



BeMSA
Belgian Medical Students' Association

Medicine and the Involvement of the Pharmaceutical Industry

Policy document

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Publisher

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About BeMSA

The Belgian Medical Students' Association (BeMSA) is a Belgian student-run organisation. As of the 2019-2020 academic year, it unites medical students from 9 faculties across the country, while also establishing international connections through the existing network of 133 national member organisations of the International Federation of Medical Students' Associations (IFMSA).

Each year, BeMSA organises a series of events on a local, national and international level. Additionally, our clinical and research exchange programs send over 100 Belgian students abroad every year, while accommodating the same number of foreign students. This allows them to explore innovations in medicine, healthcare systems and healthcare delivery in various settings across the globe.

BeMSA brings people together to exchange, discuss and initiate projects with the goal of creating a healthier world. It provides medical students with the skills and resources needed to be health leaders. With the help of the IFMSA, it also advocates for the pressing issues that matter to us to shape the world we want to live in. And it does deliver: our projects, our campaigns and our activities positively impact physicians-to be alongside the communities they serve.

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1 Policy Statement

1.1 Introduction

Health actors and the pharmaceutical industry have many objectives in common. Both of them aim for the correct use of existing drugs, are committed to research and the relationship between the two facilitates an efficient exchange of knowledge. Indeed, information about medical needs and potential therapeutic solutions is passed on to the pharmaceutical industry so that they can provide clinical research programmes, and in turn, the pharmaceutical industry offers solutions to healthcare practitioners. But despite the many common objectives, both parties have a completely different focus. While the health actors primarily focus on the patient, the pharmaceutical industry mainly needs to respond to financial imperatives. As a result, the interactions between the both parties are now questioned and ethical concerns are raised.

There are three main concerns that can be distinguished from each other. Firstly, there is a risk that drug promotion influences the health actors' decisions. And indeed, no less than 60% of the worldwide marketing budget is invested in drug advertisements. Even though most healthcare professionals are convinced that they are not influenced by drug promotion, results of review studies prove the opposite. Secondly, due to the difference in focus, there is a possibility that the interaction between the pharmaceutical firms and healthcare professionals gives prominence to the commercial part, while the quality of care to the patient and research is lost. The last main concern is that investing money by the pharmaceutical industry into research can lead to distortions in scientific evidence. About 70% of a research budget comes from pharmacy, which means that favorable results are important to them. [1]

1.2 BeMSA's position

As medical students and future healthcare professionals, the Belgian Medical Students' Association and its members believes that the quality of medical education and the safety of healthcare depend on their transparency. BeMSA regards the independence of future healthcare practitioners as a prerequisite for a good medical practice and stresses the importance of all stakeholders working together tackle the potential unhealthy relationship between the medical field and the pharmaceutical firms.

1.3 Call to action

The Belgian Medical Students' Association calls upon:

1. The Belgian Medical Student's Association's Local Committees to:
 - a. Respect the Ethical Framework on Fundraising adopted at the 3rd National General Assembly, in Jette 27/04/19 [2], when searching for a sponsorship for the Local Committee or any event or project;
 - b. Emphasise to local members the need for caution when applying for any sponsorship by the pharmaceutical and medical devices' industries and its potential harms;
 - c. Declare pharmaceutical and medical devices' industry sponsorships to the Vice-President for Finance, Executive Board and Supervising council, as

- mentioned in the Ethical Framework on Fundraising, when the sponsorship appears to be a voluntary gift;
- d. Promote peer-to-peer educational training(s) focused on:
 - i. Conflicts of interest
 - ii. Scientific integrity and publication bias
 - iii. Seeding trials in research;
2. Belgian organisations involving medical students to:
 - a. Implement an ethical framework in their own organisational committees taking into consideration the potential harm of the involvement of pharmaceutical companies;
 - b. Jointly advocate for a medical curriculum that is free from pharmaceutical involvement and that prepares students to interact with the industry while preserving their independence, such as the model proposed by the American Medical Students' Association [3].
 - c. Refuse any sponsorship that could potentially bias the medical students, more specifically from pharmaceutical companies, that could potentially bias the medical students by explicitly and/or implicitly promoting themselves;
 - d. Advocate within the Belgian medical faculties regarding the importance of transparency and accountability of any sponsorship driven by pharmaceutical research and the potential bias formed by them;
 3. Belgian medical faculties and university hospitals to:
 - a. Educate medical students and doctors about conflicts of interest that may arise when working together with pharmaceutical companies;
 - b. Ban any negative pharmaceutical influence and/or mispractice from the curriculum, such as the use of brand names in lectures, textbooks and audiovisual materials when it has no educational benefit, or the use of educational materials delivered by pharmaceutical firms;
 - c. Implement transparency in their annual budget regarding any sponsorship by pharmaceutical and medical devices companies;
 - d. Condemn seeding trials and other practices that could lead to publication and prescription bias in preclinical and clinical research;
 4. Representative groups of healthcare professionals to:
 - a. Recommend the use of International Non-proprietary Names (INN) throughout their networks;
 - b. Promote guidelines on the correct way to inform oneself about the influence of pharmaceutical advertisement;
 5. Healthcare professionals to
 - a. Implement the use of INN names instead of brand names in their daily practice;
 - b. Analyse in a meditated and critical way any information provided by sales representatives from pharmaceutical companies;
 - c. Avoid sponsorships by pharmaceutical and medical device companies at staff meetings and medical congresses.

- d. Inform themselves and be aware of the possible influence of receiving samples from sales representatives, as well as the possible influence on patients when distributing them.
6. Pharmaceutical industries to:
 - a. Refrain from using practices such as seeding trials or any practices that induce biases in clinical trials;
 - b. Indicate clearly on any content that is published or provided to medical practitioners whether it is sponsored and declare any possible conflicts of interest;
 - c. Respect WHO's Ethical Criteria for Medicinal Drug Promotion (1988) [4] when advertising for their products;
 7. Medical journals to:
 - a. Respect WHO's Ethical Criteria for Medicinal Drug Promotion (1988) [4] when including drugs or medical devices' advertisements in their issues;
 - b. Refrain from publishing content that is sponsored by pharmaceutical and medical devices' companies or, if they do, indicate clearly when this is the case;
 8. The Federal, Flemish, Brussels-Capital and Walloon Government to:
 - a. Strictly enforce the Royal Decree (NL: "Koninklijk Besluit", FR: "Arrêté Royal") of 7th of April 1995, that condemns any influence of pharmaceutical and medical device industry including but not limited to gifts and public commercials towards medical doctors and public;
 - b. Support transparency models in Medical Faculties and University Hospitals regarding the collaboration with pharmaceutical and medical devices' industry.

2 Position paper

2.1 Background

It is not uncommon for physicians to receive gifts from the pharmaceutical industry to promote their products in return. Although a good relationship between them both already led to progress in healthcare, the pharmaceutical firms' generosity towards physicians is controversial [5].

Despite existing international initiatives [6], that will be discussed later on, the motivation in controlling the pharmaceutical industry in Belgium remains scarce. An urgent need to implement strict policies keeps existing. A first step in tackling the issue of concern could be an educational program to raise awareness.

2.2 Discussion

2.2.1 *Types of strategies used by pharmaceutical companies*

Pharmaceutical firms have a dual objective, that of providing medicines and medical devices to the population as well as an economical objective. Therefore, they use a set of marketing techniques to increase their sales, which affect the healthcare practitioner.

The techniques used by the pharmaceutical industry to promote their drugs include but are not limited to relationship-based selling, product information and awareness building as well as the use of media [7, 8].

2.2.1.1 Relationship-based selling

As relationship-based methods, we find the employment of sales representatives and the offering of gifts. This could potentially lead to a conflict of interest. A conflict of interest is defined by JAMA Network as:

“Conflict of interest describes a situation in which a person is or appears to be at risk of acting in a biased way because of personal interests.” [9]

The sales representatives' role is to establish a long-lasting relationship with the medical practitioner, through visits, presence at conferences and so on. These interactions begin in the first year of medical school and increase thereafter. Indeed, the proportion of students in direct contact with the sales representatives rises from 21% in the first year to 77% in the last year [10]. The issue being that many medical practitioners, lacking time to do proper research, rely on sales representatives to obtain recent therapeutical information [8]. This information has been shown to be incomplete and biased in a way that benefits the marketed product [11]. The gift-giving begins very early in the training of medical students, with meals, sponsored lectures and other resources. The smaller and more indirect the gift, the more the doctor feels like it cannot influence his practice. However, it has been shown that all gifts create a feeling of obligation, which negatively influences prescribing practices [12].

2.2.1.2 Product information and awareness building

Amongst product awareness and the information of healthcare professionals on their benefits, some methods used by pharmaceutical companies are to provide practitioners with clinical guidelines and samples, and students with free textbooks [8, 13]. These clinical guidelines and textbooks, however practical they can be for a time-effective diagnosis and treatment or to save time when studying, can often present conflicts of interest amongst sponsors and authors and should rather be seen as a marketing tool as they are a dangerous source of information, although routinely considered as the most legitimate source of authority in medical knowledge [14]. The use of samples, on the pharmaceutical firms' side, allows for a higher awareness of available brands and initiates their use. On the doctors' and patients' side, although the initial goal is to reduce the cost of access to medicines, it actually increases prescription costs [12], as it increases the number of repeat users of more expensive medicines. A study has shown that resident physicians who received free samples were more likely to prescribe heavily advertised and more expensive medicines than their peers who did not [15].

In addition, the information that sales representatives provide when coming to a doctor's practice, a pharmacy or any other healthcare related setting, although they may seem evidence-based, can sometimes be the results of what is called seeding trials. Seeding trials are clinical trials that are used to promote an experimental drug in order to support the available information and to change the opinion of decision makers. They are also executed in the hope that the subjects who took part in the study will continue using said drug after the clinical trial, even if it has proven that the medicine does not have any added value [16].

To recognise a seeding trial, the criteria provided by Kessler et al and Sox and Rennie can be used, for more information see reference [17].

2.2.1.3 Use of media

The media that pharmaceutical firms use to reach patients and doctors are mainly medical journals and websites, but also direct-to-consumer advertising.

2.2.1.3.1 Medical literature

Companies can include content in peer-reviewed literature through several paths. The first is advertisement. Indeed, journals rely on advertising and sponsored contents as part of their incomes. However, these advertisements can contain misleading claims and incomplete information [18]. Furthermore, sponsored contents can be biased in the sponsor's interest, which can be especially harmful if it is not clearly indicated that the content is sponsored, as the reader will accept the information more easily if they believe that it is independent. If an advertisement is included in journal, it should contain the information listed by WHO's Ethical Criteria for Medicinal Drug Promotion (1988), i.e. : "Name(s) of the active ingredient(s), using either international nonproprietary names (INN) or the approved generic name of the drug", "Brand name", "Content of active ingredient(s) per dosage form or regimen", "Name of other ingredients known to cause problems"; "Approved therapeutic uses"; "Dosage form or regimen", "Side-effects and major adverse drug reactions", "Precautions, contra-indications and warnings", "Major interactions", "Name and address of manufacturer or distributor" and "Reference to scientific literature, as appropriate" [4].

Another path is to use ghost writing and guest authorship. Renowned researchers and clinicians, called key opinion leaders, are recruited to co-author papers to give them more credibility and mask their commercial function. Ghostwriting is the process of writing an article in the name of a key opinion leader; the actual author is not mentioned, or downplayed to a contributor [19–21]. This activity is not rare, as a survey has shown that in 6 leading general medical journals, 21% of research papers were ghostwritten [22].

2.2.1.3.2 Direct-to-consumer advertising

Direct-to-consumer advertising is forbidden in the European Union for prescription medicine. However, pharmaceutical firms are allowed to provide the public with information on diseases and health, as long as no direct or indirect mention of a pharmaceutical product is made. Nonetheless, concern has been raised regarding the purpose and the quality of these advertisements. Research has shown that these campaigns do not always comply with regulatory guidelines and use promotional information (31%), fear (12%), inadequate language (6%) and testimonials (12%). They can also contain misleading or incomplete information (31%), lack balance (73%) and not indicate authors or sponsors (50%) [23]. These campaigns can be correlated with an increase of prescription rates for drugs marketed by the campaign's sponsor, even if the drug is not explicitly mentioned [24].

Finally, even when they are well aware of all these risks, people, and therefore also doctors, have an illusion of unique invulnerability. It is defined in psychology as "the expectation that others will be the victim of misfortune and negative events more so than oneself" [25]. It means that doctors think that their colleagues are more likely to be influenced by pharmaceutical promotion than they are. This phenomenon has been shown to actually increase vulnerability [26].

In order to protect the consumer, commercials of medications are strictly regulated with the objective of having complete and correct information. This regulation is based on the European regulations of 2001/83/EG of the European Parliament and the European council of 6th of November 2001.

In the Belgian law, this regulation is reflected on the law of 25th of March 1964 and the Royal Decree (NL: “Koninklijk Besluit”, FR: “Arrêté Royal”) of the 7th of April of 1995. In summary, this law regulates and limits the content of the commercials of medication towards healthcare specialists and consumers.

It is important to mention that the Belgian law defines commercials of medications as any form of marketing or stimulation that will increase the prescription, delivery, giving, selling or use of the concerning medication. However, the “commercial of the medications” does not include:

- I. Leaflets and labels
- II. Letters with the intention of documentation and asked about a specific information.
- III. Warning and changes in the packaging, if there is no information of the medication
- IV. Information about health or human or animal diseases, if no direct or indirect reference to medications is made

The regulation towards commercials are, for example:

- I. Commercials towards public are prohibited if the concerning medication:
 - II. Needs a prescription
 - III. Is used to treat a disease
 - IV. Is a psychotropes
 - V. Is an anaesthetic

Furthermore, before any commercial for medications is send out through radio, television or telephone, it will be controlled beforehand by the “Commission for Commercials of Medications”.

2.2.2 Consequences of pharmaceutical strategies

2.2.2.1 Consequences on the medical curriculum

During the medical curriculum, students are bound to come across the pharmaceutical industry on several levels, e.g. through sales representatives. It has been shown in a US survey that 93% of respondent medical students had been asked or required to join a pharmaceutical or health products sponsored lunch. These interactions are likely to influence their education and lead to a potential conflict of interest, especially when students lack training on how to handle these interactions [27]. Indeed, they have been shown to increase students' positive attitudes about marketing as well as their skepticism about negative implications of these interactions. One possible explanation is that the medical students, being at the bottom of the clinical hierarchy, look to the supervisors as role models [28]. Inversely, implementing conflict of interest policies in medical faculties has been shown to positively influence the prescribing behaviour of future physicians. A practical implementation is seen in some Canadian medical schools, where students are taught how to process the information they get from industry representatives [29].

2.2.2.2 Consequences on medical doctors

A review by Fickweiler et al. [1] discussed how the interaction between a physician and a pharmaceutical sales representative influences prescribing behavior of the medical doctors.

Most physicians get a visit from one sales representative every month, with physicians who only started their careers receiving more visits than the more experienced ones. Furthermore, physicians are not necessarily against the pharmaceutical industry. Namely, they perceive it as an important source of education and funding, and do not believe their prescribing behavior is affected, while a study by Lieb et al. [30] proved the opposite. Moreover, physicians with a greater exposure prescribe a greater amount of more expensive medicines and adopt new medicines faster, including those without added therapeutic value [31].

Another source of influence on medical practitioners are key opinion leaders. They are influential doctors who are paid by pharmaceutical firms to give lectures and endorse their products, the aim being to use the key opinion leaders' reputation to increase sales. The fees can be up to \$3000 to give a scientific speech/lecture at educational events sponsored by the company, \$400/hr to give an influential advice and £200/hr to work for pharmaceutical companies on a clinical trial. These practices, especially when lacking transparency on the paid fees, are a great risk of conflicts of interest and should not be undertaken. [32]

2.2.3 Current initiatives

In order to control the influence of the pharmaceutical industry on physicians, some initiatives have already been taken. The World Health Organization (WHO) published their "WHO Ethical Criteria for Medicinal Drug Promotion" in 1998 [4]. Today, it remains a global standard for drug promotion since it still covers the major issues of concern. A manual, "Understanding and Responding to Pharmaceutical Promotion, A Practical Guide", was recently developed by the WHO and Health Action International [33]. Explanation is given there about what healthcare professionals have to know about pharmaceutical marketing.

Furthermore, most of the major pharmaceutical companies have their own code of ethics and national industry organisations in many countries have implemented codes of marketing practices and ethics as well. The European Federation of Pharmaceutical Industries and Associations (EFPIA) of the European Union, for example, adopted their Code of Practice and Relationships in 2007, with amendments in 2011 and 2013 [34]. The EFPIA is the representative body of the pharmaceutical industry in Europe. The Code of Practice and Relationships was established to ensure that the relationship between the pharmaceutical industry and patient organisations take place in an ethical and transparent manner. The Code advocates that the objectives of any partnership shall be transparent and that the pharmaceutical industry shall never request to promote a particular medicine.

The Health Action International association developed international webinars about how to understand the strategies of pharmaceutical industries, which can be found online. [35]

The International Federation of Medical Students' Associations (IFMSA) and the European Medical Students' Association (EMSA) have adopted policies on transparency and conflicts of interest in medical education, and more specifically on the influence of the pharmaceutical industry on healthcare and research [8, 36]. Additionally, medical students' associations worldwide have taken action to limit the influence of the pharmaceutical industry in their medical curriculum: the American Medical students' Association (AMSA) has published scorecards to rank american medical schools according to conflict-of-interest policies [37] ; IFMSA-Spain's project Farmacriticxs is a student-led platform that comprises local, national and online actions to raise awareness and promote transparency in relation with the pharmaceutical industry [38] ; in Germany, the UAEM (Universities Allied for Essential

Medicines), a global network of students, and the German medical students' association BVMD (BundesVertretung der Medizinstudierenden in Deutschland) have published a ranking of German medical faculties [39].

Moreover, during the National Congress of Medicine and Odontology Schools of November 2017, in France, the French Ethical charter of the Deans was adopted: "Marketing representatives of the pharmaceutical and health products (in the broadest sense) are not allowed to meet university staff in the care zones or in the presence of students. Derogatory authorizations may be issued to non-commercial purposes where only the manufacturer has the necessary knowledge (example of training on devices or specific equipment" [40]. It followed the publication of a scorecard of French medical faculties according to their conflicts of interest policies, which was updated in 2018 [41].

In Belgium, several initiatives have been taken to improve transparency in medical education and medical practice.

The GRAS, "Groupe de Recherche et d'Action pour la Santé", is an independent, self-funded group of doctors and pharmacists who advocate for the right use of drugs and provide a critical insight on advertisements and publications. They are a part of the "All trials" campaign towards the publication of all clinical trials and are a member of the "International Society of Drug Bulletins", a network of journals and actors on drug therapies who are independent from the pharmaceutical industry [42].

The non-profit-making organisation Farmaka, in collaboration with the Belgian Centre for Pharmacotherapeutic Information (CBIP/BCFI), publish transparency sheets and update them yearly. They are a summary of data describing the best drug therapy as well as non-medicinal management paths for common diseases according to benefits, risks and costs, comparing different drugs and placebos. They use independent sources of information, like the Cochrane library and affiliates of the International Society of Drug Bulletins [43].

Furthermore, the Belgian Medical Students' Association (BeMSA), as a network for medical students from all over Belgium, implemented an internal ethical framework for sponsorships [2].

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