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«Good Morning Mr. Drug Industry Representative, What's New?» Analysis of Drugs Presented by the Pharmaceutical Industry in a Basic Health Area

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Objective. To study whether the visits of technical health representatives (ITS) mean that new drugs are introduced.
Design. Prospective, descriptive study.
Setting. Urban health centre.
Participants. The products presented by 137 ITS from 83 drug laboratories in weekly sessions for a year were studied.
Main measurements. The products presented, the year they were first marketed, intrinsic value (IV), newness and use potential, cost per package and defined daily dose and material handed over were studied.
Results. 472 drug products were introduced. The most common ones belonged to the cardiovascular group (27.3%), digestion and metabolism (14.8%) and anti-infection drugs (13.3%). 65.5% had been on the market for <5 years. 84.3% had a high IV. Only 31 products (6.6%) were new (95% CI, 4.5-9.2). 71% of these supposed no or very slight therapeutic improvement, 25.8% a modest improvement and 3.2% a major improvement. Mean cost was 19.3 euros per package and 2 euros per DDD, with significant differences found (*P*<.006) on stratifying by date of marketing (more recently marketed products cost more). 61% of the products were presented with additional material (leaflets, monographs, journals), 21.6% with gifts of symbolic value, and 19.9% with samples of the product. There were significant differences (*P*<.03) between the new drugs and the normal prescriptions issued at the centre. In the new drugs, there were fewer products with high IV and cost per package and per DDD was higher.
Conclusions. The products introduced by the reps do not include any important new drugs. They are presented with abundant back-up and are more expensive than those normally prescribed.

Key words: Primary care. Pharmaceutical industry. Drugs treatment.

BUENOS DÍAS, SEÑOR VISITADOR. ¿ALGO NUEVO QUE CONTAR? ANÁLISIS DE LAS ESPECIALIDADES FARMACOLÓGICAS PRESENTADAS POR LA INDUSTRIA FARMACÉUTICA EN UN ÁREA BÁSICA DE SALUD

Objetivo. Estudiar si las visitas de los informadores técnicos sanitarios (ITS) suponen la presentación de novedades farmacológicas.
Diseño. Estudio descriptivo, prospectivo.
Emplazamiento. Centro de salud urbano.
Participantes. Se estudiaron los productos presentados por 137 ITS de 83 laboratorios mediante sesiones semanales durante un año.
Mediciones principales. Se estudiaron los productos presentados, el año de comercialización, el valor intrínseco (VI), la novedad y el potencial de uso, el coste por envase y dosis diaria definida (DDD) y el material entregado. Dichos productos se compararon con una muestra aleatoria de la prescripción anual del centro.
Resultados. Se presentaron 472 productos farmacéuticos. Los más frecuentes fueron de los grupos siguientes: cardiovascular (27,3%), digestivo y metabolismo (14,8%) y antiinfecciosos (13,3%). El 65,5% llevaba comercializado menos de 5 años. El 84,3% tenía un VI elevado. Solamente 31 productos (6,6%) eran novedades (intervalo de confianza [IC] del 95%, 4,5-9,2). De ellos, el 71% supuso una nula o muy pequeña mejora terapéutica, el 25,8% una modesta mejora y el 3,2% una importante mejora. El coste medio fue de 19,3 euros por envase y de 2,0 euros por DDD, con diferencias significativas (p < 0,006) al estratificar por la fecha de comercialización (coste superior en los productos más recientemente comercializados). El 61% de los productos se presentó con material adicional (folletos, monografías, revistas, libros), el 21,6%, con regalos de valor simbólico, y el 19,9%, con muestras del producto. Se observaron diferencias significativas (p < 0,03) respecto a la prescripción habitual del centro: proporción inferior de productos con VI elevado y coste superior por envase y por DDD.
Conclusiones. Los productos presentados por los ITS no suponen novedades importantes, se presentan con abundante soporte y son más caros que los prescritos habitualmente.

Palabras clave: Atención primaria. Industria farmacéutica. Tratamiento farmacológico.

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A commentary follow this article (pág. 562)

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Introduction

Prescribing medications is unquestionably one of the most relevant aspects of medical practice. For primary care physicians, this is a particularly important activity, as it is generally the family physician who writes the most prescriptions.

The pharmaceutical industry obviously tries to influence prescribing practices. Among the mechanisms used most commonly is advertising in medical journals, to the extent that almost 40% of the pages of a number of journals consist of advertising.[1] Direct marketing by medical representatives, also known as drug industry sales representatives, is another frequently used mechanism. Although no information is available on spending by the pharmaceutical industry on advertising, staff costs and out-sourcing[2] accounted for 42.5% of all operating costs in Spain in 1998.

The main job of these representatives is to sell new pharmacological products marketed by the pharmaceutical industry.[3] Others have drawn attention to the large amount of time (and hence money and resources) primary care physicians spend listening to drug sales presentations. One editorial went so far as to estimate the cost of this time in monetary terms.[4] Nevertheless, this editorial makes only passing mention of the time and expense primary care physicians devote in Spain to drug industry sales representatives.[4] One talk given at a congress[5] centered on medications publicized by direct advertising by the industry. However, neither of these sources[4,5] investigated whether visits by sales representatives fulfilled their main function, i.e., to describe new pharmacological products to doctors.

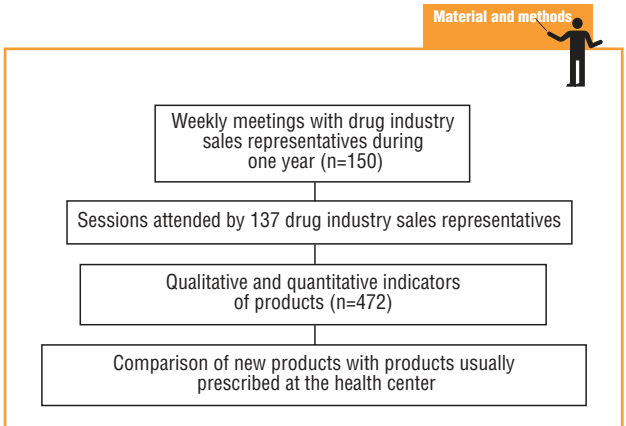
The main objective of the present study was to determine whether visits by drug industry sales representatives served to describe novel pharmacological products to primary care physicians, and whether these products offered any actual therapeutic improvement. An additional aim was to investigate qualitative and quantitative indicators of the products described by drug representatives, and the manner in which they presented the products. A final aim was to investigate whether the products described by these representatives differed from those habitually prescribed by physicians at our center.

Material and methods

During a 13-month period from May 1998 to May 1999 we collected data from group meetings with drug industry sales representatives held at an urban health center serving a basic health area and accredited for training activities. At the time the study was begun, a total of 34 878 medical records were held at the center. All presentations were given in a single weekly session held on a weekday (Friday) from 2:00 PM to 3:00 PM. A maximum of 7 industry representatives made presentations during each session. All representatives had registered previously for a scheduled appointment, and all were drawn from a list of 150 representatives assigned to our basic health area, provided by the Professional Association of Drug Industry Sales Representatives. All variables were recorded with a specially designed, standardized form. The unit of analysis was the representative, and information was recorded only for the first visit made by each representative at our center. This was because our aim was to investigate whether the initial visit by a new representative was used to present new drugs for primary care physicians. The following variables were recorded:

1. Given name and surnames of the representative, and name of the pharmaceutical firm represented.
2. Pharmaceutical products presented, anatomical therapeutic chemical (ATC) code[6] and years on the market.
3. Intrinsic value of the product, as stated on the lists of prescription medications authorized by the Catalonian Health Service.
4. Evaluation of the novelty of the product in four categories: product presented previously, new active principle, new indication, or new route of administration. We also examined its therapeutic usefulness according to the classification of the *Boletín de Información Terapéutica del Sistema Nacional de Salud*:[7] group A (substantial therapeutic improvement), group B (some therapeutic improvement) or group C (little or no therapeutic improvement).
5. Cost per unit and per defined daily dose (DDD) according to the ATC Classification Index of the World Heath Organization.[6]
6. Material provided by the representative: pamphlets, monographs, journals or journal reprints, books, small gifts (pens, calendars, notepads, adhesive notes, etc.) and product samples.

To compare the products described by the industry representative with products habitually prescribed by the physicians at the health center, we selected a random sample of the same number products from the list all products prescribed during the study period by physicians at the health center, and compared intrinsic value, cost per unit and cost per DDD.



General scheme of the study

Prospective, descriptive study of the products presented by drug industry sales representatives during their visits to a health center during a 1-year period.

Statistical analyses were done with SPSS software. Mean values were compared with Student's *t* test and analysis of variance, and proportions were compared with the χ^2 test. In all cases an alpha value of 0.05 was used.

Results

A total of 44 sessions with drug industry sales representatives were held at our center during the study period. Data were obtained for 308 presentations by 137 different representatives (91.3% of all industry representatives listed in the Professional Association of Drug Industry Sales Representatives directory for Barcelona), who represented 83 different pharmaceutical firms.

We studied a total of 472 pharmaceutical products. The representatives described a mean of 3.1 products during each visit (SD, 1.6; range, 1-7 products). Distribution according to ATC classification is shown in Table 1. 66 products (14%) had been on the market for less than 1 year, 138 (29.2%) had been available for 1 to 3 years, 105 (22.3%) for 3 to 5 years, and 163 (34.5%) for more than 5 years. Intrinsic value was high for 398 products (84.3%).

Table 2 shows that most products had been described in earlier presentations (93.4%). In fact, only 5.1% of the presentations were for new medications, and 1.5% were for new indications or new routes of administration. In other words, only 31 products (6.6%; 95% CI, 4.5-9.2) were novel. Their therapeutic usefulness was classified as group C (little or no therapeutic improvement in 22 medications (71%), group B (some therapeutic improvement) in 8 (25.8%), and group A (substantial therapeutic improvement) in 1 (3.2%). Four of the 31 novel medications (Table 2) were subsequently withdrawn because of severe side effects.

Mean cost per unit was 19.3 euros (SD 24.6 euros). Mean cost per DDD was 2.0 euros (SD 4.2 euros). Both cost per package and cost per DDD differed significantly (P<.006) when we stratified the products by date of appearance on the market: medications marketed more recently were more expensive both per package and per DDD (Table 3).

As shown in Table 4, supporting materials were used in the presentations of most of the products. Only 48 products (10.2%) were presented with no additional marketing aids.

Comparisons with habitual prescribing practices at our health center (Table 5) showed significant differences (P<.03) in the proportion of products with a high IV (the proportion was lower among products presented by drug industry representatives), cost per unit and cost per DDD (new products presented were more expensive).

TABLE 1 Number and percentage of pharmaceutical products described by drug industry sales representatives according to ATC classification

ATC group	No. (%)
A: Alimentary tract and metabolism	70 (14.8)
B: Blood and body fluids	11 (2.3)
C: Cardiovascular	129 (27.3)
D: Dermatological	31 (6.6)
G: Genitourinary and sex hormones	8 (1.7)
H: Systemic hormones	5 (1.1)
J: Anti-infectives	63 (13.3)
L: Antineoplastics	0 (0)
M: Musculoskeletal	40 (8.5)
N: Nervous system	50 (10.6)
P: Antiparasitics	2 (0.4)
R: Respiratory system	56 (11.9)
S: Sensory organs	7 (1.5)
V: Other	0 (0)

TABLE 2 New pharmacological products described by drug industry sales representatives

	N (%)
New active principle[a]	24 (5.1)
New indication	1 (0.2)
New route of administration	6 (1.3)
Previously described medications	441 (93.4)

[a]Four were subsequently withdrawn because of severe side effects: cerivastatin, grepafloxacin, trovafloxacin and tolcapone.

TABLE 3 Cost per unit and per defined daily dose (DDD) of the pharmaceutical products in the present study, according to year of appearance on the market

	Cost per unit in euros[a]	Cost per DDD in euros[a]
Less than 1 years (n=66)	27.6	3.6
1-3 years (n=138)	25.1	2.8
3-5 years (n=105)	18.6	1.3
More than 5 years (n=163)	11.4	1.0

[a]P<.006 (analysis of variance).

Discussion

The results of the present study show that visits from drug industry sales representatives are made essentially for the purpose of promoting products that had already been presented previously. On a very few occasions, novel pharmaceutical products were presented—the main reason why physicians attend such talks.[3] The few new products described do not often provide relevant therapeutic advances. Products presented shortly before, which are already on the market, are described with the aid of generous supporting materials but are backed by little scientific evidence, and are more expensive than the prod-

TABLE 4 **Additional material provided by drug industry sales representatives during product presentations**

	N (%)
Pamphlets	288 (61%)
Monographs	9 (1.9%)
Journal articles or similar	50 (10.6%)
Journal with IF	25(5.3%)
Journal with no IF	12 (2.5%)
Advertisements/Sponsored symposia	13 (2.8%)
Books	29 (6.1%)
Small gifts	102 (21.6%)
Product samples	94 (19.9%)

TABLE 5 **Comparación de los productos presentados por los ITS con una muestra aleatoria de la prescripción del centro**

	Described by representatives (N=472)	Prescribed at the center (N=472)
Products of high IV[a] (n and %)*	398 (84.3)	422 (89.4)
Cost per unit in euros*	19.3	10.5
Cost per DDD[b] in euros*	2.0	0.7

[a]Intrinsic value. [b]Defined daily dose.
*P<.03.

ucts habitually prescribed by physicians in our basic health area.

This study has certain limitations. Not all requests for an appointment from representatives were honored, and the proportion of representatives who missed their appointment was small. Some representatives, however, may have arrived for their presentation at a time or on a date other than the time allotted for them, and the behavior of some representatives may have been different when they spoke individually with physicians at the center.

To our knowledge no similar studies in Spain have been published, although the drug industry sales representative phenomenon has generated a number of editorials and commentaries.[3,4,8-10] In fact, only one editorial[4] discussed the costs (in terms of time and other expenses) incurred by drug representatives' visits at a health center, and gave some significant figures: 104 hours per physician per year, at a cost of 475 000 Spanish pesetas (2854.1 euros) per year. At our health center the total number of hours per year was lower, possibly because of the different organizational model for arranging and scheduling these visits. Biurrun et al[5] studied quantitative and qualitative indicators of the products presented by industry representatives during a 3-month period, with results similar to ours. Specifically, the proportion of products with a high IV was 81.1%; the most frequent ATC groups were cardiovascular, anti-infectives, and alimentary tract and metabolism; and the most recently marketed drugs were also the most expensive.[5] The cost per DDD was lower (215.4 pesetas, or 1.3 euros), given that their study was done in 1994.[5]

The substantial amounts of time primary care physicians invest in talking to industry representatives does not seem reasonable, given that during the study period they obtained information on only 31 novel products, most of which are of little relevance. Most of the novel medications were «me-too» drugs, and 4 new products were later withdrawn because of severe side effects. Some of the time might be better spent reading current publications that provide objective information for free, such as the *Boletín de Información Terapéutica del Sistema Nacional de Salud* (Bulletin of Therapeutic Information of the National Health System, prepared by the Spanish Ministry of Health).[7]

A further notable finding is that the medications presented by the pharmaceutical industry are much more expensive than those prescribed habitually. Overall, the cost per DDD (Table 5) was nearly 3-fold as high. These new drugs usually provide no additional benefits in comparison to cheaper drugs already on the market. In this connection, current Spanish legislation facilitates marketing practices by the pharmaceutical industry, a phenomenon that may contribute to the increasing costs of pharmaceutical products provided through the national health system.

It would be unrealistic to assume that repeated presentations with abundant supporting material are not accompanied by increased prescribing of these products. The enormous investments[2] in advertising by the pharmaceutical industry aim to convince physicians to prescribe their products[9] and thus to increase profits. This legitimate goal is clearly being achieved, as shown by the fact that despite their huge investments in advertising, pharmaceutical firms are most profitable in countries such as the USA.[11] Similarly, it would be ingenuous to assume that the gifts offered to physicians (although of little monetary value), sponsorship of training activities, and free meals represent acts of altruism by industry representatives.[9] The clearest proof of this is that the pharmaceutical industry forbids its own employees from receiving gifts from suppliers or clients.[12] It has been shown that industry sponsorship of activities such as congress organization is accompanied by changes in physicians' prescribing practices.[13] Even accepting small gifts, which doctors believe will not modify their prescribing practices, is accompanied by changes in clinical judgment, and therefore creates a conflict of interest.[14]

In light of these developments, we should not be surprised that the Spanish Ministry of Health and Consumer Affairs as well as autonomous regional health administrations have attempted to regulate drug industry sales representatives' visits through guidelines emanating from the central government *(Reales Decretos)* and internal circulars. The Barcelona College of Physicians[3] recently took a

Discussion
Key points

What is known about the subjec

- The main function of drug industry sales representative visits is to present novel pharmacological products.
- Visits by drug industry sales representatives consume large amounts of the family physician's time.
- The pharmaceutical industry invests considerable resources in promoting their products.

What this study contributes

- Visits by drug industry sales representatives do not provide family physicians with information on new pharmacological products, and the novel products presented are of little therapeutic relevance.
- Large amounts of supporting material used during the visits are aimed basically at presenting recently marketed drugs.
- The products presented are much more expensive than those habitually prescribed by family physicians.

stand regarding the relationships between physicians and the pharmaceutical industry, although the guidelines this organ developed are less stringent than those of the American College of Physicians (ACP).[13] In general, there is a consensus, shared by the national health administration and professional associations, that industry representatives' visits should be regulated, scheduled in advance, and limited in duration to a reasonable time.

The conclusion to be drawn from the present study is that visits from drug industry representatives do not provide physicians with relevant information regarding new drugs. It is therefore difficult to justify the large investments in time and money devoted to sessions with drug sales representatives. As other authors have appropriately observed,[4,8,9] the model of industry relationships needs to be changed. Physicians should cease to be passive receptors of an enormous flow of information, most of little relevance, and adopt a role informed by users' needs and efficient pharmacological alternatives. These considerations have led to the proposal to move from an individual model toward a group model based on scientific information and training needs.[8]

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COMMENTARY

The Regulation of Medical Visits: Necessary but Insufficient

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The journal Farmaindustria[1] published a survey of 359 physicians in the Autonomous Community of Madrid (70.5% in primary care) on drug industry representatives' site visits to medical practices. The results show that 81% of the physicians felt these visits to be worthwhile, and that the element they valued most highly was the information provided. Most of those surveyed (97.5%) felt that these encounters should be used to present new therapeutic products. Curiously, when they were questioned about the industry representative´s appearance and manner, the features participants appreciated most highly were physical appearance, ability to establish rapport, and communication skills—which were valued more highly than scientific and technical knowledge, rigor, quality and content of the supporting materials, or scientific expertise.

These rather self-congratulatory results notwithstanding, visits from pharmaceutical industry representatives, and in general all relationships between physicians and the pharmaceutical industry, are currently under debate in Spain and in other countries.[2,3] Many believe that patients would benefit if the relationship between prescribers and industry were characterized by a greater degree of detachment.[2]

Current Spanish legislation, as set forth in Real Decreto 1416/94 on advertising for medications for use in humans, define visits by medical representatives in the following terms: «*The visit to a physician by a medical representative is the medium by which a relationship is established between pharmaceutical firms and persons authorized to write prescriptions or dispense drugs, with the aim of informing about and promoting drugs; [the visit is] made by the medical representative, and is based on the communication of appropriate technical information to permit an objective evaluation of the drug's therapeutic usefulness. In due performance of his or her functions the medical representative should promote the appropriate use of drugs.*»

Clearly, visits by medical representatives fulfill the goal of promoting drugs, but what is less clear is whether they fulfill the second part of this description. Are these visits built on the communication of technical knowledge? Is the information objective? Is the information useful to prescribers or practitioners who dispense drugs? Do these visits promote the appropriate use of drugs?

Key points

- Relationships with the pharmaceutical industry should be clear and transparent to avoid damaging the relationship of trust between physicians and patients.
- The nature of promotional visits by pharmaceutical industry representatives needs to be reformed to dignify the role of all parties involved, and to fulfill the basically information-providing mission of these encounters.
- Greater access should be available to research and educational activities that are not underwritten by the drug industry.

The results of the study titled «Good morning Mr. Medical Representative, What's New?» Analysis of Drugs Presented by the Pharmaceutical Industry in a Basic Health Area suggest that these expectations are not being met. Only 6.6% of the products presented were novel, and of these, 71% were considered to provide little or no therapeutic improvement. Moreover, the authors offer another figure that should be cause for reflection: of all products presented, the percentage with high intrinsic pharmacological value was small, and the new products were significantly more expensive than those habitually prescribed at the center.

Another issue to consider, although it was not specifically investigated in this study, is the influence visits by medical representatives can have on prescribing, and hence on the use of medications by patients. One recent study[4] found a significant relationship between physicians who had closer contacts with drug industry representatives and a greater willingness to prescribe new drugs, and to yield to patients' unjustified requests for prescriptions. According to the study just published in ATENCIÓN PRIMARIA, it appears

that the information provided during the visits is not useful to physicians in enhancing the appropriate use of drugs.

Another point the study raises and that merits attention is the manner in which visits by medical representatives are organized at the health center. The customary face-to-face encounter (known to be the most effective way to modify prescribing habits) has been replaced with group sessions, to make the encounter more «professional» and less mercantile. Group sessions undoubtedly serve to restrain and filter out certain types of «special treatment» toward the client. These behaviors are a reflection of certain ethical connotations together with the serious problem of pharmaceutical costs. In an earlier editorial published in ATENCIÓN PRIMARIA, Altisent[5] noted that the main problem does not lie with immoral behavior, which occurs in only rare cases, but rather with the confusing environment we are immersed in, and which can undermine relationships of loyalty and trust between physicians and their patients. Headlines in the daily newspapers that read «Pharmaceutical industry to limit gifts to doctors» (*El Periódico de Catalunya,* July 22, 2003), published after the new code of good professional practice for the pharmaceutical industry was announced, do not inspire trust in the physician-patient relationship.

Because of ethical considerations, visits by medical representatives should be modified to dignify the role of all parties involved, and to improve upon other aspects such as the undue time they take up, and patients' negative perception of these visits. Farmaindustria shares these concerns and has called for these visits to be reorganized in a way that will integrate them into the health care activities of health professionals. Moreover, this group is committed to guaranteeing, on a permanent basis, the quality of these visits as educational opportunities.[6]

In response to this situation, health authorities have published new regional regulations that include detailed procedures regarding how, where and when medical representatives should meet with doctors, the responsibilities and rights of medical representatives and doctors, and how compliance with regulations should be monitored. However, regulations, codes of conduct, and other guidelines will be futile unless there are changes in certain circumstances that lead inevitably to situations which are often undesired by both parties involved.

The omnipresence of the pharmaceutical industry at scientific congresses, in continuing professional education, in research, in science journals and in scientific societies indicates that something is amiss.[3] Health professionals believe that their integrity is immune to the overtures of the pharmaceutical industry, and often justify their relations with industry by citing their educational needs. Administrators, while concerned about the cost of medicines, tolerate these relations to compensate for perpetual budgetary shortages. There is always a pretext to be found to justify the relationship, and this situation makes it difficult to remain free from bias.

Visits by medical representatives need not have negative connotations, but to avoid these connotations, they should fulfill their basic function as opportunities to provide information. The relations between medical representatives and physicians should be clear and transparent, and each party should accept due responsibility for bringing about change.

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