REPACKAGING OF INTRAVITREAL BEVACIZUMAB

FONDAZIONE IRCCS ISTITUTO NAZIONALE DEI TUMORI

What was done?

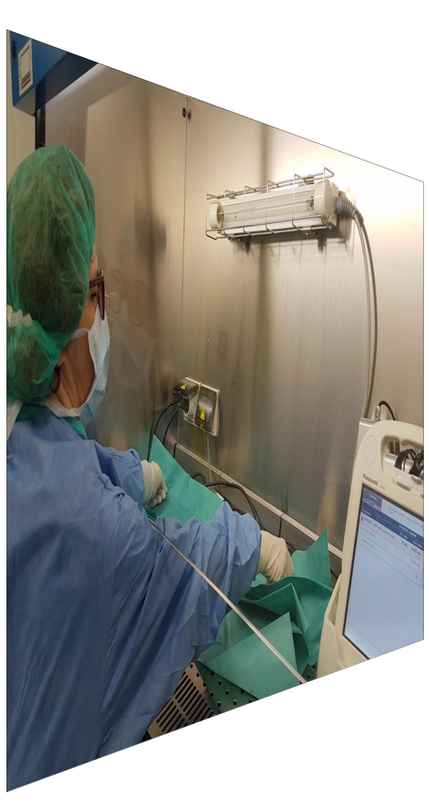
We implemented a production process to repackage a drug to be used in treatments not covered by marketing authorisation. Bevacizumab was split into fractional doses for off-label intravitreal injections; the doses obtained were given to our hospitalised patients as therapy for uveal melanoma and provided to hospitals in our region as therapy for patients with age-related macular degeneration (AMD) and diabetic macular oedema.

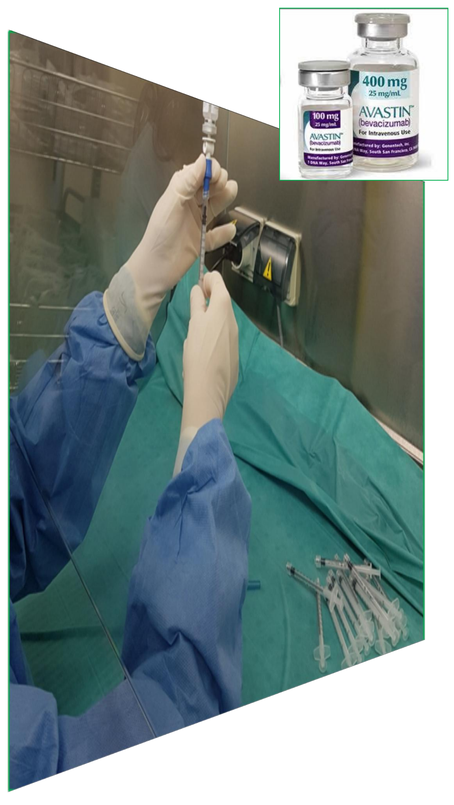
Why was it done?

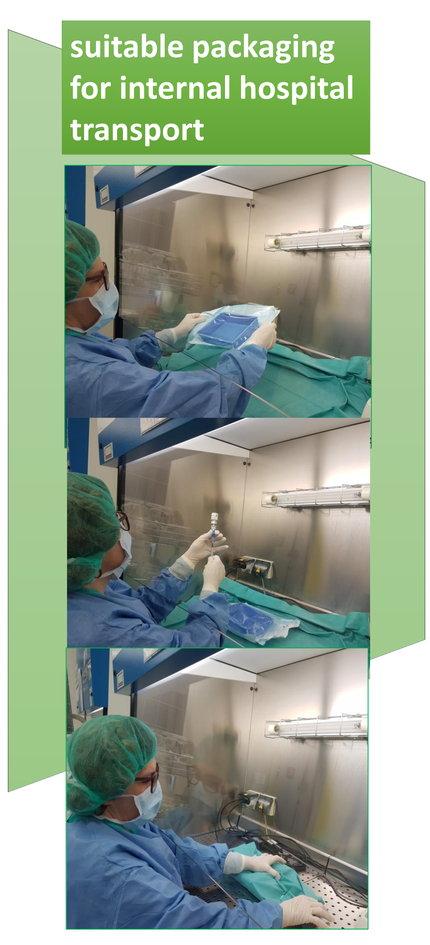
Intravitreal bevacizumab is refunded by National Health System for AMD and diabetic macular oedema but the splitting process must be carried out only by authorised pharmacies. Recently the established **regional refund price** was lowered to **€55/dose** that covers the costs of **intravitreal bevacizumab** but not the other authorised drugs ranibizumab and aflibercept. Our Centralized Pharmacy operated the repackaging of intravitreal bevacizumab for internal patients but we implemented a new process and a new procedure in order to provide doses to hospitals not equipped in performing sterile preparations.

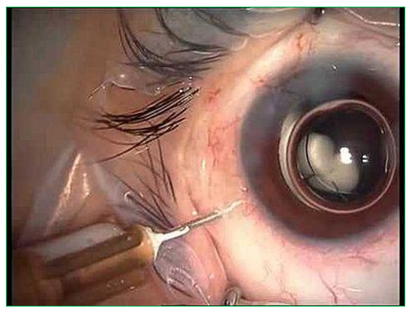
How was it done?

The procedure for preparing intravitreal injections was reviewed to optimise traceability aspects of processing batches, individual doses of finished products and particularly to choose the most suitable packaging for transport to hospitals that will administer the drug. Further quality control to regional law was established on processes and finished product: environmental, instrumental, maintenance controls. All processes were validated in accordance with applicable regulations. Agreements related to prescription, purchase, conservation and transport of bevacizumab doses were signed with the hospitals that administer the drug.









What has been achieved?

The price refunded for a single intravitreal dose of an **anti-VEGF** (vascular endothelial growth factor) drug from August 1 2019 is **€55**, previously the price for each single dose of **ranibizumab** was **€660**. Considering that AMD therapy requires a **monthly injection for about a year** we can assume a **standard average cost saving** of **€6540/patient**.

What next?

AMD is the leading cause of blindness among populations over 50 years old. To provide treatments to all those affected by degenerative eye diseases in the next years, we must operate cost savings policies safeguarding patient security. The practice described is worthy of implementation in hospital realities.

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