Labelling exemption requests under article 63 of Directive 2001/83/EC examined by QRD group

See also ‘Recommendations for the implementation of the exemptions to the labelling and package leaflet obligations in the centralised procedure’ document.
<table>
<thead>
<tr>
<th>Product name</th>
<th>Active substance</th>
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<th>Outcome</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pemetrexed Fresenius Kabi</strong></td>
<td></td>
<td>September 2019 (written procedure)</td>
<td>Fresenius Kabi Deutschland GmbH</td>
<td>1) minimum particulars on 20-ml and 40-ml vials (63.3)</td>
<td>Positive</td>
<td>The full pharmaceutical form should be used in all vials for consistency. The statement &quot;For single use only&quot; is important and should be displayed on the vial.</td>
</tr>
<tr>
<td><strong>VeraSeal</strong></td>
<td></td>
<td>August 2019 (written procedure)</td>
<td>Instituto Grifols, S.A.</td>
<td>1) omission of particulars on the multilingual blister label (63.3)</td>
<td>Positive</td>
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<tr>
<td><strong>Quofenix</strong></td>
<td></td>
<td>July 2019 (written procedure)</td>
<td>A. Menarini</td>
<td>1) minimum particulars for vial label</td>
<td>Positive</td>
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</tr>
<tr>
<td><strong>Polivy</strong></td>
<td></td>
<td>July 2019 (written procedure)</td>
<td>Roche Registration GmbH</td>
<td>1) minimum particulars for vial label</td>
<td>Positive</td>
<td></td>
</tr>
<tr>
<td><strong>Mepsevii</strong></td>
<td></td>
<td>June 2019 (written procedure)</td>
<td>Ultragenyx Europe GmbH</td>
<td>1) translation exemptions for the outer carton and the package leaflet (63.1).</td>
<td>Positive</td>
<td>MAH should ensure that each patient is provided with a printed package leaflet in the local language (a printed Dutch version in the case of Belgium in order to cover the three national languages). Similarly, the SmPC in local language should be provided to any healthcare professional upon request.</td>
</tr>
<tr>
<td><strong>Ultomiris</strong></td>
<td></td>
<td>April 2019 (written procedure)</td>
<td>Alexion Europe SAS</td>
<td>1) Minimum particulars for vial label</td>
<td>Positive</td>
<td></td>
</tr>
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<tr>
<td>Vyxeos</td>
<td>daunorubicin/cytarabine Art. 63(1)</td>
<td>October 2018</td>
<td>Jazz Pharmaceuticals Ireland Limited</td>
<td>English only outer carton, vial and package leaflet</td>
<td>Positive for outer carton and vial Negative for package leaflet</td>
<td>A consensus was not reached regarding the decision related to the package leaflet.</td>
</tr>
<tr>
<td>Kalydeco</td>
<td>ivacaftor Art. 63(1)</td>
<td>September 2018 (written procedure)</td>
<td>Vertex Pharmaceuticals (Europe) Ltd</td>
<td>English only blister foil sealed in a wallet</td>
<td>Positive</td>
<td>English only blister foil as follows: Invented name, strength, INN, EXP and Lot.</td>
</tr>
</tbody>
</table>
| Luxturna          | voretigene neparvovec Art. 63(3) | July 2018 (written procedure) | Spark Therapeutics Ireland Ltd                    | US vial label (for the concentrate and solvent)       | Positive                 | The QRD members agreed to have the vial marketed with the US label until Q1 2020 as a temporary measure, because of severe availability issues, with the following comments:  
- Distribution of the US pack in the EU should be accompanied by a communication letter informing HCPs about the US vials and its differences compared to the EU vial label, as follow:  
  - Clarification on what does the sentence ‘Rx only’ means and why it appears on the label (only applicable to US market)  
  - To re-emphasise in particular the need for dilution before use as the Ph. Form ‘concentrate’ is not |
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<tr>
<td><strong>Symkevi</strong></td>
<td>June 2018</td>
<td>Vertex Pharmaceuticals (Europe) Ltd</td>
<td>Omission of particulars on the blister foil sealed in a wallet</td>
<td>Negative</td>
<td>The Group requested to have the minimum particulars to be printed in English only on the blister foil as follows: Invented name, strength, INN, EXP and Lot.</td>
</tr>
<tr>
<td><strong>Nityr</strong></td>
<td>May 2018 (written procedure)</td>
<td>Cycle Pharmaceuticals Limited</td>
<td>Minimum particulars on bottle label (above 10 ml)</td>
<td>Positive</td>
<td>With the following particulars to be included: Bottle label: “Contains lactose” Outer carton and bottle label: “Shelf life after first opening - 2 months Open date: ”</td>
</tr>
<tr>
<td><strong>Vyxeos</strong></td>
<td>April 2018 (written procedure)</td>
<td>Jazz Pharmaceuticals Ireland Limited</td>
<td>Minimum particulars on vial label (50 ml)</td>
<td>Positive</td>
<td>The QRD Group has accepted the request for exemption with the following remark: Consideration should be given to the inclusion of the storage statement on the vial label, i.e. “Store in a refrigerator in an upright position”</td>
</tr>
<tr>
<td><strong>Dzuveo</strong></td>
<td>April 2018 (written procedure)</td>
<td>FGK Representative Service GmbH</td>
<td>1/ Omission of particulars from immediate label 2/English only immediate</td>
<td>1/Positive 2/Positive</td>
<td>The particulars agreed to be printed in English only on the immediate label are: Dzuveo 30 mcg sublingual tablet sufentanil</td>
</tr>
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<td>Product name</td>
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<tr>
<td>Verzenios</td>
<td>abemaciclib</td>
<td>March 2018</td>
<td>Eli Lilly Nederland B.V.</td>
<td>Omission of particulars on a blister sealed inside a card wallet</td>
<td>Negative</td>
</tr>
<tr>
<td>Delstrigo</td>
<td>Outside Art. 63</td>
<td>March 2018</td>
<td>Merck Sharp &amp; Dohme Limited</td>
<td>1/Latin or English INN on the secondary packaging 2/Minimum particulars for the bottle label</td>
<td>1/ Negative 2/ Negative</td>
</tr>
<tr>
<td>Dectova</td>
<td>zanamivir</td>
<td>March 2018</td>
<td>GlaxoSmithKline Trading Services Limited</td>
<td>Minimum particulars on vial label (26 ml)</td>
<td>Positive</td>
</tr>
<tr>
<td>Product name</td>
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<tr>
<td>Poteligeo</td>
<td>mogamulizumab</td>
<td>March 2018</td>
<td>Kyowa Kirin Limited</td>
<td>1/ English only vial label 2/ English only outer carton</td>
<td>1/ Positive 2/ Negative</td>
</tr>
<tr>
<td>Tookad</td>
<td>padeliporfin</td>
<td>March 2018</td>
<td>STEBA Biotech S.A</td>
<td>Omission of particulars on the vial label</td>
<td>Positive</td>
</tr>
<tr>
<td>Exondys</td>
<td>eteplirsen</td>
<td>October 2017</td>
<td>AVI Biopharma International Ltd</td>
<td>English only vial label</td>
<td>Positive</td>
</tr>
<tr>
<td>Prevymis</td>
<td>letermovir</td>
<td>October 2017 (Written procedure)</td>
<td>Merck Sharp &amp; Dohme Limited</td>
<td>Minimum particulars on the 30ml vial label</td>
<td>Positive</td>
</tr>
<tr>
<td>Mepsevii</td>
<td>vestronidase alfa</td>
<td>October 2017</td>
<td>Ultragenyx Germany GmbH</td>
<td>English only vial label</td>
<td>Positive</td>
</tr>
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| **Crysvita** | brosumab         | October 2017       | Kyowa Kirin Limited| 1/ English only vial label  
2/ Omission of particulars from the outer carton to have 2 tri-lingual cartons to cover all EU markets (EN/FR/DE and ES/IT/PT)  
3/ The package leaflet to be made available only in the 6 languages available for the outer carton. | 1/Positive  
2/Positive | 3/ Negative  
The company is requested to have two tri-lingual package leaflets and not one single package leaflet with 6 languages. Furthermore, the leaflet in each national language should be provided with the pack. |
| **Alofisel** | darvadstrocel    | June 2017          | Tigenix           | 1/ English only vial label  
2/ English only outer carton | 1/Positive  
2/Negative | 2/ For the outer carton, simplification of the label should be made and multilingual options should be developed. |
<p>| <strong>Mvasi</strong>    | bevacizumab      | June 2017          | Amgen             | Minimum particulars on a 20 ml vial | Positive | The Group accepted to have the minimum particulars on the 20 ml vial label, with the statement on the reconstitution step to be added, and the total content per total volume highlighted. |</p>
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<td><strong>Prevymis</strong></td>
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</tbody>
</table>
letermovir  
Art. 63(1) | March 2017 | Merck Sharp & Dohme Limited | 1/English only blister foil  
2/English only vial label | 1/Positive  
2/Negative | The Group accepted the translation exemption for the blister, with the use of the short term of the pharmaceutical form, i.e. "tablets". However the request for the English vial label was rejected because the dilution steps were considered too critical for the safe administration of the product. |
| **Myalepta** |  
metreleptin  
Art. 63(1) | March 2017 | Aegerion Pharmaceuticals Limited | 1/ English only outer carton  
2/ English only vial label | 1/Negative  
2/Positive | The Group rejected the request for English only outer carton, and accepted the English only immediate labelling. The company could still apply for a translation exemption request of the outer carton at national level, after marketing authorisation is granted, as per Art.63.3, making use of the severe availability provision. |
| **Defitelio** |  
defibrotide  
Art. 63(1) | March 2017 | Gentium S.r.l. | 1/English only outer carton and vial label in 7 countries (CZ, HR, EL, SL, BG, HU, and PL).  
2/English only package leaflet in 4 of those 7 countries, i.e. EL, SL, HR and PL. | 1/Partially positive  
2/No consensus | 1/All MSs accepted the company’s request with the exception of PL.  
2/ The applicant should submit this specific request separately to each Member State, in accordance with Art.63.3. Nevertheless, HR and SL confirmed their acceptance of the leaflet in English. |
| **Bronchitol** |  
mannitol  
Art. 63(1) | March 2017 | Pharmaxis Pharmaceuticals Limited | Bilingual English/German pack in 13 countries (BG, CZ, ET, EL, HU, LV, LT, MT, PL, PT, RO, SK, SL) | Negative | The Group rejected the request based on a number of important warnings on the outer carton which should be translated. The Group requested the MAH to first look into the possibility of developing multilingual packs. |
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<tr>
<td><strong>Cystadrops</strong></td>
<td>March 2017</td>
<td>Orphan Europe S.A.R.L.</td>
<td>Bilingual French/Dutch outer carton in Belgium</td>
<td>Positive</td>
<td></td>
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<tr>
<td>mercaptamine</td>
<td></td>
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<tr>
<td>Art. 63(1)</td>
<td></td>
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<tr>
<td><strong>Ixiaro</strong></td>
<td>October 2016</td>
<td>Valneva Austria GmbH</td>
<td>1/ English only syringe label</td>
<td>Positive</td>
<td>2/The Group did not accept the printing of expiry date in abbreviated English. The use of a numerical format was proposed instead.</td>
</tr>
<tr>
<td>japanese encephalitis vaccine (inactivated, adsorbed)</td>
<td></td>
<td></td>
<td>2/Exemption from printing of expiry date (month) in English on the carton, blister and syringe label.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Art. 63(3)</td>
<td></td>
<td></td>
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<tr>
<td><strong>Lutathera</strong></td>
<td>October 2016</td>
<td>Advanced Accelerator Applications</td>
<td>1/English only vial label with minimum particulars (10 ml)</td>
<td>Positive</td>
<td>2/Positive</td>
</tr>
<tr>
<td>lutetium (177Lu) oxodotreotide</td>
<td></td>
<td></td>
<td>2/ Simplification of package leaflet (omission of manufacturer)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Art. 63(1) and 63(3)</td>
<td></td>
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<tr>
<td><strong>Lamzede</strong></td>
<td>October 2016</td>
<td>Chiesi Farmaceutici S.p.A.</td>
<td>English only vial label</td>
<td>Positive</td>
<td></td>
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<tr>
<td>velmanase alfa</td>
<td></td>
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<tr>
<td><strong>Truxima</strong></td>
<td><em>rituximab</em></td>
<td>October 2016</td>
<td>Celltrion Healthcare Hungary Kft.</td>
<td>Minimum particulars on vial label (50 ml)</td>
<td>Positive</td>
</tr>
<tr>
<td><strong>Sirturo</strong></td>
<td><em>bedaquiline</em></td>
<td>October 2016</td>
<td>Janssen-Cilag International NV</td>
<td>English only blister label</td>
<td>Positive</td>
</tr>
<tr>
<td><strong>Spinraza</strong></td>
<td><em>nusinersen</em></td>
<td>October 2016</td>
<td>Biogen Idec Ltd</td>
<td>1/English only outer carton 2/English only vial label</td>
<td>1/Negative 2/Positive</td>
</tr>
<tr>
<td><strong>Tecentriq</strong></td>
<td><em>atezolizumab</em></td>
<td>June 2016</td>
<td>Roche</td>
<td>Minimum particulars on vial label (20 ml)</td>
<td>Positive</td>
</tr>
<tr>
<td><strong>Ocrevus</strong></td>
<td><em>ocrelizumab</em></td>
<td>June 2016</td>
<td>Roche</td>
<td>Minimum particulars on vial label (15 ml)</td>
<td>Positive</td>
</tr>
<tr>
<td>Product name</td>
<td>Active substance</td>
<td>Date of discussion</td>
<td>Company name</td>
<td>Company proposal</td>
<td>Outcome</td>
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<tr>
<td>Venclyxto</td>
<td>venetoclax</td>
<td>June 2016</td>
<td>AbbVie Ltd.</td>
<td>To supply with UK/Finland/Sweden blisters/cartons initial packs for Hungary/Poland, Bulgaria/Romania, Czech/Slovakia, Estonia/Lithuania/Latvia and Croatia/Slovenia markets only.</td>
<td>Positive</td>
</tr>
<tr>
<td><strong>Orphan status withdrawn</strong></td>
<td></td>
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<tr>
<td>Revlimid</td>
<td>lenalidomide</td>
<td>June 2016</td>
<td>Celgene Europe Limited</td>
<td>English only blister label in Portugal (2.5 mg pack only)</td>
<td>Positive</td>
</tr>
<tr>
<td>Zinplava</td>
<td>bezlotoxumab</td>
<td>April 2016 (Written procedure)</td>
<td>Merck Sharp &amp; Dohme Limited</td>
<td>Minimum particulars on vial label</td>
<td>Positive</td>
</tr>
<tr>
<td>Brineura</td>
<td>cerliponase alfa</td>
<td>March 2016</td>
<td>BioMarin International Limited</td>
<td>1/ English only vial and outer carton 2/ English only package leaflet</td>
<td>1/ Positive 2/ No consensus</td>
</tr>
<tr>
<td>Product name</td>
<td>Date of discussion</td>
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<td>Company proposal</td>
<td>Outcome</td>
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<tr>
<td><strong>EndolucinBeta</strong>&lt;br&gt;lutetium (177 Lu) chloride&lt;br&gt;Art. 63(3)</td>
<td>March 2016</td>
<td>ITG Isotope Technologies Garching GmbH</td>
<td>Omission of “For administration after <em>in vitro</em> radiolabelling“ and pharmaceutical form from the vial label</td>
<td>Positive</td>
<td>The exemption for 250 English packages to be marketed in Poland was confirmed by the Polish QRD member. This exemption is granted as a temporary measure, since the MAH confirmed that an outer carton in Polish was being developed and would be available shortly.</td>
</tr>
<tr>
<td><strong>Imnovid</strong>&lt;br&gt;pomalidomide&lt;br&gt;Art. 63(1)</td>
<td>March 2016</td>
<td>Celgene Europe Limited</td>
<td>EN only outer carton in Poland</td>
<td>Positive</td>
<td></td>
</tr>
<tr>
<td><strong>Vizamyl</strong>&lt;br&gt;flutemetamol (18F)&lt;br&gt;Art. 63(3)</td>
<td>March 2016</td>
<td>GE Healthcare Ltd</td>
<td>Simplification of package leaflet (omission of manufacturers)</td>
<td>Positive</td>
<td>The Group agreed, due to the particularities of this product (radiopharmaceutical), to the Company’s request to include the manufacturer’s details only on the vial label. It should be requested that the manufacturer is also displayed on the shield.</td>
</tr>
<tr>
<td><strong>Dinutuximab beta</strong>&lt;br&gt;Apeiron&lt;br&gt;dinutuximab beta&lt;br&gt;Art. 63(1)</td>
<td>October 2015</td>
<td>APEIRON Biologics AG</td>
<td>1/ English only vial label&lt;br&gt;2/ English only outer carton&lt;br&gt;3/ English only package leaflet</td>
<td>1/Positive&lt;br&gt;2/Negative&lt;br&gt;3/No consensus</td>
<td>2/ The applicant should first explore the possibility to accommodate as many languages as possible of those countries most affected by the disease. To this end, current text on the carton could be simplified. 3/ To be submitted nationally (as per Art.63.3).</td>
</tr>
<tr>
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<tr>
<td>Pandemic influenza vaccine H5N1 MedImmune</td>
<td>October 2015</td>
<td>MedImmune</td>
<td>Omission of common name &quot;Pandemic influenza vaccine&quot; from the immediate packaging</td>
<td>Positive</td>
<td></td>
</tr>
<tr>
<td>pandemic influenza vaccine (H5N1) (live attenuated, nasal)</td>
<td>Art. 63(3)</td>
<td></td>
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</tr>
<tr>
<td>Wakix pitolisant</td>
<td>October 2015</td>
<td>Bioprojet Pharma</td>
<td>EN only outer carton and bottle label</td>
<td>Negative</td>
<td>First option should be the creation of multilingual packs.</td>
</tr>
<tr>
<td></td>
<td>Art. 63(1)</td>
<td></td>
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</tr>
<tr>
<td>Strimvelis</td>
<td>October 2015</td>
<td>GSK</td>
<td>Minimum particulars on the label pouch</td>
<td>Positive</td>
<td></td>
</tr>
<tr>
<td>autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence</td>
<td>Art. 63(3)</td>
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<tr>
<td>Iclusig ponatinib</td>
<td>October 2015</td>
<td>Ariad Pharma</td>
<td>EN only blister and pouch label</td>
<td>Positive</td>
<td>Short term of the pharmaceutical form (tablets) should be used in the blister and pouch foil.</td>
</tr>
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<td><strong>Zerbaxa</strong></td>
<td>ceftolozane / tazobactam</td>
<td>July 2015</td>
<td>Cubist Pharmaceuticals</td>
<td>Minimum particulars on vial label (20 ml)</td>
<td>Positive</td>
</tr>
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<td>Art. 63(3)</td>
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| **Zepatier** | grazoprevir/elbasvir | June 2015         | Merck Sharp & Dohme Limited | 1/ English only blister label  
2/ Omission of EXP and Lot from the wallet label  
3/Braille on inner side of the wallet carton  
4/ EXP and Lot in English only on the outer carton | Positive | 1/ The QRD Group accepted the request to have the blister label in English only with the following information to be displayed on the blister label: Invented name, INN (English and latin), EXP, Lot and 2D code. |
<p>| Art. 63(1) |            |                    |              |                 |         |          |
| <strong>Praxbind</strong> | idarucizumab | June 2015          | Boehringer Ingelheim International GmbH | Simplification of vial label (50 ml) | Positive | The excipients and the ‘single-use’ statement should be part of the vial label. The MAH details can be removed to gain space and the overall design of the label will need to be addressed. The abbreviation for the route of administration can also be used in case of space constraints. |
| Art. 63(3) |          |                    |              |                 |         |          |
| <strong>Coagadex</strong> | human coagulation factor X | June 2015 | BIO PRODUCTS LABORATORY | English only outer and inner label, and package leaflet | Negative | The QRD Group suggested to explore first simplification of the labelling to allow the combination of several languages; if the assessment of the multilingual packs is not satisfactory, then the request of English only packaging may be reconsidered. The Group suggested to apply |</p>
<table>
<thead>
<tr>
<th>Product name</th>
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<th>Company name</th>
<th>Company proposal</th>
<th>Outcome</th>
<th>Comments</th>
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<tbody>
<tr>
<td><strong>Zalviso</strong></td>
<td>June 2015</td>
<td>Grunenthal GmbH</td>
<td>Omission of particulars (expiry date) from cartridge label</td>
<td>Positive</td>
<td>nationally to those MSs that could accept an English only package leaflet.</td>
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<tr>
<td>sufentanil</td>
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<td>Art. 63(3)</td>
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<tr>
<td><strong>Sirturo</strong></td>
<td>March 2015</td>
<td>Janssen-Cilag</td>
<td>English only labelling</td>
<td>Negative</td>
<td>The Group rejected the request. Despite the orphan status, an English only label for a medicine to be handled directly by the patient raised concerns for a number of Member States. The Group suggested exploring multilingual labelling in order to cover as many markets as possible.</td>
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<tr>
<td>bedaquiline</td>
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<td>Art. 63(1)</td>
<td></td>
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<tr>
<td><strong>Kyprolis</strong></td>
<td>March 2015</td>
<td>Amgen</td>
<td>Minimum particulars on vial label</td>
<td>Negative</td>
<td>The request was rejected and the applicant will be asked to look into alternative options to fit the full set of particulars (e.g. concertina labels).</td>
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<td>carfilzomib</td>
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<tr>
<td>Art. 63(3)</td>
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<tr>
<td>Product name</td>
<td>Active substance</td>
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<td>Company proposal</td>
<td>Outcome</td>
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<tr>
<td><strong>Strensiq</strong></td>
<td>asfotase alfa</td>
<td>March 2015</td>
<td>Alexion</td>
<td>Partial translation exemption of labelling and leaflet</td>
<td>Negative</td>
</tr>
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<td></td>
<td>Art. 63(1)</td>
<td></td>
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| **Signifor** | pasireotide     | March 2015         | Novartis Europharm Ltd | Omission of certain particulars on intermediate label (blister tray) | Negative | The Group concluded that the applicant’s proposal to display the invented name along with EXP and Lot of the injection kit is misleading and, therefore, not acceptable. Deletion of all particulars from the plastic tray foil would be acceptable, as an alternative solution. |
|              | Art. 63(3)       |                    |              |                  |         |          |

<p>| <strong>Revlimid, Thalidomide, Imnovid</strong> | lenalidomide, thalidomide, pomalidomide | March 2015 | Celgene Europe Ltd | English only outer carton in Baltic States | Negative | The Group rejected the request. Multilingual outer carton was recommended due to important warnings and self-administration by patients, but certain translation exceptions could be allowed (e.g. INN). |
|                                    | Art. 63(1)       |                    |              |                  |         |          |</p>
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<th>Outcome</th>
<th>Comments</th>
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<tbody>
<tr>
<td><strong>Zavicefta</strong></td>
<td><strong>ceftazidime / avibactam</strong></td>
<td>March 2015</td>
<td>AstraZeneca</td>
<td>Minimum particulars on 20 ml vial label</td>
<td>Positive</td>
<td></td>
</tr>
<tr>
<td><strong>Evarrest</strong></td>
<td><strong>human fibrinogen / human thrombin</strong></td>
<td>December 2014 (written procedure)</td>
<td>Omrix Biopharmaceuticals N. V.</td>
<td>Minimum particulars on foil pouch label</td>
<td>Partially positive</td>
<td></td>
</tr>
<tr>
<td><strong>Lenvima</strong></td>
<td><strong>lenvatinib</strong></td>
<td>October 2014</td>
<td>Eisai Ltd.</td>
<td>1/English only outer carton 2/Simplification of blister label (omission of pharmaceutical form to have an English only label)</td>
<td>1/Negative 2/Partially positive</td>
<td>1/The justification was not considered strong enough and, on the other hand, the product was meant to be handled directly by patients. Multilingual packs could be an option provided readability is not compromised. 2/The Group was in agreement to have an English only blister that includes the pharmaceutical form.</td>
</tr>
<tr>
<td><strong>Unituxin</strong></td>
<td><strong>dinutuximab</strong></td>
<td>June 2014, October 2014 and June 2015</td>
<td>United Therapeutics Europe</td>
<td>1/ English only labelling (outer and inner) 2/ English only package leaflet</td>
<td>1/ Positive 2/Negative</td>
<td>2/ The applicant should apply for the translation exemption individually at each NCA based on Art 63.3.</td>
</tr>
<tr>
<td>Product name</td>
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<td>Company name</td>
<td>Company proposal</td>
<td>Outcome</td>
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<tr>
<td><strong>Amyvid</strong></td>
<td>florbetapir (18F)</td>
<td>June 2014</td>
<td>Avid Radiopharmaceuticals</td>
<td>Simplification of package leaflet (omission of manufacturers)</td>
<td>Positive</td>
<td>The Group agreed, due to the particularities of this product (radiopharmaceutical), to the Company’s request to include the manufacturer’s details only on the vial label. It should be requested that the manufacturer is also displayed on the shield.</td>
</tr>
<tr>
<td><strong>Uptravi</strong></td>
<td>selexipag</td>
<td>June 2014</td>
<td>Actelion Registration Ltd.</td>
<td>English only blister</td>
<td>Positive</td>
<td>The Group considered the proposal acceptable if the unit is spelt out.</td>
</tr>
<tr>
<td><strong>Raplixa</strong></td>
<td>human fibrinogen / human thrombin</td>
<td>June 2014</td>
<td>ProFibrix BV</td>
<td>Simplification of vial label</td>
<td>Negative</td>
<td>The Group concluded that more elements should be included on the label, i.e. active substance, strength and pharmaceutical form.</td>
</tr>
<tr>
<td><strong>Quinsair</strong></td>
<td>levofloxacin</td>
<td>June 2014</td>
<td>Aptalis Pharma</td>
<td>English only ampoule label</td>
<td>Positive</td>
<td></td>
</tr>
<tr>
<td><strong>Procysbi</strong></td>
<td>mercaptamine</td>
<td>June 2014</td>
<td>Raptor Pharmaceuticals Europe BV</td>
<td>Translation exemption of 'EXP' and 'Lot' on outer carton and inner label</td>
<td>Partially positive</td>
<td>BG, LV, ES, IT, LT and PL accepted to use EXP and Lot on both the outer carton and bottle label on the grounds of its orphan status. DE only accepted to use EXP and Lot on the bottle label, but not on the outer carton.</td>
</tr>
<tr>
<td>Product name</td>
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<td>Company proposal</td>
<td>Outcome</td>
<td>Comments</td>
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</tr>
<tr>
<td>Vimizim <em>elosulfase alfa</em></td>
<td>October 2013</td>
<td>BioMarin</td>
<td>English only vial label</td>
<td>Positive</td>
<td>No concerns were raised</td>
<td></td>
</tr>
<tr>
<td>Entyvio <em>vedolizumab</em></td>
<td>June 2013</td>
<td>Takeda Pharma</td>
<td>Minimum particulars for the 20 mL vial label</td>
<td>Positive</td>
<td>No concerns were raised</td>
<td></td>
</tr>
</tbody>
</table>
| Xofigo *radium Ra223 dichloride* | June 2013      | Bayer Pharma       | EN only vial label                                     | Positive| With regards to the proposal from the company to have multi-layered label for the lead pot, the QRD Group agreed in principle to this concept, but with the following comments:  
  - The first and last language of the booklet should be English, so that the immediate attached label is in English (in case the other languages are lost);  
  - The label should be printed on one side only (one language per page);  
  - There should not be any sticky part on the label. |
<p>| Zevalin <em>ibritumomab tiuxetan</em> | June 2013        | Spectrum pharmaceutic al | EN only for outer carton and vial label                | Positive| The Group accepted the request. However, due to the prevalence of the disease in Germany, the company should consider providing a German outer carton and vial label for this market. |</p>
<table>
<thead>
<tr>
<th>Product name</th>
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<th>Company proposal</th>
<th>Outcome</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Imnovid</td>
<td>pomalidomide</td>
<td>June 2013</td>
<td>Celgene</td>
<td>EN only for blister foil</td>
<td>Positive</td>
<td>No concerns were raised.</td>
</tr>
<tr>
<td>Ceplene</td>
<td>histamine dihydrochloride</td>
<td>June 2013</td>
<td>Meda AB</td>
<td>EN only for outer carton and vial label</td>
<td>Positive</td>
<td></td>
</tr>
</tbody>
</table>
| Spherox           | spheroids of human autologous matrix-associated chondrocytes                      | March 2013         | CO.DON AG     | Simplification of labelling               | Positive| a) The applicant’s proposal to only include batch number and number of spheroids in the immediate container (application system or syringe) was agreed by the Group.  
                        |                                                                                 |                    |                                           |         | b) Proposal to only include the patients’ ID in the secondary packaging (tube) was agreed by the Group.  
<pre><code>                    |                                                                                 |                    |                                           |         | C) Proposal to omit both statements ‘Keep out of the sight and reach of children’ and ‘Read the package leaflet before use’ on the outer packaging (pouch) was agreed by the Group.  |
</code></pre>
<p>| Granupas          | para-aminosalicylic acid                                                          | March 2013         | Lucane Pharma | EN only sachet labelling                   | Positive| The Group agreed to have the main particulars in English only (pharmaceutical form, INN, EXP and Lot) and requested to include the full warning translated in all languages on the sachet ‘Do not use if sachet is swollen or the granules have lost their light brown. |</p>
<table>
<thead>
<tr>
<th>Product name</th>
<th>Active substance</th>
<th>Date of discussion</th>
<th>Company name</th>
<th>Company proposal</th>
<th>Outcome</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>Naglazyme</td>
<td>galsulfase</td>
<td>March 2013</td>
<td>BioMarin</td>
<td>EN only for vial label</td>
<td>Positive</td>
<td>No concerns were raised.</td>
</tr>
<tr>
<td>Vantobra</td>
<td>tobramycin</td>
<td>March 2013</td>
<td>Pari Pharma</td>
<td>1/ EN only ampoule labelling 2/ Simplification of ampoule labelling</td>
<td>Positive for both requests</td>
<td></td>
</tr>
<tr>
<td>Lucentis</td>
<td>ranibizumab</td>
<td>May 2012</td>
<td>Novartis</td>
<td>To omit the route of administration 'intravitreal use' from the pre-filled syringe label in all languages</td>
<td>Negative</td>
<td>The QRD Group felt the current information provided on the pre-filled syringe label could be re-arranged in order to gain some space to fit the route of administration; e.g. by decreasing the importance given to the trade name and company name.</td>
</tr>
<tr>
<td>NovoThirteen</td>
<td>catridecacog</td>
<td>November 2011</td>
<td>NovoNordisk</td>
<td>EN only for outer carton and vial label</td>
<td>Positive</td>
<td>No concerns were raised.</td>
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colour and are dark brown or purple’ together with the warning ‘Do not chew’.
<table>
<thead>
<tr>
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<th>Company name</th>
<th>Company proposal</th>
<th>Outcome</th>
<th>Comments</th>
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<tbody>
<tr>
<td>Tysabri</td>
<td>natalizumab</td>
<td>June 2011</td>
<td>Elan Pharma International Ltd</td>
<td>Minimum particulars on the 15 ml vial label</td>
<td>Positive</td>
<td>No concerns were raised.</td>
</tr>
<tr>
<td>Nexavar</td>
<td>sorafenib</td>
<td>March 2011</td>
<td>Bayer</td>
<td>INN in EN only for the blister foil</td>
<td>Positive</td>
<td>No concerns were raised.</td>
</tr>
<tr>
<td>Zinforo</td>
<td>ceftaroline fosamil</td>
<td>November 2010</td>
<td>AstraZeneca</td>
<td>Vial (20ml) label simplification</td>
<td>Positive</td>
<td>The group agreed to implement the minimum particulars for the vial label of Zinforo.</td>
</tr>
<tr>
<td>Xofigo</td>
<td>radium Ra223 dichloride</td>
<td>November 2010</td>
<td>Bayer Pharma AG</td>
<td>1/ EN only and simplification of vial (10ml) labelling 2/ EN only labelling for the lead container</td>
<td>1. Positive 2. Negative</td>
<td>1. The request from the company to have the particulars set out in Art.66 on the vial label in EN only has been accepted by the Group. 2. However, the Group would allow the exclusion of certain particulars considered not critical in order to gain space.</td>
</tr>
<tr>
<td>Product name</td>
<td>Active substance</td>
<td>Date of discussion</td>
<td>Company name</td>
<td>Company proposal</td>
<td>Outcome</td>
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<tr>
<td>Bronchitol</td>
<td>Art 63(1)</td>
<td>September 2010</td>
<td>Pharmaxis</td>
<td>EN only and simplification of blister labelling</td>
<td>Positive for the EN only. Negative for the simplification</td>
<td>The full pharmaceutical form (inhalation powder, hard capsules) should be displayed on the labelling.</td>
</tr>
<tr>
<td>Glybera</td>
<td>Art 63(1)</td>
<td>March 2010</td>
<td>Diamond Biopharm Ltd</td>
<td>EN only labelling for vial and protective casing</td>
<td>Positive</td>
<td>No concerns were raised.</td>
</tr>
<tr>
<td>Scintimun</td>
<td>Art 63(3)</td>
<td>November 2009</td>
<td>CIS bio international</td>
<td>EN only labelling for certain MS (considered as small markets) and FR &amp; NL only labelling for BE pack.</td>
<td>Positive</td>
<td>By law, all three languages (NL, FR and DE) have to be included on the label for BE. However, in BE for radiopharmaceuticals kits, an exception for small immediate packs is possible and therefore an EN only label could be accepted.</td>
</tr>
<tr>
<td>Tracleer (paediatric formulation)</td>
<td>Art 63(1)</td>
<td>September 2009</td>
<td>Actelion Pharmaceuticals Ltd</td>
<td>Multi-lingual blister foil DE/ES/FR/IT/PT/EN for the 6 bigger markets (AT, DE, ES, FR, IT, PT) EN only for outer carton and blister foil for the rest of the Member States</td>
<td>Positive</td>
<td>With reservation of EL to be included as the 7th biggest market.</td>
</tr>
<tr>
<td>Firdapse (previously Zenas)</td>
<td></td>
<td>June 2009</td>
<td>EUSA Pharma SAS</td>
<td>EN only ampoule label</td>
<td>Positive</td>
<td>No concerns were raised.</td>
</tr>
<tr>
<td>Product name</td>
<td>Active substance</td>
<td>Date of discussion</td>
<td>Company name</td>
<td>Company proposal</td>
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<tr>
<td><strong>Pedea</strong></td>
<td>Art 63(1)</td>
<td>June 2009</td>
<td>Orphan Europe</td>
<td>EN only ampoule label</td>
<td>Positive</td>
<td>No concerns were raised.</td>
</tr>
<tr>
<td><strong>Ixiaro (withdrawal of orphan designation)</strong></td>
<td>Review of QRD decision made at June 2008 plenary. Now the orphan designation has been withdrawn, company’s justification falls under 63.3. Therefore, translation exemptions can still be applied to the package leaflet but not to the labelling anymore.</td>
<td>June 2009</td>
<td>Intercell</td>
<td>EN syringe label Tri-lingual outer carton (EN/ES/IT, DE/FR/NL, SE/FI/NO) Tri-lingual package leaflet (EN/ES/IT, DE/FR/NL, SE/FI/NO)</td>
<td>Negative</td>
<td>The Group suggested to have another combination of 3 languages for the package leaflet (including Greek) and to translate the labelling in all languages. Moreover, the company should ensure, and, if necessary, consult with the relevant national authorities, that the combination supplied in a given MS is the preferred one by the respective national authority.</td>
</tr>
<tr>
<td><strong>Insuman</strong></td>
<td>Art 63(3)</td>
<td>March 2009</td>
<td>Sanofi-Aventis</td>
<td>EN/FR labelling (outer carton, label and package leaflet)</td>
<td>Positive</td>
<td>Provided that: a sentence, translated in all relevant languages, is included in the bilingual FR/EN Package Leaflet informing the patient that the package leaflet is available in their language on the EMA website; the company will provide on request the package leaflet to the patient concerned in their own language; and the company will inform EMA in case of change in the</td>
</tr>
<tr>
<td>Product name</td>
<td>Date of discussion</td>
<td>Company name</td>
<td>Company proposal</td>
<td>Outcome</td>
<td>Comments</td>
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| **Treprostinil sodium**  
Art 63(1) | September 2008 | United therapeutics Europe Ltd | EN only labelling | Positive | Request in principle acceptable, however, the request to delete the INN in the immediate packaging due to readability concerns was rejected, since other particulars such as the name of the MAH could be left out instead. |
| **Ixiaro**  
Art 63(1) | June 2008 | Intercell | EN only syringe label  
Tri-lingual outer carton: EN/ES/IT, DE/FR/NL and DK/FI/NO.  
Tri-lingual package leaflet: EN/ES/IT, DE/FR/NL and DK/FI/NO. | Positive | Labelling in EN only was considered acceptable. For the package leaflet in the national language, the A4 format in all national languages would be delivered by the company, separate from the pack. |
| **Evicel**  
Art 63(3) | June 2008 | OMRIX Biopharmaceuticals S.A. | EN only vial label | Positive |  |
| **Cayston**  
Art 63(1) | June 2008 | Gilead Sciences International Ltd | EN only diluent label | Positive | Provided that an appropriate explanation is provided in the package leaflet. |

sales status for this product, as the current decision will then need to be reassessed by the QRD group.