

# Off-Label Use of « High-cost » drugs in Paris area hospitals

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## Background

- In France, every year, a list of innovative “high-cost” drugs is fixed by health authorities. This list includes different classes of medicines (anticancer drugs, biotherapies for autoimmune diseases, Human coagulation factors...)
- Sickness Insurance reimburses 100% of these “High-cost” drugs if they were prescribed for indications included in “the summary of product characteristics” or supported by strong scientific evidence.
- In 2012, in Paris area hospitals, total spending in « High-cost » drugs amounted to € 473 million.

- Off-Label Use (OLU) of these drugs is often not supported by strong scientific evidence.

## Purpose

To assess the prescriptions’ adherence to the good practice guidelines for « High-cost » drugs and to identify OLU situations emerging that could lead to an update of the standards.

## Setting and Method

- Every year, hospitals are asked to report their OLU indications related to the “High-cost” drugs prescriptions.
- The data were collected by OMEDIT, from 218 Paris area hospitals over a period of six months (January to June 2012).
- For each OLU situation recorded, the following data were collected :
  - Drug name ;
  - Therapeutic indication ;
  - Clinical and literature justifications ;
  - Frequency (number of patients affected).
- **Main outcome measures :**
  - Rate of patients involved in Off-Label “High-cost” drug use.

## Results

- This analysis has shown that off-label use may account for approximately 12% of patients.
- 1499 OLU situations were described and 3267 Patients were concerned.
- The most Prescribed drugs (Bevacizumab, Trastuzumab, Infliximab, Rituximab and IVIG) were the most involved in the OLU situations.
- The OLU of anticancer drugs affected 53% of patients vs 47% for the other clinical areas.

## OLU situations mainly described

Drug name	OLU indication
Human prothrombin complex	Haemostasis disorders in open heart surgery with extracorporeal circulation
Rituximab	Lymphoma (regarding to the type, stage and/or line of therapy)
Bevacizumab	Glioblastoma
IVIG	Organ transplantation (prevention of rejection, humoral rejection)

## Conclusion

For OLU indications, benefit-risk assessments for real life prescribing practices should be set up to ensure a safe use. Regional working group takes all appropriate measures to inform health care professionals and prevent OLU. In France, Temporary Recommendations for Use (TRUs) could represent an adequacy framework to regulate the Off-Label drug use and the National Agency of Medicine (ANSM) may be alerted to the possible need for TRU.

## Drugs mostly involved in OLU situations

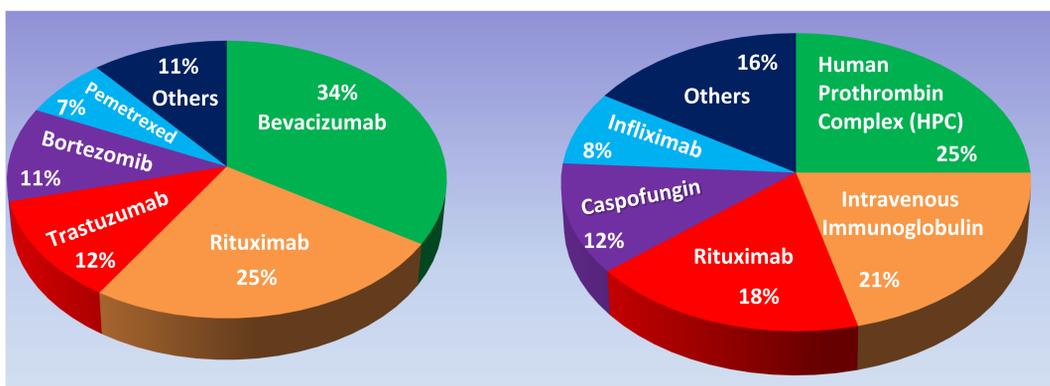


Fig. 1 Anticancer drugs

Fig. 2 Other drugs

- Five drugs were involved in 89% of anticancer OLU indications (**Fig. 1**)
- For other clinical areas, five drugs accounted for 84% of OLU situations (**Fig. 2**)