

Drugs in France: The opaque nature of the Transparency Commission

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Drugs are a favourite target in the public control of health care spending in France. The refundable drug "market" is subject to price control by the public authorities.

In this regulated process in the French pharmaceutical market, the Transparency Commission holds a special place. The French know probably very little about this public body, which rarely comes up in the debate. Its decisions, however, can have a serious impact on their state of health.

The Commission's findings serve in effect as a "foil" for the public authorities, which use them to impose price controls on pharmaceutical products or to exclude them from the list of refundable drugs. These findings are presented as "scientific" but actually hide a bureaucratic process that leads to delays in the commercial release of some drugs in France – or sometimes even to their non-release – to the detriment of the quality of life of patients who might have benefited from them. Under pressure from the public authorities, the Commission thus becomes an instrument for controlling health care costs, penalising pharmaceutical innovation.

THE TRANSPARENCY COMMISSION IN THE DRUG REGULATION PROCESS

France's compulsory health insurance system has a monopoly on prescription drug coverage. To be eligible for reimbursement, new products must go through a complex regulatory process involving various public bodies, including the Transparency Commission (see Figure 1).

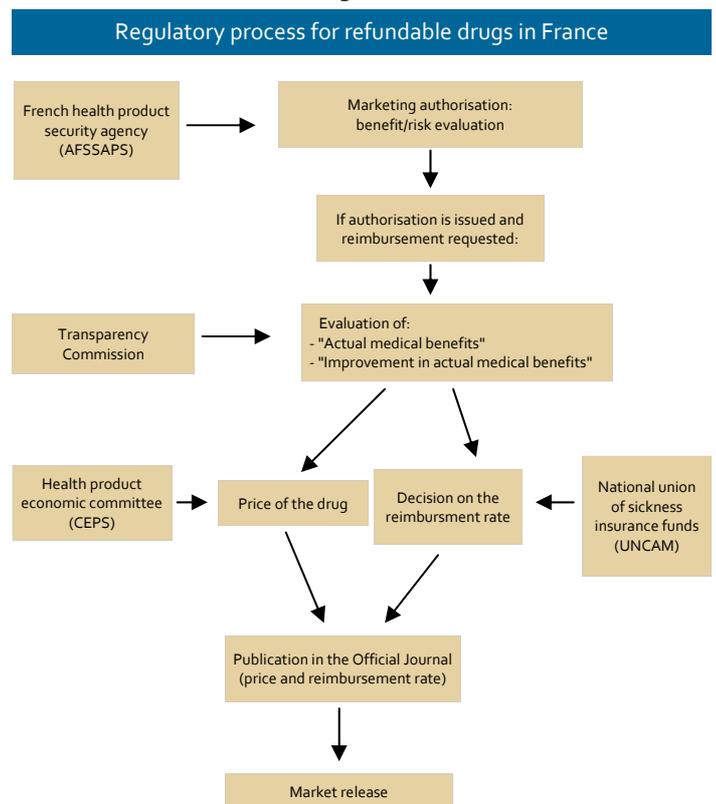
Drug firms must first obtain marketing authorisation attesting in particular to a new product's safety and therapeutic effectiveness. Then, if they want their drugs to be eligible for refund, they must produce and submit a file to the Transparency Commission.¹

Consisting of 20 voting members² and integrated with the Haute Autorité de Santé since 2005, the Transparency Commission has a dual role in examining each case.

In its findings, the Commission determines the "actual medical benefits," namely whether the drug has a therapeutic value, what place it has in relation to existing treatments, etc. It may judge these benefits to be major, significant, moderate, minor or insufficient. The Commission also tries to evaluate the level of *improvement in actual medical benefits*. This involves determining if new drugs provide "added value" compared to existing drugs. The Commission's findings are seen as aiming to "quantify" this by setting five levels of improvement (see Box 1).

These are the two elements in Commission findings – namely actual medical benefits and improvement in these benefits – that subsequently set the conditions for the reimbursement rate and the price of new drugs.³

Figure 1



Source: Nathalie Grandfils, "Fixation et régulation des prix des médicaments en France," *Revue française des affaires sociales*, N° 3-4, 2007, p. 65.

1. The file contains a new drug's precise indication, i.e. the conditions or symptoms it treats, etc. The Commission conducts an examination, and issues a finding, only on the therapeutic situation or indication for which the drug is intended (a drug can be the subject of several findings – one per indication – if it can be prescribed in various treatments).

2. See Commission de la transparence, "Règlement intérieur du 22 juin 2005 modifié les 20 juillet et 19 octobre 2005, les 18 janvier, 29 mars, 10 mai, 19 juillet et 4 octobre 2006 et le 2 juillet 2008," available at: http://www.has-sante.fr/portail/upload/docs/application/pdf/ri_ct_2005_v.04-10-06.pdf. Six substitute members, plus eight members in an advisory role, are also part of the Transparency Commission.

3. Drugs are then re-evaluated every five years.

Box 1

Actual medical benefits and improvement in benefits

Rating of "actual medical benefits" seeks to take account of:

- a drug's effectiveness and its undesirable effects;
- its place in therapeutic strategy, especially compared to other available therapies;
- the seriousness of the condition for which it is intended;
- the preventive, curative or symptomatic nature of the drug treatment;
- the drug's value to public health.

Actual medical benefits are rated as major, significant, moderate, minor or insufficient for refunds.

"Improvement in actual medical benefits": the five Levels are:

- I: Major therapeutic progress
- II: Significant improvement in terms of therapeutic effectiveness and/or reduction in undesirable effects
- III: Moderate improvement in terms of therapeutic effectiveness and/or reduction in undesirable effects
- IV: Minor improvement in terms of therapeutic effectiveness and/or reduction in undesirable effects
- V: Absence of improvement.

Source: Transparency Commission.

The public authorities rely on the actual medical benefit level to decide whether, and at what rate, the drug will be eligible for reimbursement. An insufficient level leads to denial of reimbursement.

The public authorities thus depend on Commission findings to justify the prices at which these drugs will be commercialised. The level of improvement in actual medical benefits is one of the factors (for example, the prices of competing treatments or hoped-for sales volumes⁴) that help determine the price of a drug.

On the improved benefits scale, ratings at Levels I, II or III, or, for some drugs, Level IV (offering savings compared to existing treatments), give drug firms the chance to use the so-called "price submission" procedure. Under this procedure, which has existed since 2003, drug makers suggest to the health product economic committee a price similar to what they charge in other European countries. Unless the committee objects, the firm is authorised to market the product at the price submitted. Through this procedure, only the price of drug rated at Level V for improved benefits remains under the full control of the French public authorities.

On paper, the Transparency Commission has only an advisory role,

and the public authorities are not obliged to act on its findings when setting downstream reimbursement rates and drug prices. But in reality, the role of its findings is set in law, and they are thus followed as a general rule. These findings, viewed as "scientific" elements⁵ for helping the authorities arrive at decisions, serve as true "foils" for them, intended to legitimise their actions on the drug "market."

This "quantification" process in pharmaceutical innovation and the decisions taken by the Transparency Commission are, in reality, irredeemably arbitrary.

OPAQUE OPERATION AND ARBITRARY DECISIONS

The Transparency Commission is a body of experts and scientists. From this it is generally extrapolated that the Commission's findings reflect scientific truth.

This is hardly the case, however. Although the Commission conducts an analysis of the data and scientific studies on a drug, its therapeutic environment and so on, the process and criteria used in decision-making contain a number of arbitrary aspects that go beyond the simple therapeutic evaluation that is set out.

First, while the official aim may be to evaluate drugs solely from a therapeutic standpoint, the Commission does not escape from implicitly taking account of economic and financial considerations in its decisions.

These aspects remain little known to the public. For example, whereas the process of judging a drug's actual medical benefits to be insufficient should take account only of the therapeutic values of the drug being evaluated (to see whether or not it provides therapeutic value⁶), the Commission itself states that this finding indicates "an inadequate level to justify providing care by national solidarity."⁷ What justifies or does not justify "providing care" inevitably involves financial and cost considerations that do not come under the Commission's ambit.

Second, grids of this type that serve to "quantify" the value and therapeutic progress of a new drug are not in themselves the results of confirmed scientific findings. On the contrary, they are the result of numerous compromises that consist of applying certain criteria in some countries and excluding them in others. The outcome is that the grids vary from one country to the next.⁸ On the contrary, scientific truth has indeed no geographic boundaries.

The improved medical benefit grid also varies over time, generally with changes of Transparency Commission president.⁹ Why were only the criteria of a treatment's effectiveness and undesirable effects applied in determining Levels I, II, III and IV starting in 2004? What leads to rejecting criteria of acceptability, ease of use or observance or extended product range in awarding Level IV, which was part of the

4. See Valérie Paris, "La régulation du prix du médicament en France," *Regards croisés sur l'économie*, 2009/1, No. 5, p. 221.

5. See, for example, Jacques Massol and Claire Le Jeune, "Comment évaluer l'intérêt des médicaments?," *La Presse Médicale*, Vol. 36, No. 3, Mars 2007, p. 506, who note that "the [Commission's] findings have an exclusive scientific character." On this subject, see also the article by Commission president Gilles Bouvenot, "Service médical rendu des médicaments," *Revue du Rhumatisme*, 73, 2006, p. 412.

6. On this subject, unlike the Transparency Commission, doctors often decide that the therapeutic value of drugs with supposedly insufficient medical benefits is largely sufficient for them to be prescribed to their patients. For example, according to one study, one product out of five prescribed drugs in 2001 was with insufficient medical benefits; see Florence Naudin and Catherine Sermet, "La prescription de médicaments à service médical rendu insuffisant en 2001," *Questions d'économie de la santé*, IRDES, 2004, No. 82, pp. 1-5.

7. See the 2005 annual report of the Haute Autorité de Santé, p. 22, available at: <http://lesrapports.ladocumentationfrancaise.fr/BRP/054000591/0000.pdf>.

8. See Catherine Sermet, "La prise en compte de l'innovation thérapeutique dans les politiques de prix et de remboursement des médicaments," *Revue française des affaires sociales*, Nos. 3-4, 2007, p. 322 concerning so-called "added therapeutic value grids" in several OECD countries, including France.

9. See Claude Le Pen, "Evaluation du médicament : l'innovation incrémentale est-elle maltraitée?," *Étude du CRIP-IMS*, January 2009. The various grids referred to here have thus borne the Commission president's name.

grid before that?¹⁰ This type of innovation – potentially important for patients and their day-to-day quality of life – no longer has its place in the grid.¹¹ It seems obvious that the grid is truncated or altered arbitrarily by the Commission.

Third, decisions on medical benefits or improvement in medical benefits are also the result of compromises that strip them of their scientific character. Commission members vote by simple majority based on syntheses from experts, relying on the latter's choices of selection and interpretation. Voting of this type is, by its very nature, a form of political decision-making, alien to the scientific approach. It is not through votes that science advances and scientific truths are established.

In addition, while scientific debate takes place in scientific journals where arguments can be aired openly, this is hardly the case with the Commission. On the contrary, those taking part in debate during its sessions are obliged to keep the content secret.¹²

The Commission's findings are thus vitiated by their arbitrary nature and incorrigible opacity. These are decisions that – by their nature and in the French drug evaluation framework – are fundamentally political, with repercussions on all insured persons.

Yielding uncritically to these findings, under the pretext that they are "scientific," amounts to ignoring their arbitrary nature and future perverse effects.

AN OBSTACLE TO INNOVATION TO THE DETRIMENT OF PATIENTS

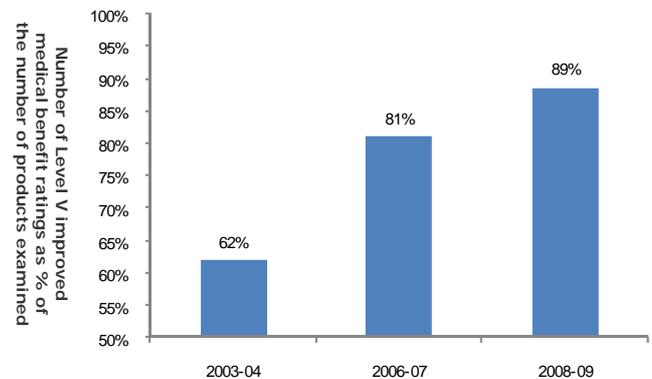
Normally, whatever the nature of a new product or service, its innovative character and the progress it represents are evaluated directly on the market. Consumers decide if it represents added value and if they prefer it to the existing alternatives by showing their willingness to pay its price. Through a spontaneous and meticulous process, innovation is evaluated by all market players based on their preferences. If a new product does not represent progress, it is not in demand, and its manufacturer has a direct incentive to halt its production.

In the drug field, this logic has been entirely pushed aside by the public authorities. The appreciation of progress represented by new drugs is left in the hands of bureaucratic organisations such as the Transparency Commission. The people these drugs are intended for, namely patients advised by their doctors, have no voice in the matter. The natural link that exists in the market has thus been broken, and there exists a real separation between those who evaluate new products and those who are supposed to gain from the future benefits they represent.



Figure 2

Changes in the number of Level V improved medical benefit ratings, 2003-2009*



* This is an average calculated over each two-year period shown. The total number of products examined corresponds to notices of initial registration and of extended indication.

Sources: Activity reports from the Transparency Commission (2003-04) and annual reports from the Haute Autorité de Santé (2006-2009); calculations by the author.

This discrepancy involves, in particular, the value of gradual innovation – concerning enhancement to an existing drug through a more precise or different dosage, through a means of administering the drug that is less painful or easier for the patient (a patch or oral means instead of an injection given by a doctor), etc. Although this type of innovation may represent added value in patients' eyes, it no longer receives formal recognition, especially since 2004. The Transparency Commission systematically gives it a Level V improved benefit rating, substituting itself for patients and their doctors in concluding that there is an absence of improvement. The number of such ratings has kept rising, and Level V is being applied to nearly 9 out of 10 products examined (see Figure 2).¹³

There are dual consequences of this failure to attach value to gradual innovation.

First, the issuing of a Level V improved benefit rating by the Transparency Commission means that manufacturers will have to settle for lower prices than they get for existing treatments, even when those prices apply to generic drugs and were set 10 or 15 years earlier – without being indexed to inflation – and although pharmaceutical R&D costs have risen considerably. Also, compulsory price reductions may be substantial, as much as 75%, as

10. Level IV was thus equivalent to a "minor improvement in terms of acceptability, ease of use and observance or justified extended product range" (our emphasis); see Commission de la transparence, *Rapport annuel 2003*, p. 4, available at: <http://www.has-sante.fr/portail/upload/docs/application/pdf/ctrapact2003.pdf>.

11. Nothing, however, prohibits the Commission from deciding to take account of this, if need be.

12. See Commission de la transparence, "Règlement intérieur du 22 juin 2005," *op. cit.*, p. 5.

13. Professor Claude Le Pen describes this shift as a slide "to the bottom" in improved benefit ratings (i.e., fewer ratings at Levels I to IV and an increase in Level V ratings); see Claude Le Pen, 2009, *op. cit.*, p. 19.

was the case with an analgesic that received a Level V rating in 2006!¹⁴

These artificially low prices lead to delays in commercial release of drugs, or even to their non-release in France, despite their availability elsewhere. For example, in the treatment of Parkinson's disease, with the reference treatment dating from the 1960s and producing substantial side effects, new treatments added to the therapeutic arsenal received Level IV or V improved benefit ratings. The excessively low prices resulting from this prevented their commercial release in France.¹⁵

Moreover, prices administered in this way undeniably affect drug firms' margins and return on investment. These artificially low bureaucratic prices penalise gradual pharmaceutical innovation (so called incremental innovation), which offers advantages both in therapeutic terms (broader choice available to doctors in treating their patients) and in economic terms (better quality of life, more intense competition with existing drugs, etc.).

Failure to recognise this type of innovation risks leading over time to fewer products in the future, affecting the health and well-being of tomorrow's patients.

CONCLUSION

Pharmaceutical innovation must be appreciated in the case of each patient, advised as need be by his or her doctor. It cannot be appreciated validly in centralised fashion for all insured persons, as the Transparency Commission seeks to do. What stems from this is a broad margin of discretion and arbitrariness in the findings it issues.

From the perspective of public control of pharmaceutical spending, the Commission easily becomes a tool aimed at limiting the cost for the health insurance system, instead of evaluating pharmaceutical innovation from the perspective of having it benefit patients. Because of inadequate recognition, new drugs – representing gradual innovation compared to existing drugs – are especially penalised, and their manufacturers may decide not to release them in France because of prices that they regard as insufficient.

Despite the lower "short-termist" prices of pharmaceutical products for health insurance, this bureaucratic evaluation by the Transparency Commission brings a degree of longer-term danger to gradual innovation. This innovation is threatened at the ultimate expense of people who fall ill, without their having a choice in the current monopolistic health insurance system.



14. Taking account of the cost of daily treatment, the price was set at 0.32 euro, compared to 1.22 euros for the existing treatment (see Claude Le Pen, 2009, *op.cit.*, p. 22).

15. See Claude Le Pen, *op.cit.*, p. 25, who gives a number of examples in this regard.



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