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Category: Drug Information and Pharmacotherapy.

OFF-LABEL USE: A DESCRIPTIVE RETROSPECTIVE ANALYSIS.

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OBJETIVES

The aim of the study is to analyse off-label use frequency, what drugs and indications are prescribed off-label and its economic burden in a hospital setting.

METHODS

A retrospective observational study was conducted. Off-label uses during 2013 were registered. The information was assessed by reviewing our Hospital Pharmacy databases. Costs were calculated according to the purchase prices of our hospital within the budget. The financial risk is for Public Health Service.
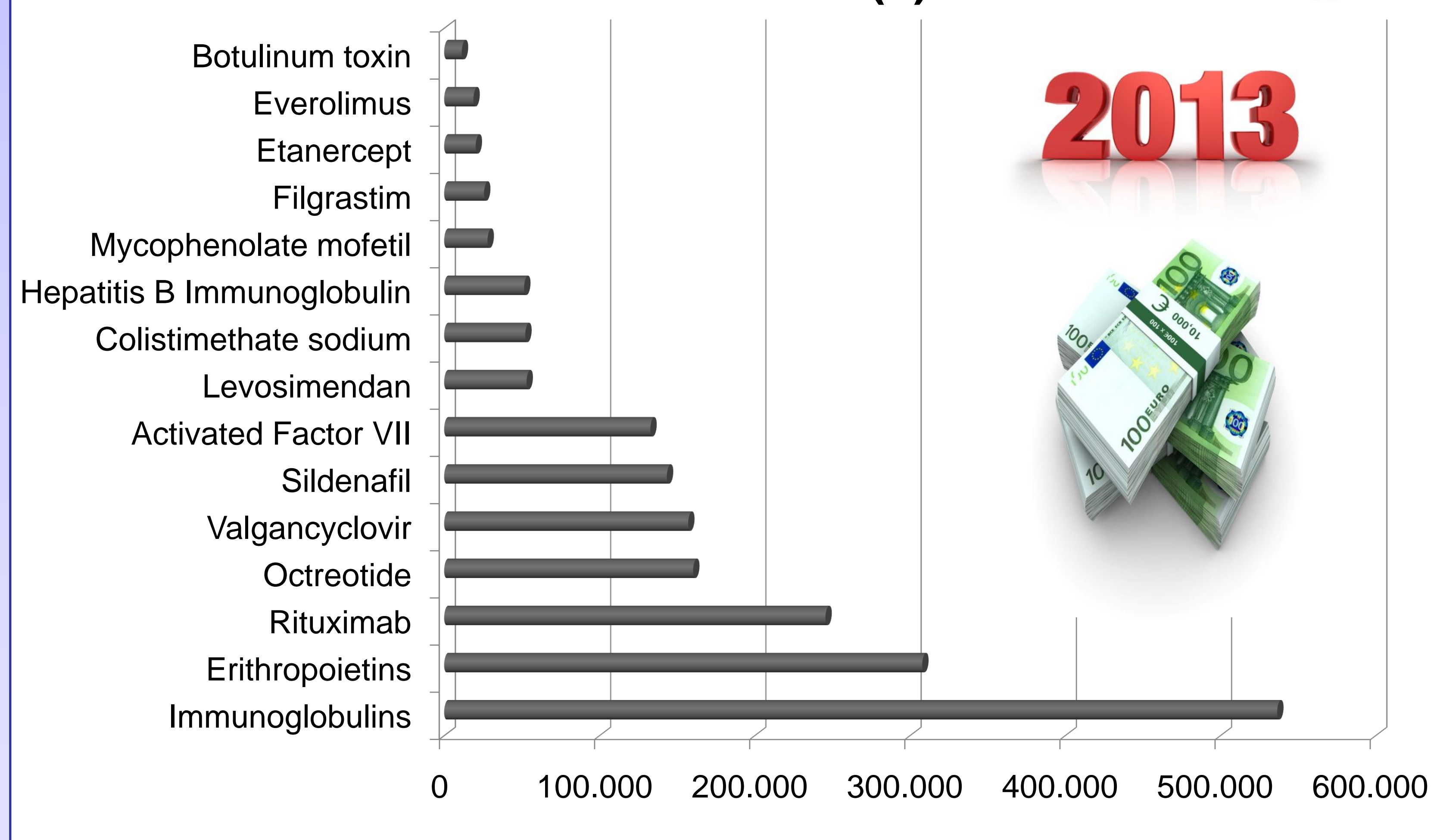
VARIABLES COLLECTED
• Drug name.
• Therapeutic use.
• Number of patients.
• Cost.

RESULTS

FRECUENCY

DRUG	OFF-LABEL USE	PATIENTS (N)
Erithropoietins	Myelodysplastic anemia	87
Sildenafil	Pulmonary Hypertension in Children	87
Mycophenolate mofetil	Lupus	55
Activated factor VII	Bleeding after surgery or trauma	41
Darbepoetin alfa	Anemia during hepatitis C treatment	38
Valgancyclovir	Cytomegalovirus reactivation in hematopoietic transplantation	32
Filgrastim	Neutropenia during hepatitis C treatment	31
Levosimendan	Heart failure in children	29
Octreotide	Angiodysplasias and bleeding	26
Immunoglobulin	Myasthenia Gravis	26
Valgancyclovir	Cytomegalovirus reactivation in hematopoietic cancer	22
Everolimus	Lung transplantation	22
Rituximab	Lupus	19
Hepatitis B immunoglobulin	Lung transplantation	15
Immunoglobulin	Polyneuropathy	13

TOTAL COST (€)

2013

We found 62 drugs in 131 off-label indications. These drugs were used by 809 patients. The 18.3% were children. The 29% of these drugs were used by 86% of patients. In all cases, there are not other therapeutic options.

CONCLUSIONS

An important number of medications are off-label prescriptions. high economic burden. Pharmacist control, registration and effectiveness and safety of the off-label drugs.

Furthermore, off-label use is associated with assessment are required to evaluate the

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