IDENTIFY FRAUD RISK IN HEALTH INSURANCE DRUG-REIMBURSEMENT

GROUP 4

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EXECUTIVE SUMMARY

1.   Painpoint
Social Fraud is on the rise and yet it 's pretty poorly monitored, **health insurance fraud alone rose by 20%** between 2011 and 2012

2.   Context
The social security needs to **save money** and **ensure its consumers' health**.
Unlike Tax evasion, health insurance fraud can have dire consequences on **public health**.
Monitoring health insurance fraud can **save it money aswell as limit the complications, misuse and overconsumption and their consequences on public health**

3.   Analysis
Analysis **datasets of drugs, diseases & reimbursements** (segmentation, principal componant analysis, decision tree, correlation analysis) in order to better **understand the works and risk factors of off-label use** and to **propose means of prevention**
Creation of structured historical data for off-label use

4.   Objectives
Identify the different types of fraud and the drugs that are more prone to it
Recommend action to **prevent or fight** the different types of fraud

5.   Recommendations
Stricter monitoring of the prescription to diagnosis relevance
Harder prescription conditions to limit access to the riskiest medications in order to limit both the financial and the public health risk

All sources and references can be found in annexe

THE COST OF HEALTH INSURANCE FRAUD IS BOTH HUMAN AND FINANCIAL

It is thus a matter of both Health insurance and Public Health

The costs of misuse of drugs, such as the Mediator, is split between a financial and a human cost

FINANCIAL COST OF MEDIATOR

879M€ *To reiumburse prescribed Mediator Boxes for the Health insurance between 1976 and 2009*

+ 313M€ *To cover for the costs of complications linked to the Mediator Between 1976 and 2009*

1,2 B€ *Paid by the Health insurance and the tax-payer*

HUMAN COST OF MEDIATOR

1750 *Patients had to undergo a surgical procedure Due to the off label use of Mediator as a diet-drug*

2000 *Patients died Due to the off label use of Mediator as a diet-drug*

80% *Of Mediator's 500 000 patients used it as a diet-pill Which means many more are at risk of cardiac complications*

OBJECTIVE

CURB FRAUD IN THE SOCIAL SECURITY BY:
> MONITORING THE MEDIATOR FACTOR IN REIMBURSABLE DRUGS
> SCORING REIMBURSABLE DRUGS FOR POTENTIALLY DANGEROUS OFF-LABEL USE

IDENTIFYING WHAT MAKES A DRUG MORE ELIGIBLE FOR OFF-LABEL USE IS THE KEY

As most abuse is at patients' request, the more desirable a drug the more likely it is to be prescribed off-label

Method:
Using **past data** (articles, research) aswell **the data of the Medication data base on prescription requirement** and **usage information** we determined a scale from one to 9 for different **desirability factors that we assume may drive off-label use.**

1 SUBSTITUABILITY

Is there a known use of this category of drugs as a substitute for a non reimbursable product?

Categ	Use	Score
Emollients	Face care	9
Diabetes drugs	Diet pills	9
Anti parasites	Veterinary use	9
…	…	…

2 EASE OF ACCESS

How easy is it to use the drug without a professional's help?

Type	Description	Score
Liste I	GP*, no renewal specifications	9
Liste II, Liste I secure presc.	GP*, renewal specifications and conditions	6
Specialists only		4
Hospital only		3
Special services only		1

3 EASE OF USE

Once you have it, how easy is it to use it?

Description	Score
A pill to take or cream to spread or a simple injection: no need for any understanding of what you're doing	9
An more technical injection	4
An actual medical procedure	1

*GP stands for General Practitionner.

THERE ARE 8 GROUPS OFF PHARMACOLOGICAL COMPOUNDS WITH VARYING RISK LEVELS

With 8 segments each with definite profiles and characteristics

Method:

1) We ran a segmentation in order to **create groups of medication with similar risk characteristics** (desirability and commercial interest) and to **assess their off-label risk**

2) We then used all the data available in medical reviews, internet forums and articles to determine the **hit rate** (part of off-label use in the segment) **for fraudulent off-label use**.

1 LOW RISK - 595 ATC CLASSES - 62%

COMMON MEDICATION	70%
Description: easy to use but restricted access	
Hit rate:	-
% fraudulent reimbursement/total:	-
Growth of prescriptions:	8%

NICHE MEDICATION	12%
Description: Easy to access and use, low commercial interest (very few products for each ATC class), not very well reimbursed and very precise use	
Hit rate:	7%
% fraudulent reimbursement/total :	0,03%
Growth of prescriptions:	1%

PRECISION MEDICATION	18%
Description: Very well reimbursed, for very serious diseases	
Difficult to use, low commercial interest, no substituability	
Hit rate:	4%
% fraudulent reimbursement/total:	0,04%
Growth of prescriptions:	4%

2 MEDIUM RISK – 160 ATC CLASSES – 17%

CONFIDENFIAL & SPECIALIZED	22%
Description: easy to use but restricted access (specialists only)	
Hit rate:	14%
% fraudulent reimbursement/total :	0,75%
Growth prescriptions:	33%

BROAD & SPECIALIZED	78%
Description: easy to use but restriction to access (specialists only)	
Hit rate:	14%
% fraudulent reimbursement/total :	2,38%
Growth of prescriptions:	16%

RISK ASSESSMENT:

Financial threat: low – All together, their potentially fraudulent compounds account for **3,30%** of all reimbursement issued

Public health threat: low – most of these are related to the lack of appropriate medication

HIGHER OFF-LABEL USE COMES WITH HIGHER HEALTH AND FINANCIAL RISKS

pose a real threat to the patients and may cause tremendous aftermath

3 **HIGH RISK - 210 ATC CLASSES - 22%**

PERFORMANCE ENHANCEMENT	33%
Description: Drugs often used for doping, ADHD or for their effect on the nervous system	
Hit rate:	25%
Part of fraudulent reimbursement /total:	4,32%
Growth prescriptions:	57%

TYPE OF DRUG	OFF-LABEL REPORT
Respiratory system	Doping
Cardiovascular	Doping/ADHD
Nervous system	Sleeping pills, others
!!!	**Side effects**

SUBSTITUABLES	51%
Description: Drugs with highly substituable properties that make them highly desirable for patients	
Hit rate:	53%
Part of fraudulent reimbursement /total:	2,24%
Growth of prescriptions:	11%

TYPE OF DRUG	OFF-LABEL REPORT
Antiparasitics	Used on animals/cattle
Metabolism	Dieting
(diurétics, laxatives, diabetis)	
Vitamines	Beauty use/health trends
Dermatology	Beauty use

DANGER ZONE	16%
Description: Very substituable, easy to use, very strong commercial interest and very strong reimbursement	
Hit rate:	63%
Part of fraudulent reimbursement /total:	10,98%
Growth of prescriptions:	96%

TYPE OF DRUG	OFF-LABEL REPORT
Metabolism	Dieting, others
Cardiovascular	Migraines, hairloss, others Diovan
Anti-infective	Sleep, abusive, schyzoph
Nervous system	Recreational, self-medication (OD risk)

RISK ASSESSMENT:
Financial threat: High – All together, their potentially fraudulent compounds account for **17,54%** of all reimbursement issued
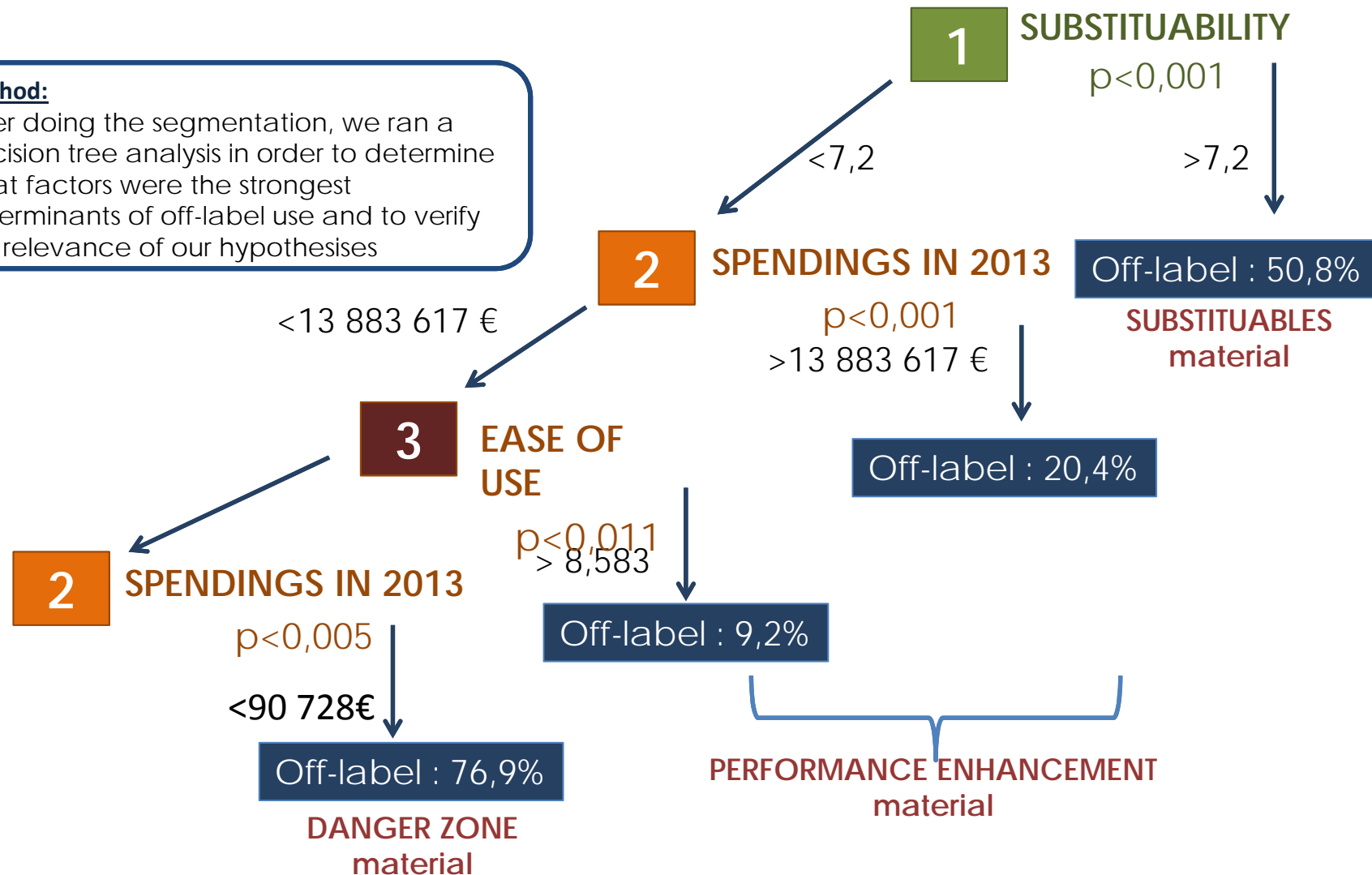**Public health threat: High**– off-label use very far from the original recommandation (from herpes to schizophrenia!) , self medication and recreational use that come with high OD risk, strong side effects

OVERALL, THERE SEEMS TO BE COMMON FACTORS THAT DETERMINE OFF-LABEL USE

Fraudulent off-label drugs are identifiable only when you look at the deviation from their original use

Method:
After doing the segmentation, we ran a Decision tree analysis in order to determine what factors were the strongest determinants of off-label use and to verify the relevance of our hypothesises

1 SUBSTITUABILITY
$p < 0,001$

<7,2

>7,2

2 SPENDINGS IN 2013
$p < 0,001$

Off-label : 50,8%

SUBSTITUABLES material

<13 883 617 €

>13 883 617 €

3 EASE OF USE
$p < 0,011$

Off-label : 20,4%

2 SPENDINGS IN 2013
$p < 0,005$

> 8,583

<90 728€

Off-label : 9,2%

Off-label : 76,9%

DANGER ZONE material

PERFORMANCE ENHANCEMENT material

Our hypothesises are comfirmed and **there are indeed determinants that increase the risk of off label use**. However, these determinants are not discriminating enough for us to understand what the best way of tackling the off-label issue is.

HOWEVER IT IS HARD TO IDENTIFY THEM WITH CERTENTY AS OFF-LABEL USE DOESN'T HAVE UNIVERSAL CHARACTERISTICS

Fraudulent off-label drugs are identifiable only when you look at the deviation from their original use

READING THE GRAPH

LEGEND:
1: Metabolism & alimentation
2: Anti parasitic products
3: Cardio vascular system
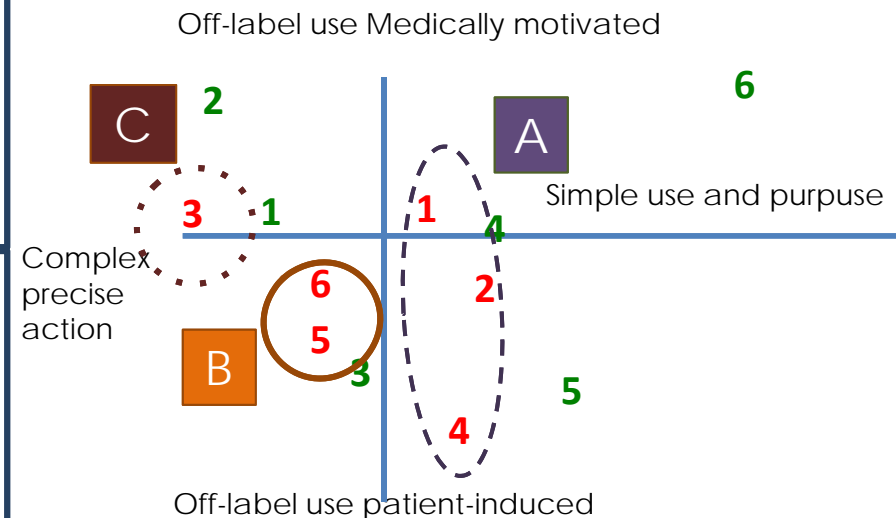4: Dermatologicals
5: Antiinfectives
7: Nervous system

Fraudulent Off-label/ **Acceptable** use

DIMENSIONS DESCRIPTION

Dimension 1 (43% of variance explained):
➤ *How complex/precise is the drug's use?*

Dimension 2 (24,26% of Variance explained
➤ *Who is pushing for the off-label use?*

DEVIATION FROM ORIGINAL USE IN THE OFF-LABEL USE

Off-label use Medically motivated

C   2   A   6

3   1   1   4   Simple use and purpose

Complex precise action

6   2
B   5
3   5

4

Off-label use patient-induced

INTERPRETATION

Very different drugs can be used off-label with **the same mind set**.

We can distinguish **3 types of off-label uses** from the <u>large variations between the acceptable-use positionning and the fraudulent off-label use positionning</u>

These different mindsets also have an impact on **the average level of risk** for the patient.

THEREFORE WE CAN BETTER UNDERSTAND THE DIFFERENT TYPES OFF OFF-LABEL USE AND ASSESS THE RISK THEY CARRY

In order to then provide recommandations and assess impact

A SIMPLIFYING USE

DESCRIPTION:
Prescribed at the patient's request as he wants to benefit from one simple characteristic of the drug, usually as a substitute for a non-reimbursable product
MINDSET:
Goal oriented: immediate and direct simple effect

HEALTH RISK ASSESSMENT:
✓ **Low to Average -** here are usually few side effects but the risk exists nonetheless
FINANCIAL RISK ASSESSMENT:
✓ **High -** these drugs account for **688 M€** in spendings each year and their off label use is prevalent

B SIDE EFFECTS CAPITALISATION AND ABUSIVE PRESCRIPTION

DESCRIPTION:
Prescribed by generalists at the patient's request
When these drugs would call for a more specialized diagnosis.
MINDSET: abusive use, recreationnal use, comfort use

HEALTH RISK ASSESSMENT:
✓ **High –** these drugs are known to cause addiction, and are used in most medication-induced suicide cases. These drugs may come with strong side effects that are not monitored sufficiently and be abused
FINANCIAL RISK ASSESSMENT:
✓ **High –** These drugs account for **53.9M€** in spendings each year

C MAD SCIENTISTS EXPERIMENTS

DESCRIPTION:
Use very far from the original prescription
Really risky and experimental use
MINDSET:
Physicians's experimenting

HEALTH RISK ASSESSMENT:
✓ **High –** No one really knows if the drugs are efficient in their off-label use or what the side effects might be
✓ **Low -** Off-label use for these drugs is not prevalent.

STRICT MEASURES NEED TO BE IMPLEMENTED TO REDUCE FINANCIAL AND HUMAN RISKS

We suggest you take three steps against off-label and prescription abuse

1 PREVENTION & REDUCTION OF ACCESS	**2** IMPLEMENTATION OF A CHECKING DATABASE	**3** DETERRENCE OF COMPLACENTS
Limit access to high-risk drugs and enforce diagnosis Limit prescription to specialists' prescriptions and ask for new consultations to renew their prescriptions (ex: antidepressant) **Estimated cost:** 120M€	**Implement a diagnosis/drugs/patients/physicians database to make sure there is a match** Between disease and prescription. In case of discrepancies between the common prescriptions for a diagnosis, deny reimbursement as a deterrent	**Control potentially fraudulent physicians through "fake" patients** asking for off-label prescriptions in order to prevent ultimately off-label prescriptions providers from providing.
Get proof to give drugs Ask patients to make specific analysis, the results of which must be attached to the prescription (ex: diabetic drugs) **Estimated cost:** 24,65M€	**Monitor side effects to detect the riskier drugs for patients** The earlier you can identify side effects, the better you can care for those affected with the lowest cost	**Implement an increasing fine system** • **3000 euros** for the first offence • **5000 euros** for the second one • **10 000 euros** for the third one
Primary deterrence Reduce the reimbursement rate of some drugs Ask the reimbursement request to be specified on the prescription **Estimated cost** 0€	**Cost estimate** May vary depending on the current state of monitoring and precision of data base Suggestion of structure in Annexes.	**Cost estimate** If the monitoring and detection are efficient enough they could be pretty low. Once again, it depends on the current forces.

NB: The step 2 can also be accomplished by putting the datasets mentionned in the Suggestion of structure annexe in the open data with anonymized identifyers.
NB: All Hypothesis are explained in annexes

PROPOSITION FOR DATA BASE STRUCTURE (for STEP 2)

The goal is to create a comprehensive data base, designed to help detect outliers and cut off-label fraud at the source.

ACTORS

CLIENT
Social security ID
Reimbursment
Noticed side-effects

ANALYSIS LAB
N°
Location
Priors

PHYSICIANS
Licence ID (FINESS N°)
Location info
Specialty/Generalist
Previous alerts

PHARMACIES
ID Number (ARS licence)
LocationPhysician ID
Pharmacy ID
Pre-conditions (analyses results, diagnosis)

ACTS

CONSULTATIONS (key: N°)
Social security ID
Physician ID
Diagnostic
Date
Next step

ANALYSIS (key N°)
N° lab
N° Client
Type
Result

PRESCRIPTIONS (key: N°)
Consultation N°
Social security ID
Physician ID
Pharmacy ID
Drug
Pre-conditions (analyses results, diagnosis)
Date of prescription:
Date of delivery:

REFERENCES

DISEASES
ID
Name
Symptomes
List of approved prescriptions

DRUGS
ID
Laboratory
ATC class
Off-label report
Side effects
Prescription conditions…

This data base is more of a super structure of data-bases than an actual creation. Data should be anonymized too.

EACH OF THEM YIELDS STRONG IMPACT BOTH FINANCIAL AND HUMAN: SAVE MILLIONS AND SAVE LIFES

FINANCIAL IMPACT:

Steps **1** & **2** can help the health insurance save : **150M€ a year**

	Substituables	Performance	Danger Zone
Symplifying use	€ off label 158M€ % Fraud (*) 50% savings with step 1 79 000 000 €		
Abusive	€ off label 230M€ % Fraud (*) 25% savings with step 1 57 500 000 €	€ off label 228,9M€ % Fraud (*) 20% Savings with step 1 45 700 000 €	€ off label 132,5M€ % Fraud (*) 10% savings with step 1 13 200 000 €
Mad Doctor	€ off label 30,9M€ % Fraud (*) 10% Savingswith steps 1&2 3 090 000 €	€ off label 793M€ % Fraud (*) 10% savings with steps 1&2 79 300 000 €	€ off label 228M€ % Fraud (*) 5% savings with steps 1&2 11 400 000 €

195,4 M€
- 120 M€ (Costs of specialists)
- 25 M€ (Costs of analysis)

= 50 M€ of deficit reduction

94 M€ of deficit reduction

(*) According to our hypothesis (available in annexes slide)

Steps **3** ensures the minimization of fraud opportunities

PUBLIC HEALTH IMPACT: Better life quality, aftermath risk

Reduce aftermath risk and duration of treatment

Drecrease over-consumption and addiction risk

Improve follow-up to make sure the treatment is to the point

Means **better life quality** and amounts **millions euros savings each year**

POTENTIAL LIMITS TO OUR ANALYSIS

To be totally accurate

1 DATA SELECTION ACCURACY

REDUCTION OF DATA:
Deletion of 1 700 products that didn't have any historical records before 2013 on internet
Deletion of 1 700 products that didn't have any match between our different files
➔ **From 13 000 to 10 000 indexed products**
Smaller selection of data ➔ Maybe our model is not taking into account an important feature of off-label use that is not present anymore in our data selection
The data accuracy might have been affected by the aggregation choices we made
✓ **Possible solution   : Find more complete datasets to match every product thanks to its CIS code, its CIP7 code and its ATC class.**

2 REPORTS OF OFF-LABEL USE

LIMITS OF INTERNET REPORTS AND INFORMATION
Assignation of 0 (No off-label use report) or 1 (Off label-use report) **depends entirely on our research** and if an off-label use of this product has been at least once indexed in a medical journal or on a forum.
For the first group, common medication, **assignation of a 0 to all products** because the risk was considered very small and there were too many products (400) to look for information for each of them.
But this can lower the validity and accuracy of our model.
It is also very difficult to estimate how common is the off-label use on this basis.
✓ **Possible solution : Go and see hospitals, specialized institutes and medical professional that can give us non reported off-label uses on Internet**

3 HYPOTHESIS ACCURACY

FORMULATION OF HYPOTHESIS TO ESTIMATE THE FINANCIAL GAIN FROM OUR MEASURES:
We made assumptions to calculate the financial impact of the measures we want to implement to reduce off-label use : **how to estimate precisely how many physicians will continue to prescribe off-label drugs** despite the first fine of 3000 euros, then the second of 5000 euros, and even the third one ?
Moreover, we used **average values** for the cost of a specialist consultation or a proper diabetic analysis.
All these estimations don't enable us to be very precise in the estimation of the financial gain.
✓ **Possible solution : Go and see physicians that can give us precise values for each type of different drugs.**

HOWEVER NEARLY EVERY DRUG CAN BE PRESCRIBED OFF LABEL

As a necessity and without posing a threat to public health so not every off-label prescription can be percieved as fraudulent

OFF-LABEL PRESCRIPTION IS NECESSARY

- **Description: Using a drug outside the framework defined by its marketing authorizations is necessary and a way of making progress in the medicinal field**
- Exemples: Pediatry (very little drugs approved), rare diseases…
- **The risk is minimal:** open label trials, use of the drug restricted to a defined field, usually closely related to it's labelled prescription.

> 40% of all prescriptions are off-label prescriptions

ABUSIVE PRESCRIPTION: THE MEDIATOR FACTOR

- **Description:** reimbursable drugs prescribed for comfort purposes/personal use or as substitution for non-reimbursable products, usually regardless of diagnosis.

- **Risk:** over consumption **of unnecessary drugs** that are nevertheless reimbursed, substitution with beauty/comfort products and recreational use.

This poses a **threat both financially and humanly**:
- The further the prescription from the labelled used, the higher the **public health risk.**
- The most common the off label prescription the **higher the financial cost**

DANGEROUS PRESCRIPTION : THE DIOVAN CASE

- **Description:** drug prescription outside marketing authorization without strict monitoring or open trials.

- **Risk**: unknown but potentially serious adverse effects

HOW CAN WE FOCUS ON ABUSIVE OFF-LABEL PRESCRIPTION AND MAKE IT APPART FROM « NORMAL » OR « TOLERATED » OFF-LABEL PRESCRIPTION?

UNDERSTANDING THE DATASETS AND THE VOCABULARY

Is necessary to understand the analysis

DATA SETS

AMELI data base of reimbursements
➢ Reimbursement basis for each commercial drug
➢ Effective reimbursements for each commercial drug

Data base of medications 2013
➢ Prescription conditions for each drug
➢ Usage information for each drug

VOCABULARY

Product:
Reference of a drug in a laboratory. This is based on the overall name given to the drug in a specific laboratory and doesn't take format into account. Different products may belong to the same ATC class.
ATC Class:
main active molecule in a drug (several laboratories may use the same molecule).
Anatomical class:
prefered zone of action of a molecule.

Formulas

Hit rate:

$$\frac{\text{Number of molecules with fraudulent off-label uses}}{\text{Number ot molecules in the segment}}$$

% fraudulent reimbursement vs Tot:

$$\frac{\text{Reimbursement of drugs known for fraudulent off-label}}{\text{Total reimbursement for the group}}$$

Growth of prescriptions: *growth of the number of boxes prescribed in 2013 vs. 2012*

HYPOTHESIS USED TO DETERMINE IMPACT

So that you can get a better understanding of our results and estimates

COST ESTIMATE

COST ESTIMATE FOR SPECIALIST CONSULTATIONS
The average cost of a consultation at a specialist's is 40 euros
The largest and main pool of patients affected is that of those under Nervous system medication and the number of such patients is estimated to 3M in France
Eg: **40*3 000 000 = cost of specialists**

COST ESTIMATE FOR TEST-ANALYISIS
The average cost of the diabetis tests is 10 euros
The off-label uses are detected on type II diabetis (non insuline dependant) and account for 85% of the total diabetis cases. There are 2,9M type II diabetis patients in France
Eg: **10*0,85*2 900 000 = cost of analysis**

YIELD ESTIMATE

FRAUD % ESTIMATE
We estimated the Fraud pourcentage of the different categories by working under a set of hypothesis
Mediator use was 80% off-label which hints to a **very high off-label use for the same type of drugs.**
Drugs requiring medical knowledge are not as rempant in terms of off-label use
Drugs that have no street value and can't be abused have rather low off-label frequency.
This is how we evaluated our 5, 10, 20, 25 or 50% of fraud, according to each group's specificities.

However, without any pas report on fraud uncoverings, these are estimations only.

Annexe 3 - SOURCES

GOVERNMENTAL DATA
Médicaments remboursés par l'assurance maladie – Data.gouv
Données de consommation du médicament Médiator – Data.gouv
Base de données des médicaments – Medicaments.gouv
Normes d'étiquetage – Médicaments en vente libre – Santé Canada
Oral delivery of meglumine antimoniate-beta-cyclodextrin complex for treatment of leishmaniasis – NCBI Gov
Off-label use in children – NCBI Gov
Off-Label Use of Atypical Antipsychotics: An Update – US Department of Health&Human Servcies
ATC/DDD Index 2014 – Norwegian Institute of Public Health
All centralized human medicinal product by ATC code - Public Health, European Commission

MEDICAL WEBSITES
Le calcium, idéal pour la santé des os et la synthèse de la vitamine – Passeport Santé
Index des Médicaments vétérinaires autorisés en France
Niclosamide – ADWIA Phramaceuticals Co.
Is OFF LABEL USE a side effect of Pentamidine Isethionate ? – MedsFacts
Is OFF LABEL USE a side effect of Glimepiride ? – MedsFacts
Valacyclovir (Valtrex) – eMedExpert
TINIDAZOLE: CAPSULE – Wedewood Pharmacy, Veterinary
Mediator, combien de morts ? La réponse se précise – AlloDocteurs
Pourquoi le Bumétanide n'est pas un médicament contre l'autisme – Médiapart
Normes d'étiquetage – Médicaments en vente libre – Santé Canada

BOOKS
The Guide to Off-label Prescription Drugs: New Uses for FDA-approved
Compléments alimentaires : Peut-on prendre n'importe quel magnésium ?

MAGAZINES/NEWSPAPERS
Peut-on maigrir grâce aux plantes ? – Le Point
Comment maigrir en toute quiétude avec lactulose – Magazine Science
Ramipril lowered cardiovascular risk, but vitamin E did not - Cleveland Clinic Journal Of Medecine
Novartis to pay $422.5M in off-label marketing case – Fierce Pharma Newsletter
Dossier : Mediator, du drame sanitaire au scandale politique Marianne
Le Mediator a coûté au moins 1,2 milliard à la Sécu – Le Figaro
Mediator : 80 % des prescriptions n'avaient rien à voir avec le diabète – Le Parisien
Le diabète, «un choix infiniment plus rentable pour les labos» - Libération
Comment les antidépresseurs font grimper le nombre de dépressifs – L'OBS

BLOGS/FORUMS
Vivier Redness Solution Complex – Rejunevation Blog
Clarithromycine : Risque cardiaque accru – Vivre avec l'insomnie
L'huile de paraffine… à éviter – FemininBio
Doctissimo : Médicaments pour maigrir / macrogol – FORUM Médicaments
Dexeryl : Ma crème à tout faire d'enfer – Blog Marine Magpie
Effets secondaires de la consommation de crème de tartre – Healthy
Metformine (Glucophage®, Stagid®) et cancer – Blog D'Hélène Bénardeau
A New - Old Drug That Is Making a Major Difference for Me – The Social Network for Health
Nexium and Off Label Use – DrugCite
OffLabel: cladribine – Multiple Sclerosis Research Blog
Problems in Research: Regulations—The Diethylstilbestrol Tragedy – MedicalBag

OTHER ARTCLES
Pyrantel contre la prévention des infestations parasitaires chez les animaux – Wikipédia
Fentanyl, analgésique – Wikipédia
Désinfectants : hypochlorite de sodium – Lenntech, Water Treatment Solutions
Médecins suivant le statut et la spécialité en 2014 – INSEE