INTRODUCTION

Of over twenty different antiretroviral (ARVs) currently available in France, only four have generics authorized (Efavirenz 600mg, Nevirapine 200mg, Lamivudine 150mg and 300mg and the fixe-dose combination of Zidovudine 300mg/Lamivudine 150mg) to which should be added Abacavir® and Kaletra® in 2016 or Ténofivir® in 2017 and Truvada® in 2021

The substitution of Branded by generic antiretroviral could, in a few years become evident, given the patent expiry of some branded antiretroviral and for the purpose of cost reduction. Thus:

• The association of Efavirenz (Ge) + Truvada® (€ 126 + € 520 = € 646) would decrease the price of € 100 per month and par patient compared to Atripla® (€ 746), resulting in two tablets, once a day instead of one tablet, once a day
• The association of Efavirenz (Ge) + lamivudine (Ge) + Viread® would allow a discount of € 182 per month and per patient compared to Atripla®, resulting in three tablets, once a day instead of one and the substitution of Emtricitabine by Lamivudine

According to the report of experts published in 2013, the substitution of branded antiretroviral by generics should resulted in a significant decrease in treatment cost but instead would increase the daily number of tablets to be taken by the patient. The pharmaco-epidemiological impact of increasing the daily number of tablets to be taken and/or the number of times that the patient should take the medicine per day is subject of discussions according to several studies, but most agree that the level of adherence decreases when a patient passes from Single Tablet Regimen to Multiple Tablet Regimen and/or from once daily dose to two or more daily doses.

However, no study at our knowledge that examined the pharmaco-epidemiological impact of the substitution branded antiretroviral by generic antiretroviral.

It is in this regard that this pharmaco-epidemiological study in patients with HIV, whose one or more branded antiretroviral have been or could have been substituted by currently available generics in France, was proposed, to determine the impact of this substitution and therefore, the increase of the daily number of tablets or daily dose on the effectiveness of, and adherence to treatment in real world settings

OBJECTS

This study has firstly the objects:

- To quantify the level of exposure to generic antiretroviral in patients with HIV in Midi-Pyrénées since their authorization in France,
- To assess whether the patients who switch from branded to generics stay on generics or return to branded antiretroviral, and
- To analyze and compare the adherence between generic antiretroviral users and branded antiretroviral users

STUDY DESIGN AND METHODS

This is an observational pharmaco-epidemiology study of patients followed in Midi-Pyrénées healthcare settings

The collection of data is made using the database of the health insurance (SNIIRAM) in Midi-Pyrénées

Study patients are those who received a treatment that includes at least one of the following antiretroviral: Efavirenz, Lamivudine, Nevirapine or the fixe-dose combination of Zidovudine/Lamivudine, at least once from March 2013,

To explore the adherence to generic antiretroviral a comparison will be made between generic exposed group and branded exposed group

PRELIMINARY RESULTS

Since the authorization of the first generic antiretroviral in France in March 2013:

ARVs were delivered at least once to 3,521 patients, among them 1,964 (55,8%) have received antiretroviral likely to be substituted by least one of authorized generics, by breaking the fixe-dose combination or not. Among these:

828 (42,2%) have received antiretroviral likely to be substituted without breaking the fixe-dose combination

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Substitution of branded by generic antiretroviral

Only 149 patients have received generic antiretroviral. This represents 18% of patients likely to receive a generic antiretroviral without breaking fixe-dose combinations and 7,6% if patients whose substitution of branded involves the break of fixe-dose combinations, are included

CONCLUSION AND EXPECTATION

This study will help to determine the pharmaco-epidemiological impact of substitution of branded by generic antiretroviral in HIV treated patients in France

This is crucial while savings in health sector are expected through the use of generics