

## COMMENTARY

## Drug distribution and expenditure

## The issue of Epoetin in Italy

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The pattern of distribution and utilization of specific drugs can vary substantially across and within countries, with important implications for availability and costs. Epoetin constitutes one such example in Italy.

Epoetin, the human recombinant form of erythropoietin, has been used effectively for the treatment of anaemia in chronic renal failure for over a decade<sup>1</sup> and has been approved for this indication by the American FDA and the European EMEA since 1989. Since then, several studies have examined its potential usefulness as an alternative to transfusion in the management of anaemia in cancer patients.<sup>2</sup> Epoetin is reimbursed by the Italian National Health Service (NHS) for anaemic patients with chronic renal failure undergoing dialysis, and for chemotherapy-associated anaemia in cancer patients, i.e. selected and relatively limited numbers of patients. Nonetheless, in 2001 alpha-epoetin was the fifth highest drug in terms of total out of hospital expenditure by the NHS, accounting for € 209 million, i.e. 1.7% of the total NHS drug expenditure.

More important, the rank of alpha-epoetin expenditure was extremely variable across regions, more than for any other type of drug. In most of northern and central Italy, it was below 10 among the top ranking drugs, i.e. 11<sup>th</sup> in Lombardy, 30<sup>th</sup> in Veneto, 90<sup>th</sup> in Valle d'Aosta, 94<sup>th</sup> in Emilia, 59<sup>th</sup> in Tuscany, 97<sup>th</sup> in Umbria. In Liguria and Latium, however, it was the second ranking drug in terms of expenditure, and in Abruzzo it was third. In all southern Italy, alpha-epoetin was among the top few ranking drugs, i.e., first in Campania, second in Basilicata and Sicily, and third in Apulia and Calabria.<sup>3</sup>

The top-ranking at the overall Italian level and the regional variation in out-of-hospital sales are generally attributed to the preferred administration of epoetin during the hospital setting for dialysis in most northern and parts of central Italy, whereas in other areas of the country epoetin is usually prescribed out of hospitals.<sup>3</sup> In Campania, the defined daily dose (DDD) is approximately 4/10,000 individuals. Assuming a prevalence of subjects in dialysis of 7/10,000 inhabitants, and a 70% frequency of use of epoetin,<sup>4,5</sup> this would imply that over

80% of the drug is prescribed out of hospital. In Lombardy, such a proportion would be about 20%.

In terms of expenditure, the cost to the NHS of epoetin through hospital administration is about half the cost of external pharmacy prescriptions. Moreover, although recent clinical trials and systematic reviews confirm the role of epoetin for managing anemia associated with cancer therapy,<sup>2,6</sup> a limited and poorly defined proportion of epoetin was likely utilized for Italian cancer patients.<sup>5,7</sup>

The regions with the highest expenditures for epoetin were also those with the highest overall per capita drug expenditure, i.e. an excess of 24 € per capita in Sicily, 23 € in Campania, and 19 € in Latium, compared to the national average. In Sicily and Campania, alpha-epoetin alone accounted for about one-third of this excess expenditure. On account of the substantial impact of epoetin on drug expenditure, it is time to provide clearer guidelines on the most cost-effective way to deliver the drug in Italy.

With variable degrees, such a problem may well be present in other (European) countries, and may be even more important in the future if the use of epoetin in the treatment of cancer chemotherapy-induced anaemia becomes more widespread.

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