Doping analysis on solid ground

In a comment in Tidsskriftet no. 18/2011, with reference to the so-called Tysse case, Waaler et al. share some reflections on doping testing generally and in this case in particular (1). Race walker Erik Tysse was found guilty of breach of the provisions of the World Anti-Doping Code and the statutes of the Norwegian Olympic and Paralympic Committee and Confederation of Sports (NIF), because CERA (continuous erythropoietin receptor activator), an erythropoietin (EPO) product, was detected in his urine sample. It should be mentioned that the authors are commenting on this case after the decision by NIF’s Adjudication Committee. The decision was subsequently appealed to the Court of Arbitration for Sport (CAS) in Lausanne, where the ruling of NIF’s Adjudication Committee was upheld (2).

When it comes to the general description of an analytical method’s characteristics such as reproducibility, sensitivity and specificity, or the explanation of random and systematic errors and prediction power, we have nothing to add. This is because the authors explain these concepts, understandably enough as applied to medical problems, very well. The problem arises when incorrect conclusions are drawn about the validity of an analytical method by relying only on the record of the Adjudication Committee’s ruling and repudiated statements from the verbal proceedings.

The validity of the method was not documented by means of an A- and B-analysis of an athlete’s urine sample, but was based on an accreditation procedure in each individual WADA-accredited laboratory in accordance with international laboratory standards. This is also expressed in the assessment of a competent and independent panel of judges in the Court of Arbitration for Sport in paragraph 8.15 (2). We are on solid ground with respect to both analytical and legal toxicology when it comes to proprietary validation of this method and all other analytical methods in doping analysis.

The prerequisite for a WADA-accredited laboratory being able to use an analytical method is that the method is approved by WADA and accredited according to international ISO/IEC standard 17025. 2005. In addition, WADA issues a specific technical document that is written by professionals who have particular experience of the method in question. The document is the result of an intensive consultation process. The criteria and requirements for detection of recombinant EPO and analogues are described there, together with relevant references (3).

Specificity (selectivity) is the most important validation parameter for not producing false positive results. In the period 2000–2007, when CERA was not yet on the market, more than 8,000 urine samples were tested at WADA laboratories in Rome, Paris and Oslo using the analytical method for detecting EPO. None of these samples had an isoelectric EPO profile that was similar to a positive CERA test, and this demonstrates the degree of specificity of the chosen method.

Our conclusion is that a correct analytical and legal process was followed in the Tysse case before a final ruling was handed down by an independent court.

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