

The role of clinical pharmacists monitoring regarding the effectiveness and tolerance of expensive drugs prescribed off-label

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Background :

Since 2015 in our french hospital, prescribers must fill a justifying form (JF) for each off-label initiation of expensive treatments. The medical and financial follow-up is carried out by clinical pharmacists regarding chronic diseases. Furthermore, the patient must be informed about the off-label use of his treatment, and the JF must be included in patient file.

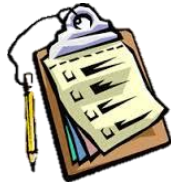
Purpose : ensure the justified maintenance of off-label treatments in terms of effectiveness, tolerance and cost.



Material and method : Restrospective study over 2016-2017

Contains :

References of publications
Clinical argument
Criteria of : - effectiveness
- tolerance



Off-label JF

For each chronic indication

Computerized patient file Orbis® : evaluation of effectiveness and tolerance

Tracability of the JF

Phedra® software : dispensing data and costs

Results :

77 patients but 63 JF found (82%)

Most common indications : Horton and Behçet diseases, Hypoglobulinemia, Sarcoidosis, Undifferentiated inflammatory arthritis

Archiving

93% pharmacy
0% computerized patient file Orbis®

Estimated hospital cost : 735k€
(including Canakinumab 191k€)

63 patients had a chronic condition

77% effectiveness
4 healings

Interruption
19% : ineffectiveness
4% : adverse effects

Most found departments
Internal medicine
Rheumatology

Most prescribed treatments
Tocilizumab,
Adalimumab,
Infliximab, IV Ig

17.5% of JF fully completed
Most filled : clinical argument (86%)
Least filled : date of multidisciplinary consultation meeting (43%)

7 cases of subcutaneous relay

Conclusions :

Off-label initiations are mostly justified. The reformulation of some items of the JF and its computerization in Orbis® are necessary to improve tracability. Clinical effectiveness is found for more than 2/3 of chronic off-label prescriptions. Horton and Behçet's diseases have recently obtained their label, strengthening the validity of these prescriptions. The clinical pharmacist monitoring of treatment effectiveness and safety allows to quickly interrupt an expensive and inefficient treatment.