Healthy Communities PROMOTE Healthy Minds & Bodies
APHA 139TH ANNUAL MEETING AND EXPOSITION OCT 29 - NOV 2, 2011 WASHINGTON, DC

# Clinical Management and Risk-Sharing Agreements in the Acquisition of New Drugs

APHA


| VARIABLES | WEIGHTS |
|---|---|
| 6 Minutes Walking Distance Test (6MWDT) | 50% |
| Time Period until Clinical Worsening (TPCW) | 25% |
| Functional Class WHO (FC) | 10% |
| Dyspnea Borg Index (DBI) | 5% |
| Short Form Questionnaire SF-36 (QoL) | 5% |
| Brain Natriuretic Peptide (NT-Pro BNP) | 5% |

Healthcare resources must be effectively utilized. This is the central issue in the clinical management strategy currently being developed by the Andalusian Healthcare Service. The incorporation of new technologies plays a key role in dynamically allocating health resources. This is particularly true for technologies that concern the incorporation of new drugs. In this vein, the University Hospital Virgen de las Nieves (HUVN) recently signed a risk sharing agreement (RSA) with GlaxoSmithKline to acquire Volibris. The aim of the agreement is to make the final purchase price dependent on the results regarding the effectiveness of the drug for patients treated in the HUVN.

Volibris (ambrisentan) is a drug used to treat patients with pulmonary arterial hypertension (PAH). The effectiveness of this drug in idiopathic PAH and PAH associated with connective tissue disease has been demonstrated. In this case, a minimum sample size of 20 patients has been agreed on to evaluate effectiveness. Each of the patients included in the sample will be evaluated at the beginning of treatment and again after 12 weeks. Individual variation, based on six variables with different weights, will be assessed during that period. Subsequently, the average variation will be obtained for these 20 patients. This result will then be compared with the theoretical value of efficacy obtained in EPAR Report, the product information sheet, and the pivotal studies ARIES 1 and 2.

Effectiveness results for patients treated with Volibris in the HUVN are not yet available. Based on the PAH diagnosis frequency in this hospital, we calculated that the sample will be completed in a period between 12 and 18 months. A technical document covering the process of enrolling patients in the sample, data collection, and the method of transferring results to the purchase price of the drug has been developed. This document was approved by a tracking committee in which all those involved in the agreement were represented, both from the hospital and GlaxoSmithKline. Though we are still in the initial stage of the agreement, we have, so far, progressed through a crucial phase in the arrangement from the first contacts to the contract signing.

The relevance of the case presented is that it opens the way for innovative negotiations in the area of public procurement of drugs. But, while the risk sharing agreement is a pioneering tool, it should not replace the standard pharmacoeconomic analyses (CEA, CUA) and the evaluation guidelines for the acquisition of new drugs. Instead, it could be regarded as a complement for traditional techniques.

Servicio Andaluz de Salud CONSEJERÍA DE SALUD
HOSPITAL VIRGEN DE LAS NIEVES

Authors: Navarro Espigares, JL; Martínez Martínez, E. Contact information: **José Luis Navarro Espigares.** Hospital Universitario Virgen de las Nieves. Avenida Fuerzas Armadas. 18014 Granada – **Spain**. E: josel.navarro.sspa@juntadeandalucia.es

American Public Health Association
Healthy Communities PROMOTE Healthy Minds & Bodies
APHA 139TH ANNUAL MEETING AND EXPOSITION OCT 29 - NOV 2, 2011 WASHINGTON, DC