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15 years of monitoring and one simple conclusion: don't expect sales representatives to help improve healthcare quality

● **Prescrire's sales representatives (reps) monitoring network was created in 1991 at the initiative of a group of subscribers. For the last 15 years, members of the Network have compared sales reps' claims with the information contained in the summaries of product characteristics.**

● **A variety of methodological precautions were taken to minimise the biases inherent in any 'sentinel' type of observational system. Results have been remarkably consistent over the years.**

● **Sales reps highlight the efficacy of the drugs they present, often for unapproved as well as approved indications. In contrast, adverse effects are not mentioned in three-quarters of visits.**

● **Participation in the Network requires monitors to become better informed about the drugs that are being promoted in order to decipher reps' claims. After a few months, many Network observers decide they no longer want to see sales reps, and opt instead for reliable and independent sources of information.**

● **Similar conclusions have been reached by monitoring networks in other countries. Internationally, a growing movement exists of healthcare professionals who have removed themselves from the sphere of influence of pharmaceutical companies.**

● **Prescrire's sales reps monitoring network ceased its sentinel observational work earlier this year. New research and new actions are planned, focusing on other types of promotion aimed at both healthcare professionals and the public.**

The idea of creating a sales reps monitoring network of subscribers to *la revue Prescrire* was launched in the late 1980s with the aim of helping the editorial staff: with better knowledge of reps' strategies and claims, they would be better able to help subscribers understand the difference between the misleading claims they often heard and accurate information. A one-year pilot phase (1989-1990) showed that it was possible for prescribers to observe reps, to note down their claims, and to build up a sentinel-type observational system (1).

An initiative by practising healthcare professionals

The need for a well-organised network became clear during the controversy that followed the publication, in September 1990, of an editorial in *la revue Prescrire* entitled *Une année sans VM* ("A year without sales reps") (2). This editorial recommended that prescribers observe an experimental one-year period without seeing sales reps. Prescribers could keep track of the amount of additional time available for other activities, discover new sources of information, and report any negative effects. The editorial sparked a heated debate in the form of letters from subscribers (hospital physicians and general practitioners), sales reps, and drug companies (3). Some subscribers decided to take a year off from sales reps. Others decided instead to contribute to an observational study of rep visits.

Prescrire's sales reps monitoring network was thus born in 1991, under the aegis of what was to become 'Association Mieux Prescrire' (a non-profit group representing readers and members of the bulletin *la revue Prescrire*).

First results published in May 1991.

Based on experience gained in the pilot phase (1989-1990), a standardised reporting form was developed and tested by volunteers. The results of the first 169 reports, published in May 1991, were even worse than expected: 24% of the indications that reps promoted differed from approved indications listed in the summary of product characteristics (SPC); 14% of dose regimens quoted

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ed by the reps differed from those recommended in the SPC; and, in 65% of cases, the reps failed to mention adverse effects and contraindications (4).

A longer study was clearly needed to confirm these findings. In June 1991, a coordinator was appointed and more observers joined the Network. At the same time, a methodological review was undertaken to improve the reliability of the data collected by the Network, and to minimise observation biases (see inset page 156 for a description of the methods).

Regular observer turnover, consistent results. During its 15 years of existence the Network rarely needed to solicit participants, as there were always highly motivated *Prescrire* subscribers available. Despite the extra workload, new general practitioners and specialists (a) stepped in to replace Network members who had stopped contributing data (often because they had simply decided to stop seeing reps...). Despite the turnover of monitors, the results were highly consistent: the trends reported during the pilot phase in 1990 were confirmed during the Network's 15 years of activity.

Yearly analyses and more thorough reviews published in 1995, 1999 and 2003 revealed very similar results: in around 25% to 30% of visits, sales reps discussed unapproved indications; 15% of dose regimens differed from those recommended in the SPC; and drug risks were rarely mentioned. Sales reps mentioned contraindications, adverse effects and precautions for use in less than 30% of presentations on a specific drug (see the 15-year summary table on page 158) (1,5,6).

This consistency of the results over 15 years has led to the decision in 2006 to stop running the sentinel observational network and to replace it with other research activities.

The Network as a training tool. On their membership application forms, candidate observers gave a variety of reasons for wanting to join the Network: "to be of service", "to inform people of what's really happening", "to improve the quality of medical representation", "to increase drug company awareness", etc. (7). Each observer spent an average of 1 or 2 years with the Network (the minimum requested participation period was 6 months). At the end of this period, most observers asked to leave the Network in order to stop seeing sales reps (8).

Many ex-observers agreed that filling out the reporting forms on reps' visits, and comparing the reps' claims with the SPCs was an excellent form of continuing professional education (6). By referring to the SPC, *Prescrire* articles, or other reliable information sources, the observers realised just how

spurious drug companies' promotional messages really were. They also discovered more about the drugs they prescribed, learned to decipher approved product information, and were better able to analyse the results of clinical trials.

Weariness. In recent years, Network members became increasingly critical of rep visits: they found that reps were less thoroughly trained, that their arguments were less and less relevant, and that they were increasingly unfamiliar with the products they promoted (9). Network members were also annoyed by the frequent references to opinion leaders' use of a new product, and by attempts to make the prescriber feel old-fashioned if he or she did not prescribe the new product (10).

What led many observers to leave the Network was the lack of any noticeable improvement in the quality of reps' visits over the years, even though the French government had introduced several changes meant to improve the situation.

A range of regulatory actions without practical impact

Several measures were taken during the 1990s, both in France and in Europe, with the stated objective of providing a more solid framework for medical sales forces, and to transform rep visits into a training tool for healthcare professionals.

1992: professional ID card and training. European Directive 92/28/EC on drug advertising (dated 31 March 1992) and French law 94-43 (dated 18 January 1994) relating to public health and welfare, required drug companies to create obligatory training courses for sales reps, and a professional ID card (11,12). Many training courses were created by universities, publicly funded continuing education bodies, private centres, individual drug companies, and various service providers (5). According to a professional agreement signed in July 1992, training must last at least 500 hours and must include 82 hours on therapeutics and 17 hours on medicines (5). A new agreement signed on 1 July 2005 increased the length of training on principles of therapeutics and medicine use to 850 hours (b).

1996: new requirements to provide specific documents. The French decree 96-531 on drug advertising, dated 14 June 1996, stated that sales reps were now required to provide physicians with several documents during the visit (13). This included the most recent Transparency Committee assessment of the product's contribution to

medical therapy, including for each therapeutic indication.

Beginning in 1997, the standardised form completed by Network members contained a box to be ticked if the rep handed the observer the relevant Transparency Committee assessment. On average, from 1998 to 2005, this box was ticked for fewer than 5% of visits! (See table page 158)

1980s: ethical codes and international guidelines. Since the late 1980s, a number of ethical guidelines, codes of good conduct, good practice guidelines, and lists of ethical criteria concerning drug promotion have either been published or strengthened. There are two key international texts: the Code of Marketing Practices of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), last revised in 2000; and the World Health Organization (WHO) Ethical Criteria for Drug Promotion, produced in 1988 and not yet revised, despite WHO discussions and consultations on the topic (14,15).

National governments and industry associations have also drawn up a range of guidelines and codes of conduct. In the 1990s, France introduced a law prohibiting gifts, but this new law had little impact on ingrained habits (16). In 2004, France also adopted a curious legal framework called the *Charte de la visite médicale* (Medical Sales Charter), governing "commercial and promotional practices that could harm the quality of health care" (17,18).

2004: a charter for sales representatives à la française. The French law on healthcare insurance, dated 13 August 2004, introduced a "Charter of professional practices for persons charged with unsolicited drug promotion" (19). This Charter was signed on 22 December 2004 by both pricing authorities and the main pharmaceutical industry association (LEEM). It is therefore not a code of conduct produced by the pharmaceutical industry, but is enshrined in national law and is enforced both by health authorities and by a monitoring committee composed of representatives of the pricing authorities, LEEM, and physician associations. The main tool used to enforce the Charter is "company certification" based on "standard practice". ►►

a- A small number of pharmacists, many of them working in hospitals, also asked to participate in the Network. Their reports provided useful confirmatory data but were not included in the global analyses, for reasons of homogeneity.

b- The professional agreement dated 1 July 2005 (ref 41) does not mention precisely how long the training period should last, but the Comité professionnel national de la visite médicale (Cpnvm) states that it should consist of 850 hours of theoretical training (between 9 and 12 months) and 3 to 6 months of practical training (ref 42).

Methods

Prescire's sales representative monitoring network has often been criticised by drug companies for the way in which it collects data (1). This is a brief description of the Network's methods.

Asentinel-type network. Prescire's sales reps monitoring network was of the "sentinel" type. Similar networks have been created to observe social or individual phenomena, to provide indicators, and to understand trends. Information thus collected generates research hypotheses or serves as a warning of a potential underlying trend. By definition, these are small networks that do not claim to be representative.

When the Network's first hundred reports showed that adverse effects had not been spontaneously mentioned in three-quarters of visits, this was just a trend. When thousands of reports subsequently indicated similar results throughout France, despite significant turnover of individual observers, the phenomenon became more disturbing.

Through regular, long-term work using standardised procedures, the Network has limited the biases inherent in its observational methods.

Geographic distribution. From the beginning, Network coordinators were careful to recruit monitors evenly distributed in different regions of France (at least two-thirds of French regions were always covered). The total number of monitors was always kept to no more than a few dozen.

Distribution among the different types of medical practice. Before joining the Network, candidates filled in a questionnaire on their type of practice (private or public, general practice or specialised medicine, group or individual practice, permanent or temporary post) and on the way in which they accepted rep visits (on demand, by appointment, frequency, etc.). This information was used to reduce data collection biases for specific cases applying only to a subgroup of prescribers or to certain well-defined time periods. A small number of pharmacists working in the community or in hospitals contributed useful confirmatory data, but their reports were not included in the analyses.

Strict anonymity. To avoid the identification of Network members and

resulting group effects (for example if individual Network members consulted with one another), names and addresses of monitors were known to only three persons: the Network's coordinating physician, a member of the Prescire editorial staff responsible for liaising with the Network, and a member of the Prescire secretariat. The sales visit monitoring forms bore the members' names and addresses, but were anonymised if they had to circulate within the editorial staff.

Standardised materials. Monitoring forms were developed to identify the product in question, whether the rep was employed directly by the drug company or through a subcontractor, and the date of the visit (a blank form is available on request). The members were asked to complete a new form only if the rep presented a new product, a new substance or a new indication (or another "novelty", whether real or claimed). The form included eight closed questions about the presence or absence of documents that the rep was supposed to provide, and whether the rep's claims matched the corresponding summary of product characteristics. There were also several open questions. Only answers to the closed questions were used for summary statistics. Answers to open answers were only included in the analysis when the same claims had been made by reps in at least three different regions of France.

Member turnover. To limit reporting biases linked to the personality of individual prescribers who volunteered for the Network, members were regularly replaced, either temporarily or permanently. The members themselves eventually asked to be replaced, because of the time-consuming nature of the work, and because they became tired of hearing the same spurious claims over and over again.

An important bias nevertheless persisted: candidates for Network membership were obviously concerned about rational use of drugs use and reliable drug information, and were probably often identified by sales reps as a certain type of prescriber with these types of concerns. This suggests that some reps were likely to tone down their claims or to limit offers of gifts.

Sustained work and careful interpretation. The first analysis of the Network's activity was only published after 4 years, in order to avoid over-interpretation of transient trends.



Prescire never published summarized data on free samples, gifts, invitations to "seminars" in fashionable resorts, etc.

These practices differed from one region to another, and sometimes from one rep to another, but they were always minor in comparison to practices in hospital and academic environments. The Network focused above all on whether the reps' claims matched the relevant SPC, and whether the reps provided all required documents.

Logical consequences. Drug companies were not very happy to see their "backyard" scrutinised in this way (a). Likewise, some prescribers were embarrassed that their patients might discover what went on behind closed doors with the sales reps they saw in the doctor's waiting room.

A growing number of physicians, concerned with the quality of the information they receive, are refusing to see sales reps and are opting for information sources independent of the pharmaceutical industry.

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a- Product brochures and other promotional materials distributed by sales reps are, in principle, controlled by the French drug regulatory agency (ref 2). Clearly, what a medical rep says in the doctor's office cannot be controlled in this way.

1- Prescire Rédaction "Visite médicale. Réactions, commentaires et discussions" Rev Prescire 1999; 19 (196): 472-475.

2- Prescire Editorial Staff "A look back at the pharmaceutical market 2005" Prescire Int 2006; 15 (82): 75-79.



► The French government apparently thought that by putting together in a single committee the public health authorities, the governmental body that sets drug prices, the companies that sell drugs and the physicians who prescribe them, they would be able “*to reinforce the role of medical sales forces in proper drug usage and in the provision of high-quality information*” (20). Unbelievably, the *Haute Autorité de Santé* (French scientific evaluation body) announced that it was intending to have sales reps distribute its healthcare guidelines, i.e. an incredible public-private partnership that triggered heated reactions from healthcare professionals and politicians alike (21-23).

No visible changes. None of the legislative, professional, ethical or pseudo-regulatory measures taken over the last fifteen years have had a practical impact on the activities of sales reps. While it may still be too early to measure the effects (positive or negative) of the Medical Sales Charter, *Prescrire*’s monitoring network has noticed no improvement since the introduction of the Charter in the accuracy of reps’ claims or in the provision of required documents during sales visits (see table page 158). The only observed changes are those linked to the economic and structural upheavals that have taken place in the world of pharmaceutical sales.

A gradual deterioration linked to increasing market competition

The last four annual Network reports reflect the practical consequences of pharmaceutical industry restructuring (mergers, acquisitions and globalization), a stunning decline in innovation, and heightened competition.

In the late 1990s, rep visits focused on (costly) new products and on “new” pharmacological or pathophysiological concepts. Promotion of old drugs was accompanied by very strong incentives to prescribe (24). Prelaunch promotion began to occur more frequently, off-label uses continued to be recommended, and Transparency Committee opinions on approved indications were rarely provided during the visit (after a slight improvement in 1999-2000) (25).

Starting in 2003, most new products were isomers of existing products, metabolites or ‘me-too’s within a specific drug class (Cox-2 inhibitors, sartans, triptans, prazoles, dronates, etc.). At the same time, drug companies began to use more sophisticated methods to seduce prescribers. Spending on sales campaigns spiraled out of control, reaching a billion dollars for the worldwide launch of yet another statin (26).

In 2005, *Prescrire*’s rep monitoring network confirmed the trends described in industry journals, with fewer in-house reps and more subcontracting (c); more sophisticated electronic tracking of physicians’ prescriptions; and a greater concentration on high volume prescribers (27). Reps also became more and more aggressive towards their competitors’ products, an approach that is hardly endorsed in the Medical Sales Charter (27).

These trends continued in 2006, during the Network’s last few months of activity, reflecting the ongoing crisis in the pharmaceutical industry (28).

An international campaign to ‘just say no’

Throughout its 15 years of activity, the *Prescrire* Network has aroused much interest both at home and abroad. Exchanges have taken place with teams studying the activities of sales representatives in other countries, and with an increasing number of movements that reject sales reps in favour of reliable information sources.

The media: intrigued, enthusiastic, irritated. The first description of the *Prescrire* Network in an international journal was published in the *Lancet* in 1994. This short article concluded with the following statement: “*It is clear that there is a message here for sales reps and physicians*” (29). In 1997, in an issue of the Essential Drugs Monitor, the World Health Organization published a review of “the encouraging experience” of *Prescrire* Network over a 7-year period (30). In France, the lay press only mentioned the Network’s existence after the second major review had been published in 1999: *Le Monde* spoke of a “*severe, painful, and highly disturbing report*”, while the *Quotidien du Médecin* (Physician’s Daily) offered a sort of ‘right of reply’ to sales reps, and *Visite Actuelle*, a monthly newsletter for medical sales forces, entitled its article *Les désinformations de Prescrire* (*Prescrire*’s disinformation) (31,32,33). Thus, some found the Network disturbing and hurtful, while others considered it useful and necessary.

Researchers interested in the Network’s uniqueness. A variety of national and international institutions working in the fields of pharmaco-epidemiology and healthcare evaluation contacted the Network asking for a presentation of its work and for permission to reproduce its reports. Consumer organisations such as Quebec’s Union des Consommateurs and Health Action International asked the Network for advice on conducting their own studies of practice guidelines for drug promotion (34-

36). Some organisations conducted observational studies using the Network as a model; for example, the Dutch Institute for Effective Use of Medication (DGV) achieved results very similar to those of *Prescrire*’s network (d)(37). Students carrying out research on sales representatives in the community or hospital setting approached the Network for more details on its methods (38). Teams carrying out academic detailing also examined the Network’s results (39).

Rejection of sales reps in favour of independent information. Many Network members in France and elsewhere decided to stop seeing sales reps and to choose their own sources of independent information. The biased nature of the messages conveyed by sales reps is now universally recognized (40).

The last few years have seen the creation and reinforcement of networks of healthcare professionals seeking to defend their freedom to practice independently of companies that market drugs or other health products. The best-known are No Free Lunch in the United States (www.nofreelunch.org) and the United Kingdom (www.nofreelunch-uk.org), and Healthy Skepticism in Australia (www.healthyskepticism.org).

Other less well-known or more recent networks share the same objectives; examples include *Gezonde sceptis* (www.gezondescensis.nl) in the Netherlands, *Publivigilance* in Belgium (created by the Group on Research and Action for Health, GRAS: www.grouperechercheactionsante.com), *No grazie, pago io!* (www.nograziepagoio.it) in Italy, and *Non merci...* in France, created at the initiative of the Association *Mieux Prescrire* (www.prescrire.org). Even if these networks have begun to conduct broader campaigns addressing many aspects of drug promotion, their initial motivation was often a refusal to see sales representatives.

It is time to move on to the next stage

The situation is clear, and not just in France: sales reps are in no way a source of useful information for conscientious healthcare professionals. They may be an important promotional tool for drug companies, but they must not be mistaken for a means of obtaining reliable information. ►►

c- The total number of sales reps has not fallen, however. In 2006 there are still about 23 000 sales reps in France, according to data posted on the LEEM website (www.leem.org, accessed 12 March 2006).

d- The study by the Dutch Institute for Effective Use of Medication (DGV) showed that, during 718 monitored medical rep visits, contraindications were spontaneously mentioned in only 12% of cases, interactions in 16% and adverse effects in 23% (ref 37).

Findings of Sales Reps Monitoring Network in 1991-2005 (a)

Observed items		91-92	92-93	93-94	94-95	95-96	96-97	97-98	98-99	99-00	00-01	01-02	02-03	03-04	04-05
Newly marketed drug		—	—	—	—	—	—	—	50	56	50	51	44	45	51
Drug not yet marketed		—	—	—	—	—	—	—	9	7	3	6	3	5	0
Old drug:									19	17	23	21	13	10	11
* modified SPC									22	20	24	22	40	40	38
* unmodified SPC (false claim)															
Did the rep give you the SPC spontaneously?	Yes	—	—	—	—	—	—	—	82	79	79	80	82	84	80
	No	—	—	—	—	—	—	—	18	21	21	20	18	16	20
Did the rep give you the health authority's opinion spontaneously?	Yes	—	—	—	—	—	—	—	3	7	2	3	1	5	3
	No	—	—	—	—	—	—	—	97	93	98	97	99	95	97
Are the claimed indications those on the SPC?	Yes	65	64	71	80	81	76	80	70	69	64	73	74	65	70
	Partly	—	—	—	—	—	—	—	21	22	26	16	18	26	21
	No	35	36	29	20	19	24	20	9	9	10	11	8	9	9
Is the claimed dose that on the SPC?	Yes	74	79	86	89	90	89	92	88	86	85	85	90	85	86
	Partly	—	—	—	—	—	—	—	7	12	10	10	9	8	10
	No	26	21	14	11	10	11	8	5	2	5	5	1	7	4
Did the rep spontaneously mention:															
* the contraindications?	Yes	19	25	20	30	24	20	24	17	18	10	22	17	8	16
	Partly	—	—	—	—	—	—	—	12	20	12	12	16	15	14
	No	81	75	80	70	76	80	76	70	59	73	64	65	73	67
	Denied them	—	—	—	—	—	—	—	1	3	5	2	2	4	3
* precautions for use?	Yes	—	—	—	—	—	—	—	17	14	9	21	17	9	14
	Partly	—	—	—	—	—	—	—	14	21	14	13	18	13	16
	No	—	—	—	—	—	—	—	66	60	73	64	61	77	67
	Denied them	—	—	—	—	—	—	—	3	5	4	2	4	1	3
* drug interactions ?	Yes	17	20	18	24	24	18	23	15	14	8	17	15	11	13
	Partly	—	—	—	—	—	—	—	13	20	10	11	13	15	13
	No	83	80	82	76	76	82	77	69	62	76	69	68	71	70
	Denied them	—	—	—	—	—	—	—	3	4	6	3	4	3	4
* adverse effects?	Yes	23	31	26	35	29	22	26	22	13	9	14	17	13	15
	Partly	—	—	—	—	—	—	—	16	23	13	16	16	17	17
	No	77	69	74	65	71	78	74	59	58	68	64	61	65	62
	Denied them	—	—	—	—	—	—	—	3	6	10	6	6	5	6
Given the nature of the drug, do you think the rep should have mentioned them spontaneously?	Yes	65	79	81	73	69	75	77	79	81	87	85	72	75	80
	No	35	21	19	27	31	25	23	21	19	13	15	28	25	20
Did the rep readily answer your questions on the subject?	Yes	80	73	69	71	72	64	67	53	44	32	46	50	50	46
	Partly	—	—	—	—	—	—	—	30	37	42	29	38	30	35
	No	20	27	31	29	28	36	33	17	19	26	25	12	20	19
Did you find the rep convincing?	Yes	18	20	17	28	35	29	33	19	14	6	9	20	12	13
	Not very	—	—	—	—	—	—	—	32	30	34	32	20	20	28
	No	82	80	83	72	65	71	67	49	56	60	59	60	68	59
Did you feel pressured to prescribe?	Yes	24	19	16	18	25	32	39	35	46	54	47	43	34	43
	No	76	81	84	82	75	68	61	65	54	46	53	57	66	57
Did the rep give you any documents?		—	—	—	—	—	—	27	23	18	15	11	17	7	15
Did the rep offer you any samples?		—	—	—	—	—	—	19	22	20	26	17	18	17	20
Did the rep offer you any small gifts?		—	—	—	—	—	—	14	17	15	15	16	13	15	
Did the rep suggest you participate in a study?		—	—	—	—	—	—	4	1	2	1	0	1	1	1
Your global score for the rep's performance (in cm, on a 10-cm scale)		—	—	—	—	—	—	—	3.7/10	3.6/10	2.8/10	3.2/10	3.4/10	3.5/10	3.3/10

a- All results, except for global score in last line of table, are expressed in percentage.

SOLIDARITY SUBSCRIPTION RATES



Solidarity Subscription Rates for *Prescrire International* are available for health professionals and NGOs working in low income countries (GNP lower than 10,000 USD).

► There is little point in prolonging the activity of *Prescrire*'s reps monitoring network, at least in its present form. Other research and actions are now needed, focusing on other promotional tools used by companies that market healthcare products to influence the medical profession and the public. One project currently underway is specific to France: a subscriber network to monitor the application of the Medical Sales Charter.

What this story shows is that prescribers can refuse to see sales reps without jeopardising the quality of their work, and that they can use the time thus spared to consult reliable sources of information.

©Review prepared and translated by the Prescrire Editorial Staff

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