marketing authorisation continues to exist without a reference SmPC, the parallel marketing holder will have the following obligations:

1. The parallel marketing authorisation holder must submit a declaration to the MEB stating that:
    a. the parallel marketing authorisation holder will keep abreast of any changes in the foreign authorisation dossier that could affect the quality, safety or efficacy of the product and will report this to the MEB;
    b. the parallel marketing authorisation holder will follow the recommendations from PSUR single assessment procedures (PSUSAs) (which can be found on the EMA website).
2. The parallel marketing authorisation holder must closely monitor any variations (particularly those relating to safety information) in the foreign package leaflet and pass those on to the MEB (see point 3).
   However, the parallel marketing authorisation holder should not bring entire sections of the parallel package leaflet (contraindications, warnings, interactions, adverse reactions, etc.) in line with the foreign package leaflet. It should only keep abreast of new safety information and submit this to the MEB.
3. As soon as the parallel importer notices a variation in the foreign package leaflet, the following documentation must be submitted to the MEB:
    a. application letter, describing the variation (e.g. which adverse reaction has been added to the foreign package leaflet);
    b. foreign package leaflet;
    c. a Dutch or English authorised translation of the complete foreign package leaflet, if the package leaflet is drawn up in a language other than Dutch, English, French or German. A translation only of the amended section(s) will not suffice.
4. In addition, the other obligations to provide information, as stipulated in Section 2 of this policy document, remain fully applicable.

Variations in the foreign package leaflet will only be adopted in the Dutch package leaflet of the parallel product if this involves safety information or certain information specific to the parallel product (e.g. storage conditions) and following assessment by the MEB. Indications, dosage, method of use and administration will remain unchanged from the indications, dosage, method of use and administration approved for the withdrawn reference product. This is in line with Section 48(2) of the Medicines Act. After all, the parallel product will not be linked to a new reference product.
With regard to the chemical-pharmaceutical particulars, the assessment by the regulatory authority in the country of origin will always be followed.

4. Obligations regarding pharmacovigilance

4.1 Reporting adverse reactions

The parallel marketing authorisation holder may obtain information about suspected adverse reactions related to the parallel product for which it has a parallel marketing authorisation. The parallel marketing authorisation holder must then notify these suspected adverse reactions as soon as possible but no later than within 15 days to the Netherlands Pharmacovigilance Centre Lareb. Notifications of suspected adverse reactions that meet the requirements for reporting to EudraVigilance will be processed and submitted by Lareb. If a parallel marketing authorisation holder has its own procedures/systems to process suspected adverse reactions and report these to EudraVigilance, it is not required to notify Lareb with regard to the parallel product. In that case, it can be reported directly to EudraVigilance. The original marketing authorisation holder in the country of origin and the marketing authorisation holder of the Dutch reference product have access to the notification via EudraVigilance

The original marketing authorisation holder is responsible for the pharmacovigilance system and the appointment of a 'Qualified Person for Pharmacovigilance' (QPPV). The parallel marketing authorisation holder does not have any obligation in this respect. In line with the EMA Q&A document (Electronic submission of Article 57(2) data, version 1.11, July 2017), it is not obligatory in the Netherlands for the parallel marketing authorisation holder to add details about the parallel product to the 'Extended EudraVigilance Medicinal Product Dictionary (XEVMPD)'.
If the marketing authorisation holder for the Dutch reference product or the original marketing authorisation holder in the country of origin requires any additional information regarding pharmacovigilance, the parallel importer must assist with this.

4.2 Reporting quality defects

Suppliers/marketing authorisation holders of medicinal products, including parallel importers, must report any quality defects in medicinal products to the MEB and to the Health and Youth Care Inspectorate (*Inspectie Gezondheidszorg en Jeugd*, IGJ). For more information, please refer to IGJ.