



**Request for a preliminary ruling from the Hoge Raad der Nederlanden (Netherlands) lodged on
11 September 2024 – Almirall BV, Almirall SA v Infinity Pharma BV, Pharmaline BV**

(Case C-589/24, Almirall)

(C/2024/7305)

Language of the case: Dutch

Referring court

Hoge Raad der Nederlanden

Parties to the main proceedings

Applicants: Almirall BV, Almirall SA

Defendants: Infinity Pharma BV, Pharmaline BV

Questions referred

1. Does a directive-compliant interpretation of Paragraphs 18(5) and 40(3) of the Geneesmiddelenwet (Law on medicinal products), in the light of the provisions of Article 3(2) of the Medicinal Products Directive, (1) reconcile the fact that the assessment of one of the exceptions to the authorisation requirement laid down in national law is also based on a quantitative measure that has been concretised by a numerical criterion?
2. Are the national authorities free to subject a medicinal product that falls under Article 3(2) of the Medicinal Products Directive, whereby the authorisation requirements regulated in Articles 6 and 40 of the same directive do not apply, to a national authorisation requirement on the basis of a quantitative condition regulated by national law and concretised by a numerical criterion?
3. Is it relevant to the answer to Questions 1 and 2 whether the Medicinal Products Directive provides for full harmonisation for the parts relevant to this case and, if so, does it provide for full harmonisation?
4. To what extent is it relevant to the answers to Questions 1 and 2 that, according to the Dutch-language version, the exception set out in the second sentence of Article 40(2) of the Medicinal Products Directive applies 'voor verstreking in het klein' ('for supply at retail') or, according to the English-, French- and Italian-language versions of the directive, appears to relate to a number of operations performed by the pharmacist in the context of retail?

(1) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67).