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**Response of *La Mutualité Française*  
to the public consultation  
by the Directorate General for Competition of the European Commission  
relative to the pharmaceutical sector inquiry**

**In summary:**

- ☛ ***La Mutualité Française* [National Federation of French Mutual Benefit Societies] represents virtually all the French mutual benefit societies, covering a total of nearly 38 million people. Deeply committed to improving the quality of health-care provision, *La Mutualité Française* has been operating an active policy in favour of generic drugs for more than 25 years.**
- ☛ **In France, the development of generic drugs is still unsatisfactory and has fallen victim to hindering strategies devised by originator companies.**
- ☛ ***La Mutualité Française* shares the analysis of the European Commission on the strategies put in place by originator companies to hinder the development of generic drugs and asks the Commission to recognise the anti-competitive character of such practices.**
- ☛ **We have tabled concrete proposals that aim to improve the quality and transparency of the European patent system, combat the generic evasion strategies devised by the originator companies and reduce their influence on GPs' prescribing habits.**
- ☛ **Furthermore we wish to draw the attention of the Commission to the fact that the free access to information afforded by the Patient Information Directive is liable to constitute a new obstacle to the development of generics.**
- ☛ **We would also submit that special attention should be paid to the question of compliance with the rules of competition in the marketing of biosimilar products.**
- ☛ **Finally, *La Mutualité* would like this highly documented work by the Commission to open a debate on European drugs policy, which must be examined today from the point of view of health-care rather than solely from an industrial standpoint.**

## **Introduction:**

France represents one of the largest pharmaceuticals markets in Europe. The sales of reimbursable drugs sold in pharmacies (excluding hospital consumption) totalled €27.3 billion in 2008 (IMS Health data, annual running total in October 2008), of which only €3.7 billion concerned generic drugs (14%).

Of the €27.3 billion expended in 2008, €21 billion was covered by mandatory health insurance. In other words, more than €6 billion remained to be paid by patients and complementary health insurance providers. Mutual benefit societies hold 60% of the French complementary health insurance market, and thus paid out €3.6 billion for drugs in 2008.

*La Mutualité Française* warmly welcomed the preliminary report of the pharmaceutical sector inquiry, which in particular provided substantial evidence of the anti-competitive practices that hinder the market availability of generic drugs. We moreover highlighted certain of these practices in our study “*Bilan de 25 ans de politique du médicament génériques. Propositions pour une politique plus ambitieuse*” [Results of 25 years of Generic Drugs Policy: Proposals for a more ambitious approach], published in October 2008 and available for consultation on the [www.mutualite.fr](http://www.mutualite.fr) website, in the “*Partenaires de santé*” [Partners in Health] section.

As a legitimate health-care stakeholder committed to the search for better health-care provision, *La Mutualité Française* wishes to share with the European Commission their concrete proposals for combating the obstructions to the development of generics put in place by the drug companies and thus encouraging them to redirect their resources principally towards research and development into true therapeutic innovations.

## 1- *La Mutualité Française*: a major health-care stakeholder in pharmaceuticals

### 1-1- About *La Mutualité Française*

The *Fédération Nationale de la Mutualité Française* [French National Federation of Mutual Benefit Societies] brings together almost all (823) of the mutual benefit societies in France. We represent them and defend their collective, moral and material interests.

Mutual benefit societies are non-profit partnerships whose principal mission is to provide complementary health insurance in order to cover health-care costs not reimbursed by the state Social Security system. Several factors differentiate a mutual company from a normal insurance company:

- Values: no selection of risk, rates not based on individual health risks, non-profit operation, solidarity;
- Mode of operation: a democratic structure that allows each member to intervene directly in the discussions of the company;
- Independence from all political, financial, trade union and philosophical influences;
- Principal mission: to guarantee equality of health-care provision and quality care for all.

Certain mutual companies are involved in the management of health and social support services (health-care institutions, pharmacies, health centres, day nurseries etc.). There are 2,200 such companies in France. Others also offer their members life assurance or pension plans.

Mutual companies insure more than 38 million people in France and represent an economic weight of €17 billion.

### 1-2- The involvement of mutual companies in the economy and in drugs policy

Drugs reimbursement represents one third of the total expenditure of mutual benefit societies, and constitutes their **largest item of expenditure**. In 2007, mutual benefit societies thus allocated €3.4 billion to drugs<sup>1</sup>, an increase of 0.2% over the previous year. They paid out nearly €110 for drugs to each of their members in 2007.

Over many years *La Mutualité Française* has developed an active drugs policy centred on quality and utility, and which aims especially to promote better use of drugs.

*La Mutualité Française* maintains a drugs observatory drawing on a database of drug sales and reimbursements (IMS Health) to develop high-added-value tools<sup>2</sup> and documents that contribute significantly to the debate in France and in Europe.

Finally, *la Mutualité Française* actively defends the interests of mutual benefit societies clients across Europe, especially through its participation in the work of the **Pharmaceutical Forum** within the *Association Internationale de la Mutualité* [International Association of Mutual benefit societies].

The scope of intervention of *La Mutualité Française* is wide-ranging, from individual members and mutual companies, to institutions and policy makers.

<sup>1</sup> Internal source, 2008

<sup>2</sup> For example, in October 2008 *La Mutualité* published a study: “Results of 25 Years of Generic Drugs Policy: Proposals for a More Ambitious Approach” which is available at [www.mutualite.fr](http://www.mutualite.fr) in the section “Partners in health”

### 1-3- *La Mutualité Française* and generics: a commitment that goes back more than 25 years<sup>3</sup>

*La Mutualité Française* has supported the policy of developing generics since the 1980s, considering that the savings generated for an equal quality of care can be used to finance costly therapeutic innovations.

It is in this perspective that we came out in favour of the development of generic drugs more than twenty years ago. *La Mutualité Française* undertakes action on the ground with mutual benefit societies clients, patients and policy-makers, and seeks to convince stakeholders of the importance of generic drugs in both economic and health-care terms.

Our action in favour of the development of generics consists especially in **encouraging** mutual benefit societies clients **to use generic drugs** by increasing awareness of their economic advantages.

Since June 2000, we have also been pushing for **prescriptions to be written in International non proprietary name (INN)** using the true name of the drugs concerned, this being one of the main levers for the prescription and delivery of generics.

Since October 2005, we have been running a **national campaign promoting INN prescription** in association with *UFC Que Choisir* [the French consumers' union magazine] and the magazine *Prescrire*. Several papers presenting the advantages of INN prescription have already been published in mutual company magazines that reach tens of thousands of readers.

As part of this strong commitment, we also publish quarterly **reports indicating progress on INN prescription rates** based on IMS Health data.

➔ ***La Mutualité Française* is a major health-care stakeholder in France, properly committed to improving the quality of health-care provision. We represent almost all the mutual companies, covering more than 38 million French citizens. The drugs bill is the largest item of expenditure for mutual companies. *La Mutualité Française* has thus developed a drugs policy oriented towards quality and efficacy and has been committed for more than 25 years to the promotion of generic drugs, which it considers as a source of finance for therapeutic innovation.**

<sup>3</sup> Extract from the *Mutualité Française* study "*Bilan de 25 ans de politique du médicament générique. Propositions pour une politique plus ambitieuse*" [Results of 25 Years of Generic Drugs Policy: Proposals for a more ambitious approach], October 2008

## 2- Strategies hindering the development of generics in France: comments and proposals by *La Mutualité Française*

### 2-1- Comments of *La Mutualité Française* on the strategies identified in the preliminary report

The preliminary report provides details, with precise documentation, of a list of tools used either singly or together by the originator companies to delay the initial marketing of generics or to prevent generics from accessing markets occupied by their proprietary drugs:

- Filing of secondary patents.
- Litigation and disputes.
- Signing of agreements with generic manufacturers.
- Influencing the regulatory authorities (marketing authorisations, pricing and reimbursement).
- Campaigns denigrating generics, directed at doctors, patients and pharmacists.
- Strategies to prevent generic manufacturers gaining access to active ingredients.
- Strategies designed to bypass generics (“follow-on products”).

*La Mutualité Française* shares the analysis of the Commission but also wishes to draw attention to another strategy that has been used in France: the practice of “**predatory pricing**”.

This practice is well illustrated by the following case: in April 2007, Glaxo SmithKline (GSK) was condemned by the French Competition Council<sup>4</sup> for pricing two major drugs (the injectable antibiotic Zinnat<sup>®</sup> and cefuroxime sodium) for sale to hospitals at below average cost, in order to block a generic laboratory from penetrating the hospital markets concerned. Once the generic manufacturer was forced out of the market, GSK raised its prices in order to make up for its losses. In its conclusions, the Competition Council specified:

*“This policy of predatory pricing was implemented with the aim of eliminating the manufacturers of competing generic drugs, in such a way as to allow GSK to raise its price later without constraint, to the detriment of the final consumer. The policy had the effect not only of eliminating Flavelab from the market, but also of deterring other manufacturers of generic drugs holding marketing authorisations, from competing with GSK in this or other markets by intimidating them with this demonstration of aggression.”*

Such are the tools that make up the strategies put in place by originator companies to hinder the development of generic drugs.

#### **Focus on strategies designed to bypass generics and the role of the medical representative**

*La Mutualité Française* seeks to attract the attention of the Commission in particular to **strategies designed to bypass generic drugs** and state its opinion on the harmful consequences of these strategies. Effectively, such campaigns:

- ↳ consume a part of the R&D resources of the major laboratories, at the expense of true therapeutic innovations.
- ↳ deflect a part of the resources of health-care financers (mandatory health insurance systems, complementary insurance providers and patients) towards more costly treatments with no additional therapeutic value over generic drugs. These resources are not assigned to financing true therapeutic innovations.

<sup>4</sup> Decision 07-D-09 dated 14 March 2007, concerning practices implemented GlaxoSmithKline, France

- ↳ uselessly multiply therapeutic offers, leading to confusion for doctors, pharmacists and patients alike.
- ↳ contribute to the denigration of generics which are thus perceived as less effective drugs.

The originator companies promote generic-supplanting products as drugs resulting from incremental innovation, which doctors and patients would not accept if they did not meet a real need<sup>5</sup>. Yet it has clearly been shown that in France, **GP prescriptions are directly influenced by visits from the drug companies' medical representatives, who concentrate exclusively on drugs that are still protected by patent**, and especially on products that bypass generics. A recent<sup>6</sup> study in France compared the development of sales, in volume and value, for drugs in five major therapeutic classes by differentiating between drugs that were promoted by medical representatives and drugs that were not. It showed that doctors' prescription habits are "dominated essentially by the promotional efforts of the drug companies". Pharmaceutical companies focus visits by their medical representatives on drugs still protected by a patent, in other words especially on those products that bypass generics.

The aim of the representative's visit is above all to promote sales, and the primary function of medical representatives is naturally to promote the products that they represent rather than to improve the quality of medical prescriptions. The information that they transmit is mostly biased but effective. The marketing departments that they work for understand how to modulate the prescriptions of specific products, depending on targets set in accordance with the industrial and conventional strategies of the company concerned.

Action is being taken in France to limit the excesses observed in the practices of medical representatives:

1) We should mention the case of the **medical representatives' Charter**, which has been signed by the French economic committee on health-care products and by representatives of the pharmaceutical industry. Applicable since 1 January 2005, the Charter "*emphasises the quality of the information transmitted to doctors by setting precise rules for the production of promotional literature and the behaviour of medical representatives*".<sup>7</sup> The application of this Charter involves the certification of the medical representative's visit by an independent body, under the responsibility of the *Haute Autorité de Santé (HAS)* [French National Authority for Health]. In early 2009, the *HAS* is scheduled to publish its analysis of the impact of the certification of the representative's visit on the information received by the doctors.

2) **Health insurance delegates** (French: *délégués de l'assurance maladie* or *DAM*) have been encouraged to organise medical oversight agreements<sup>8</sup>, and in particular to incite doctors to prescribe from a list of generic drugs. The action of the *DAMs* is vital as they provide a counterweight to the often biased information distributed by medical representatives. *La Mutualité Française* proposes that the use of this type of health reporting should be extended across Europe so that doctors in member countries can access information that is independent of all commercial and economic considerations.

<sup>5</sup> Pharmaceutical sector enquiry, preliminary report, European Commission, 28 November 2008: (853) page 301

<sup>6</sup> Impact of the medical representative's visit on the prescription of drugs in health insurance systems, Example of five therapeutic classes reimbursed by the health insurance system, François Pesty, July 2007.

<sup>7</sup> Press release by the French Ministry of Health, 30 December 2004. Available on website [http://www.sante.gouv.fr/htm/actu/31\\_041230.htm](http://www.sante.gouv.fr/htm/actu/31_041230.htm)

<sup>8</sup> In the context of the national agreement signed in France with the mandatory health insurance authorities in 2005, French GPs undertook to respect a certain number of commitments designed to improve the quality of patient care. Among these commitments figures the more systematic prescription of generic drugs.

In conclusion, *La Mutualité Française* suggests that the European Commission's final report should include the representative's visit as a strategy of hindrance to the development of generic drugs.

## 2-2- Contextual elements: the impact of generic drugs in France

### 2-2-1- The French generics market

The sales of generic drugs<sup>9</sup> in France totalled nearly €3.9 billion in 2008, up 15% in comparison with 2007.

The growth of the generics market is explained not only by the expiry of patents with strong income potential, but also by the rapid penetration of generics into the list of generic groups. Despite this strong growth, in 2008 generic drugs represented only 13% of drugs sold in pharmacies in France and 21% of the number of boxes delivered.

The list of generic groups published by the *AFSSAPS* [the French health products safety agency] constitutes a list of all generic drugs that have obtained marketing authorisations and their respective originator medicines. The B/C ratios thus correspond to the market shares of the generics list (generics + initial medicines) relative to the total drugs market. The A/B ratios in this table indicate the market shares of generic drugs within the generics list. Finally the A/C ratios correspond to the market shares of generics relative to the total drugs market.

From recent French data, we note that although the penetration of generic drugs in France has increased within the generics list (A/B), **the share of the list relative to the total market (B/C) seems to be stagnating<sup>10</sup>**.

	A/C Generics / Market		B/C List / Market		A/B Generics / List	
	2006	2007	2006	2007	2006	2007
<b>Value</b> (Turnover)	10%	11%	20%	20%	49%	58%
<b>Volume</b> (Number of boxes)	16%	18%	26%	27%	61%	69%

Source: *Mutualité Française*, drugs observatory 2008

The phenomenon of **erosion of the list** can be explained in particular by the fact that, **under pressure from the drug companies, prescriptions are moving away from drugs in the generics list towards preparations that are still patent protected.**

As the *Haut Conseil pour l'Avenir de l'Assurance Maladie* [French council for the future of health insurance] reminds us in its drugs assessment of 29 June 2006, **"the growth of generics remains insufficient"**. An international comparison of generics markets for the period 2004/2005 effectively shows that France ranks last after Germany, the United Kingdom and the United States.

<sup>9</sup> Total sales generated by generic drugs, both reimbursable and non-reimbursable.

<sup>10</sup> As all the 2008 data is not yet available, data for 2006 and 2007 are presented here.

## 2-2-2- Current and prospective savings thanks to generics

In 2007, the prescription of generic drugs rather than proprietary products in France **saved a little over one billion euros of expenditure**<sup>11</sup>. In other words, if proprietary drugs had been prescribed instead of generic drugs, the drugs bill would have been €1.16 billion higher in 2007. This methodology does not take account of any savings accumulated from one year to the next.

**Potential savings were assessed at €493 million in 2007.** These potential savings correspond to a hypothetical 100% penetration rate of the generics list by generic drugs. The figures do not take account of savings that could have been generated by extending the generics list.

## 2-2-3- Reimbursement of generics by mutual benefit societies

The reimbursement of generic drugs by mutual benefit societies increased by 21% between 2006 and 2007 while the reimbursement of originator drugs fell by 15% during the same period. **Mutual benefit societies are thus reimbursing more generic drugs and fewer originator drugs.** The share of reimbursement of originator drug in the generic list thus fell from 49% to 40% between 2006 and 2007.

The reimbursement of generic drugs represented 14% of the drugs bill for mutual benefit societies in 2007 against 12% in 2006. The share represented by generic drugs is smaller in value than in volume as these drugs are, on average, more than 40% cheaper than their counterparts.

Reimbursements by mutual benefit societies are concentrated within the generics list: nearly 20% of reimbursements concern the ten most prescribed medicines in the list.

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## 2-3- Proposals to combat strategies designed to hinder the development of generics in France

The preliminary report goes into great detail about the strategies implemented by originator companies to hinder the development of generic drugs. *La Mutualité Française* believes that this highly relevant analysis should be accompanied by proposals to combat these strategies. It is with this in mind, and on the basis of the conclusions of the report, that we wish to transmit our proposals to the Commission. We also wish to attract the attention of the Commission to the risks involved in liberalising patient information and to the necessity of ensuring that biosimilar products are marketed in compliance with the rules governing free and fair competition.

### 2-3-1- Public policy must aim to accelerate the distribution of generic drugs at fair prices

#### 2-3-1-1- Greater transparency and clarity of proceedings concerning patents:

The survival of the patent system today seems to be an important pre-requisite to the development of therapeutic innovation insofar as the system guarantees commercial exclusivity. For this reason, it appears important that the legitimacy, validity and quality of patents be strengthened.

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<sup>11</sup> This represents expenditure by all the stakeholders, with regard to all the medicines registered in the generic groups list and actually available in generic form, whether reimbursed or not.

Today, the patent system is frequently diverted from its initial aim of protecting innovation. Industrial companies use the system as a tool to obstruct competition (lack of clarity as to the duration of validity of patents, multiple patents for the same product, artificial extension of the field of protection of a primary patent, registration of defensive patents<sup>12</sup> etc.). ***La Mutualité Française* would like to see these practices cleaned up to ensure that patents meet proper quality standards and are better able to fulfil their primary mission, which is to protect true therapeutic innovation.**

- *La Mutualité Française* calls for the **clarification of the criteria used to qualify the notion of “imminent infringement of intellectual property rights” as presented in EU directive 2004/48/CE**. We point out that the notion of “imminent infringement” of the rights conferred by patents must not obstruct the development of the market for blockbuster drugs that will open up over the next few years. We also think that it would be particularly useful to differentiate between a probable infringement and a manifest infringement. We would therefore like to see this Directive transposed into French law in such a way as to ensure that the notion of “imminent infringement” unambiguously requires the same level of proof in French law as in the directive.
- **It is vital to ensure greater visibility of patent expiry dates** by creating, for example, a competent European body that could be consulted by generic manufacturers ahead of the launch of new generic products. *La Mutualité* thus proposes that a **public database** on patent expiry dates, grouped by drug, should be set up and maintained by this European body. Companies exploiting drugs under patent would be required to communicate systematically the expiry date of the patent attached to each drug for which they request a listing in the register of drugs that are reimbursable in France and/or approved by the French authorities.
- The Commission notes that 62% of proceedings in which judgement has been pronounced have found in favour of the generic manufacturers. This observation elicits three comments:
  - The lack of clarity that surrounds patents registered and maintained by the originator companies creates major legal uncertainty for generic manufacturers at the launch of a generic drug. To anticipate and/or avoid litigation, it should be possible for a generic manufacturer to **submit a marketing request file to a one-stop European patent agency at least one year prior to the presumed date of expiry of the patent of the principal**. This one-stop agency would then decide whether to accept or reject the request. Such a procedure would accelerate the marketing of generic products, reduce the costs of legal procedures and offer greater visibility to all the players involved.
  - In view of the number of disputes and proceedings concerning patents and the proportion of claims by innovating companies that are dismissed, it appears essential to redefine the criteria of acceptance of patents at the moment of registration, in order to **make them more robust**. **New selectivity criteria** must be introduced, especially for secondary patents, to avoid the excesses observed and offer each stakeholder the assurance that the patent system will not be allowed to deviate from its founding principle: the protection of true therapeutic innovation. The current system favours cumulative patents. Consequently it may be necessary to incorporate a **scale of protection commensurate with the nature of the patent**<sup>13</sup> (primary, secondary etc.). The profitability of secondary patents should not be identical to that of the primary patent.
  - **Specific measures** should be included in regulations relative to patents **to deter the originator companies from initiating abusive procedures** aiming only to delay the arrival of a generic (e.g. dissuasive fines).

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<sup>12</sup> With no commercial exploitation of the patented invention

<sup>13</sup> *Innovation et stratégies d'acquisitions dans l'industrie pharmaceutique : analyses empiriques* [Innovation and acquisition strategies in the pharmaceutical industry: some empirical analyses], thesis in economics by M. Gauthier Duflos, July 2007, University of the Sorbonne

- *La Mutualité* requests greater **clarity with regard to the holders of patents**: the development of generic products in France is obstructed by opacity and confusion as to the identity of the holders of patents relative to certain medicines that could be marketed in generic form. Effectively, registration in the generic drugs list, which governs the exercise of the right of substitution by the pharmacist, has long been legally impossible without the identification of the *spécialité de référence* [listed speciality], i.e. the name of the holder of the initial patent. This was the case with two important medicines: paracetamol and acetylsalicylic acid. The prohibition was lifted by French statute DDAC 2007-248 of 26 February 2007 adopting EU law regarding pharmaceuticals but the two products concerned are still not registered in the list of generic groups.

For information, nearly 300 million boxes of paracetamol were prescribed in 2008 in France generating income of nearly €520 million. In addition, paracetamol ranks first among the medicines reimbursed by the mutual benefit societies (€75 million reimbursed in 2008).

### 2-3-1-2- Reducing the price of generic drugs: a necessity or the search for a fair price

Several elements enter into the setting of retail prices for generic drugs in France. The two principal elements on which the funders (AMO<sup>14</sup>, AMC<sup>15</sup>, patients) still have significant room for manoeuvre are the manufacturer's price, excluding VAT, of the generic drug and the pharmacist's margin.

- The first element is determined in relation to the manufacturer's price, excluding VAT, for the originator drug, which is itself determined by the added therapeutic value of the drug and the price of alternatives. **A debate could be launched on the possibility of remunerating generic drugs on the basis of their cost price.**
- The second element is composed of the preferential margin (equal to the margin of the originator drug), discounts, rebates and any recovery of the wholesale margin in the case of direct sales. **back margins** have officially been replaced by retail mark-ups since the beginning of January 2008. As a result, legal rebates and discounts for generic drugs have risen from 10.74% to 17% of the manufacturer's price excluding VAT. Despite the changes in regulations regarding back margins, pharmacists still receive financial advantages, most often via the groups to which they belong, for listing certain generic drugs. Back margins are instruments used to disconnect the nominal price of a drug from the actual price. Generally speaking, *La Mutualité* is firmly opposed to systems that disconnect the nominal price of a drug (the price at which the drug is sold) from its real price.

### **2-3-2- Strategies conceived to obstruct generics must be identified as such nationally and challenged robustly in both economic and public-relations terms**

- ↪ **Close observation will help identify generic obstruction strategies**: just before the expiry of the patent of one of their drugs, companies will introduce onto the market a "circumventing" drug of very similar chemical structure. By inciting doctors to prescribe this "new" drug they deflect prescriptions from the soon-to-be generic drug towards a drug that is still patent-protected (e.g. omeprazole / esomeprazole, cetirizine / levocetirizine etc.).
- ↪ **Health-care institutions should develop a specific communication strategy to challenge the promotion of products that bypass generics** to enable all the stakeholders (prescribers, pharmacists and patients) to identify such products. In France, this role could be attributed to health insurance delegates, already deployed in support of prescription within the generics list, and to the *Haute Autorité de Santé* [French National Authority for Health], in particular through the distribution of best practice file-cards. These cards are edited on the basis of opinions of the *Commission de Transparence* [Transparency Commission] with the aim of providing health

<sup>14</sup> *Assurance Maladie Obligatoire* [mandatory state health insurance]

<sup>15</sup> *Assurance Maladie Complémentaire* [complementary private health insurance provision]

professionals with important information concerning specific drugs, in particular their place in therapeutic strategy.

- ↳ Once identified, these products must be **priced at the same price as the generics** they are designed to circumvent.

### 2-3-3- Doctors' prescriptions must be shielded from the influence of the drugs companies

We need four levers to achieve this: prescriptions must be written in INN (International Non proprietary Name), doctors must be encouraged to prescribe within the framework of the generic group list, a list of therapeutic equivalents must be created and finally, more widely, information intended for prescribers about drugs must be provided from a public and independent source.

- ↳ **Promoting prescription using INN:** Most of the drugs prescribed in INN concern products in the list of generic groups published by the *Agence française de sécurité sanitaire des produits de santé (AFSSAPS)* [French health-care products safety agency]. When a prescription is written using INN, it is easier for the pharmacist to deliver generic products, as the issue immediately becomes clearer and more acceptable for the patient. The delivery of generics and INN prescriptions are plainly correlated. Doctors should thus be encouraged to prescribe more in INN and patients should be encouraged to become more familiar with the system. At present, INN prescription is insufficiently developed in France<sup>16</sup>.

Specific action (to identify who does what) would enable INN prescription to develop:

- ☛ INN prescription should be facilitated, especially through the use of **prescription assistance software and drugs databases**. It so happens that the recent French law concerning Social Security funding for 2009 **introduces a requirement** that doctors in France **should write prescriptions for any speciality registered in the generics list<sup>17</sup> using common denomination**. Even so, this requirement is limited to drugs included in the list and non-compliance entails no sanctions.
- ☛ Action by *La Mutualité*: we provide **an overview of the practice** of INN prescription, especially through the publication of indicators regarding INN prescriptions and also by the forthcoming publication of **an international comparative survey of INN prescriptions**.
- ☛ **A public drugs database needs to be set up**, in particular to simplify INN prescription. This database would show not only the INN of each drug, but also data concerning marketing authorisations, medical benefits, the situation regarding reimbursement, retail prices, average treatment costs and the existence of generic products.

To this end, and also to ensure better quality health-care for European patients, *la Mutualité Française* would like **Article 14 of the proposed directive regarding the application of patients' rights in connection with cross-border health-care** to stipulate an obligation to prescribe drugs to cross-border patients in International Non proprietary Name.

- ↳ **Doctors can be encouraged to prescribe in the framework of the list of generic groups by setting quantified targets for prescription from the generics list** (also proposed by the *HCAAM*).

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<sup>16</sup> See Appendix

<sup>17</sup> Article 50 of French statute N°2008-1330 of 17 December 2008 concerning Social Security funding for 2009, JORF [Official Journal of the French Republic] dated 18/12/2008

- ↳ *La Mutualité Française* favours the **creation of a register of therapeutic equivalents**, by the *AFSSAPS* and *l'Assurance maladie* [French statutory health insurance], which would aim to simplify the development of the generic drugs market by enabling doctors to identify therapeutic equivalents, of equal efficiency, in order to procure savings for both the health authorities and patients. Doctors must be fully informed and a complementary tool in the form of a register of therapeutic equivalents, in addition to the generics list, is clearly required.

The aim of this register would be to constitute a medical and economic regulator designed to allow doctors to prescribe in a manner that is more economical for health authorities and households, with equal therapeutic efficiency.

A recent study by the *CNAMTS*<sup>18</sup> showed that 85% of the increase in the drugs bill between 2006 and 2007 was due to new drugs (less than 3 years on the market). The study also showed that “45% of this additional expenditure concerned medicines that present little or no improvement in terms of medical benefit (ASMR 4 or 5) relative to the existing therapeutic arsenal.” The *CNAMTS* added, “These new products are not only in part substitutes for existing products but also induce new prescriptions and thus additional expenditure. They are indicative of a trend that is especially marked in France: a shift in prescriptions towards more recent drugs to the detriment of older, often generic, molecules.”

The interest of such a register of therapeutic equivalents would be to provide a listing of initial originator (off patent) medicines by therapeutic class, as well as any associated generic drugs and any proprietary drugs that were very similar to the originator from a therapeutic point of view but which were still under patent. The register would also contain standard administrative data such as the situation regarding reimbursement, the average treatment costs and retail prices.

- ↳ **Information on drugs intended for prescribers must originate primarily from an independent public source.** Prescribers must be able to have access to information on drugs that is of good quality, unbiased and untainted by commercial interests. It is with this in mind that *La Mutualité Française* shares the recommendations of the *Inspection générale des affaires sociales (IGAS)*<sup>19</sup> [General Inspectorate of Social Affairs] and suggests that the *HAS* should become the central clearing house for data relative to the proper use of drugs and for recommendations regarding good prescribing practice.

#### **2-3-4- Perverse effects of the provisions of the projected “patient information” directive regarding the development of generic products and innovation**

The European Commission has just adopted a “pharmaceuticals package” that includes a proposed directive on patient information authorising the drugs industry to aim prescription drug advertising directly at patients.

*La Mutualité Française* is convinced that access to quality information on health-care, treatments and drugs is a fundamental right for the general public in Europe but stresses that this information should be non-promotional, reliable, independent, comprehensible and comparative, so that the general public can make informed choices.

**We would wish to stress that the liberalisation of direct advertising to the public by the drugs industry is liable to widen the increasing gap between promotional expenditure and R&D expenditure observed by the Commission in its preliminary report. Moreover, direct**

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<sup>18</sup> *Dépenses de médicaments en 2007 : quels sont les principaux moteurs de la croissance ?*, [Drugs expenditure in 2007: what are the main drivers of growth?] *CNAMTS*, March 2008

<sup>19</sup> *L'information des médecins généralistes sur le médicament*, [Drugs information for GPs] *IGAS*, September 2007, available at: <http://lesrapports.ladocumentationfrancaise.fr/BRP/074000703/0000.pdf>

advertising to patients will constitute an additional tool in the hands of the major companies for the promotion of potentially high-income circumventing medicines to the detriment of generic products.

### 2-3-5- The issue of biosimilar drugs

Drugs produced by biotechnology are costly drugs intended for patients suffering from serious conditions. The marketing of such products in the 1980s opened up new therapeutic perspectives funded by national health authorities.

The patents of the first biotech drugs are expiring and the first “biosimilar drugs<sup>20</sup>” started to appear in around 2005. The marketing of these biosimilars is conditional on the results of specific studies designed to show their effectiveness, quality and safety. Currently, several classes of biotech drugs are open to competition, including erythropoietin (EPO), recombinant insulins, interferons and growth hormones.

Echoing the sentiments of the vice-président of the European Commission, responsible for enterprise and industry, Günter Verheugen<sup>21</sup>, who has declared: “*Biosimilar drugs present new opportunities, with regard both to the expansion of our generic industry and to the control of national health expenditure. Nevertheless, these complex products must comply with the same strict standards of quality, safety and effectiveness as any other drugs, in the interest of European patients,*” **La Mutualité Française** wishes to see biosimilar drugs brought to market in the shortest possible time following the expiry of the corresponding patents, indeed as soon as their effectiveness, quality and safety can be proved.

*La Mutualité Française* asks the European Commission, in the framework of its sector enquiry, to look into the campaigns of denigration run by the main drugs industry designed to maintain a climate of suspicion with regard to biosimilars. Indeed, the major companies talk about the difficulty of reproducing biotech drugs in ways that are often alarmist and disconcerting.

In the next few years, biosimilar products will constitute a major opportunity to improve access to high quality treatment for a great majority of patients. It is important to ensure that these drugs will be made available with the greatest concern for safety, quality and respect for the rules of fair competition.

➡ **La Mutualité Française** shares the observations made by the European Commission in its preliminary report: the originator companies have developed very effective strategies to obstruct the development of generic drugs. We call upon the Commission to recognise that these strategies amount to anti-competitive practices.

**In France, the generic drugs market has enjoyed steady growth over recent years. However, it still remains insufficiently developed in comparison with other European countries. Under pressure from the originator companies, we are actually observing a shift away from the prescription of drugs from the generics list in favour of drugs that are still patent-protected.**

<sup>20</sup> In the sense of Directive 2004/27/CE of the European Parliament and Council of 31 March 2004 modifying Directive 2001/83/CE instituting a community code concerning drugs for human use.

<sup>21</sup> On the occasion of the April 2006 delivery of marketing authorisation for the first biosimilar drug OMNITROPE®

***La Mutualité Française* hereby puts forward concrete proposals that are designed to improve the transparency and quality of the European patent system, combat the strategies designed by the drug companies to bypass generics and shield doctors' prescriptions from drug companies influence. We also draw the attention of the Commission to the importance of ensuring that the marketing and distribution of biosimilar drugs should take place in the best conditions of quality, safety and efficiency and in full compliance with the rules of free and fair competition.**

## Conclusion

*La Mutualité Française* is extremely alarmed by the observations made by the Commission: 23% of the income from pharmaceuticals is injected into marketing as against 17% into research, with significant consequences for innovation. The report clearly confirms the drop in the number of new medicines entering the market.

The drugs industry today stands at a crossroads in its industrial history, confronted as it is by twin challenges: the challenge of modifying its R&D model to accommodate the slowdown in innovations generated by traditional chemistry and the challenge of the imminent expiry of a large number of blockbuster patents. With no new innovations to boost future growth, the collapse of the blockbuster patents will call Big Pharma's business model into question.

To confront this situation, certain originator companies have chosen to put in place strategies designed to obstruct the development of generic products. In its preliminary report, the European Commission enumerates these strategies, pointing out that they constitute a "toolbox" for use by the companies to delay loss of market share by their high-yield originator drugs.

***La Mutualité Française, which covers 38 million people in France, shares the analysis of the European Commission but would like the Commission to go further in its final report, to qualify such strategies as behaviour designed to obstruct the legitimate development of generic drugs and to emphasise the anti-competitive character of such strategies.***

Generic drugs actually represent a source of funding for the therapeutic innovation that patients will have great need of in the years ahead. To this end, ***La Mutualité Française has formulated a certain number of proposals that aim to combat these strategies.*** We call for a clarification of the current patent system in order to ensure more transparency and quality and thus prevent the industry diverting patents away from their primary purpose: the protection of innovation in order to encourage innovation. We also request that strategies designed to obstruct generic drugs should be identified as such by the health authorities and that communication strategies should be implemented in regard of health professionals to counteract those of the originator companies. We propose concrete action to shield doctors' prescriptions from the influence of the drug companies, in particular by encouraging INN prescription and the provision of an appropriate, independent and public source of information. In addition we draw attention to the risks of the proposed directive regarding patient information. Finally, we stress that the development of biosimilar products, a central challenge of the coming years, must take place in compliance with the rules of fair competition.

**In conclusion, *La Mutualité* would like this highly documented paper by the Commission to initiate a real debate on European drugs policy, which must be examined today in terms of health-care rather than from an industrial standpoint.**

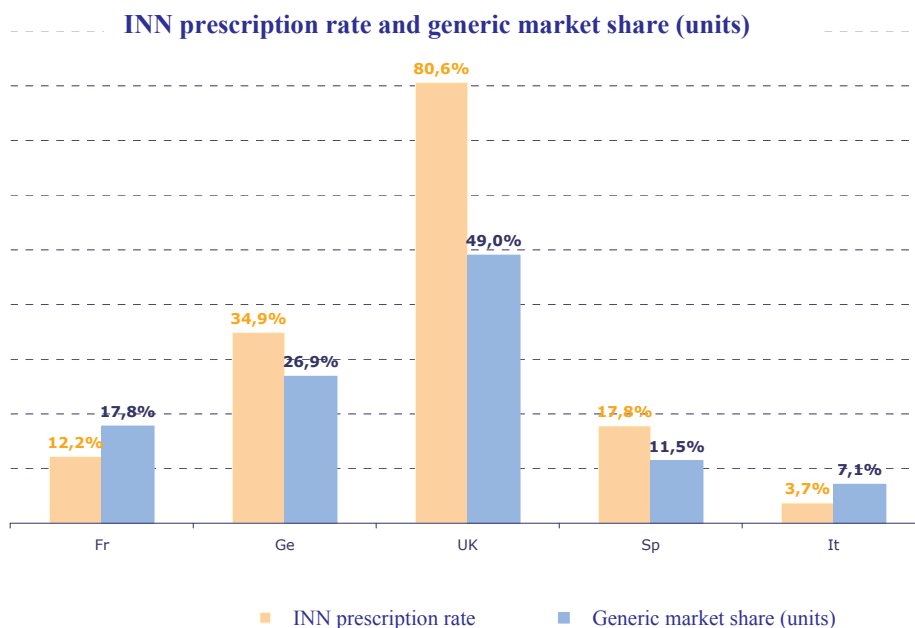
## Appendix: INN prescription is still too rare in France

*La Mutualité Française* publishes quarterly indicators of prescriptions written in International Non proprietary Name (INN) in France. The principal lessons of the latest indicators (annual running total in August 2008) are as follows:

- ↳ **A practice seeing slow but steady growth:** Following the agreement of 5 June 2002, the rate of INN prescription grew from 1% of prescription lines in May 2002 to almost 7% a little over one year later. Since autumn 2003, growth has slowed but, as of summer 2008, doctors were writing more than one line of prescription in ten (11.6%) in INN.
- ↳ **GPs write more INN prescriptions than specialists:** 12.6% of the prescription lines written by GPs are in INN, against 5.4% for specialists.
- ↳ **Strong correlation between INN prescriptions and the delivery of generics:** Most of the drugs prescribed in INN concern medicines in the list of generic groups published by the *Agence française de sécurité sanitaire des produits de santé (AFSSAPS)* [French health-care products safety agency]. If the prescription is written in INN, it becomes easier for the pharmacist to provide generic products, as the issue is clearer and more acceptable for the patient.

INN prescription, which presents many advantages for doctors and patients in terms of safety and for health authorities insofar as it simplifies the provision of generic products, is still poor in France in comparison with other European countries.

*La Mutualité Française* will shortly publish an **international comparative study of INN prescriptions in Europe**. This study shows that the rate of INN prescription varies greatly from one country to another. Thus, **France**, the second largest drugs market in Europe in volume of prescriptions, is ranked second from last as regards INN prescriptions, with merely 12% of prescription lines written in INN as at summer 2006. In contrast, the **UK** with a drugs market that is only slightly larger than that of France in volume of prescriptions, shows a rate of INN prescription of 81%: in the UK on average 8 prescription lines in 10 are effectively written in International Common Denomination. **Germany**, with a drugs market that is comparable in volume of prescriptions to that of France, shows a rate of 35%. Only **Italy** does less well than France with a rate of 4%. The following graph compares the rate of INN prescription with the market share, in volume, of generics in five European countries (France, Germany, United Kingdom, Spain, Italy). It shows clearly that **the higher the rate of INN prescription, the more developed is the market for generics**.



Source : IMS Health