Belgium Updates Rules on Parallel Distribution and Parallel Imports of Human Medicines

The Belgian Official Journal published yesterday a Royal Decree of 10 November 2025 "on parallel distribution and parallel imports of medicinal products for human use" (*see*, attached copy; the ***New RD***). The New RD repeals and replaces, effective on 11 December 2025, the current rules on parallel distribution and parallel imports as laid down in the Royal Decree of 19 April 2001 on parallel imports of medicinal products for human use and parallel distribution of medicinal products for human and veterinary use (the ***RD of 19 April 2001***).

The New RD contains the following noteworthy novelties:

- Contrary to the RD of 19 April 2001, Article 1 of the New RD includes a list of provisions of the Law of 25 March 1964 on medicinal products for human use (the ***Law of 25 March 1964***) that apply to parallel imports and parallel distribution of human medicines. This list was included at the request of the Council of State for clarity reasons even though its status is questionable (*see*, attached opinion dated 2 July 2024, point 8 at p. 13).
- Article 2 of the New RD includes new and revised definitions, some of which are rather obvious. This applies, for instance, to the new definitions of "medicinal product from the member state of origin" (*geneesmiddel uit de lidstaat van herkomst* / *médicament de l'État membre d'origine*) and "parallel-imported medicinal product" (*parallel ingevoerde geneesmidde*l / *médicament importé parallèlement*).
- Similarly to Article 3, §2 of the RD of 19 April 2001, Article 6 of the New RD requires that the parallel-imported medicine and the Belgian reference medicine be "identical or virtually identical". This requirement will be deemed to be satisfied if the parallel-imported medicine and the Belgian reference medicine meet each of the following conditions (changes compared to the RD of 19 April 2001 are marked in bold):
    - they have the same qualitative and quantitative composition in active substance(s);
    - they have the same pharmaceutical form**, if a different pharmaceutical form poses a risk to public health**;
    - they are therapeutically equivalent; and
    - **any difference(s) identified in relation to elements other than those mentioned in the previous points do not pose a risk to public health**.

  As follows from the above, and likewise to what has been the case under the RD of 19 April 2001 since it was amended in 2011, "common origin" is not provided for as a requirement (unless this requirement would indirectly follow from the new fourth condition). This is surprising, not in the least because "common origin" is an express requirement imposed on parallel-imported veterinary medicines in Belgium (and, for that matter, in all other EU Member States). Article 102(1) of Regulation (EU) 2019/6 of 11 December 2018 on veterinary medicinal products requires that the parallel-imported medicine and the reference medicine in the destination Member State should share a "common origin", which requirement implies that both products "*have been manufactured*

by the same manufacturer or by a manufacturer working under licence according to the same formulation". It is difficult to see why this requirement should not apply to human medicines as well. In other words, why would animals benefit from a higher level of health protection than humans?

- Article 12 and following of the New RD regulates in detail the obligation of the parallel importer to keep the parallel import licence up to date.
- Contrary to the RD of 19 April 2001, the New RD does not limit advertising by parallel importers to economic and reminder advertising, *i.e.*, advertising limited to the economic aspects of the medicine concerned or advertising whose sole purpose is to remind patients of the name of the medicine. On the contrary, Article 28 of the RD expressly provides that the holder of a parallel import licence should be treated as equivalent to the holder of a marketing authorisation or registration for the purposes of Articles 9 to 12 of the Law of 25 March 1964 governing pharmaceutical advertising, information, and promotion as well as the provision of samples.
- While, under the RD of 19 April 2001, a parallel import licence was valid for a (renewable) period of five years, the licence will now remain valid for an indefinite duration. In addition, Article 22 of the New RD provides that, if the parallel importer temporarily or permanently discontinues the marketing of the parallel imported medicine, the parallel import licence will expire by operation of law three years after the date of notification or determination of discontinuation, unless the medicine is again placed on the market before that date.
- Article 24, §1 of the New RD provides that, as a general rule, the expiry, withdrawal, suspension or termination of a parallel import licence implies that the parallel importer must not import or release new batches, but does not prevent the parallel importer from selling batches that have already been released and placed on the market.
- Article 24, §2 of the New RD provides that a parallel import licence will remain valid after the withdrawal, expiry or non-renewal of the marketing authorisation or registration of the Belgian reference medicine, unless the withdrawal, expiry or non-renewal is based on public-health considerations.
- Article 29 of the RD contains transitional provisions that apply to pending applications for (i) parallel import licences; (ii) amendments to parallel import licences; or (iii) the renewal of parallel import licences.

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