Survey of Promotional Practices in the Philippine Pharmaceutical Industry

Compendium Edition

Contents:

INTRODUCTION

The study set out to investigate the methods and practices employed by the Pharmaceutical Industry to promote the use of its products and disseminate information to Physicians. It focused on Manpower promotion with a particular emphasis on the vulnerability of various tactics and modes of execution to improper behaviours and influences. The scope was confined to the marketing and promotion of ethical pharmaceuticals.

The intention was to provide a “slideshow” view by taking a series of the snapshots to establish the prevailing modes of brand promotion to the medical and related professions by conducting a series of interviews with stakeholders. About 6 to 8 weeks separated the three snapshots to allow for data review and such adjustments as may be necessary to obtain the desired information.

As will be seen in the “Methods” section he study was specifically designed to recognize new categories of promotional activity and features of the landscape not foreseen in the original Inception Report and incorporate these into the survey. This flexibility proved valuable and several new sections were added during the creation of slides two and three.

This Compendium Edition combines the findings from all three slides plus the Methods, Results and Recommendations from slide three and a short overview of the possible impact of promotion on irrational use of medicines.

Methods Used

The primary methodology employed has been the face to face interview as detailed in the original inception report. Written questionnaires were sent out on a test basis but the response rate was far too low for an effective study to be undertaken. Every effort has been made to include the views of as many varied stakeholders as possible however some sectors were more forthcoming than others and as a result the views of government may be slightly under- represented

No formal questionnaire was presented to the interviewees; they were encouraged to share as broadly as they were able without being constrained by a prepared format. This approach was felt to be the most appropriate since nobody was in possession of perfect knowledge of the *status quo ante*. As the study progressed it became apparent that this was a valid design as a number of new sections not foreseen in the Inception Report were added to the document. Similarly there are some areas which did not generate the expected amount of data.

All interviewees spoke on condition of anonymity. Without this guarantee it is highly unlikely that many of the findings of this study would have been made. After the submission of the first slide a request was made by the Research Committee to validate the interviews. As a modification to the process subsequent interviewees were asked if they would be willing to stipulate that they had been part of the process with the clear understanding that they would not be asked to confirm or deny any specific statements. A number have agreed and their contact details can be made available.

Notes were taken during the interview but no recording devices were used in order to underline the anonymous nature of the discussion. The write ups for the individual slides were completed within two or three days of the interview, only on one occasion was a follow up question required for clarification. On average each interview took around one and a half hours to complete. Some interviews were conducted at the interviewee's place of work, others in a neutral environment. Choice of location was left to the interviewee in order to provide a relaxed yet confidential environment.

Representative Detailing

1. Representative Detailing
    a. Number of Medical Representatives Operating
    b. Calculated Cost of Industry Sales Force
    c. Products Promoted
    d. Number of Calls Made
    e. Time Spent per Call
    f. Call Content
    g. Promotional Items Left
    h. Samples Given
    i. Entertainment
    j. Services Provided
    k. Payments for Privileges

Number of Medical Reps Operating: Data are still being collected to estimate the total employed field forces. So far information for the largest (top 10 to 15) companies points to a field force size of 350 to 600 plus.

According to one former GM Field force numbers depend on the product and the perceived audience for it. Highly specialized products with limited "target" MDs may have a field fore of as few as 5 representatives nationally. Oncology products would be a good example of this. More "Mass Market" brands could have a field force of over 50. Companies' in- house field forces can be augmented by contracting third party sales teams. This is generally done in two different sets of circumstances during the product life cycle: At launch where the company wishes to spread the word as fast as possible as widely as possible and: Late in the life cycle when promotion budgets are small and a less expensive outsourced field force can maintain a steady level of business.

A Sales and Marketing Director stated that 105 representatives were currently employed promoting and off- patent anti- hypertension education together with one to two other products.

The largest employer of Medical Representatives is a local company which has around 1,100 on the payroll. This figure is slightly misleading however as the company operates as a number of separate divisions (about 10), each of which runs its own sales and marketing, Within the divisions sales force sizes range from 30 to around 300. The determining factors according to a senior corporate executive are the market potential for the specific product portfolio and the consequent number of doctors likely to have a need for said products.

Calculated Cost of Industry Sales Force: There is insufficient data so far to make a reliable estimate. Ranges from 6 to 12% of sales have been reported. A Regional Compliance Director responsible for 14 countries from Pakistan to New Zealand stated that Philippine sales force costs were above average and

productivity below. A former GM noted that entry into a new business line (where the company has no experience or market presence) is more expensive than expansion within a category. The major expense item is the recruitment of a new sales team to promote the new product. Levels of promotional investment are adjusted so that break even is achieved within 18 months to 2 years for an expansion; for a new line the cost of hiring, training and supporting the field force pushes back break even to 3 years or more with 5 being seen as the realistic maximum. This is partially a function of patent life remaining.

In terms of cost one estimate from an executive in a position to know was that a Representative cost around P1,000,000 per year to deploy. Provision of a company car is the norm and over the years the standard of vehicle has gradually ratcheted up. This number includes on- costs such as other payroll charges and expenses and is for a large local company marketing branded generics.

The head of Sales and Marketing at a medium sized local company advised that the budget for promotion was arond12- 15% of sales and that the field force cost was roughly double that amount at 22-27%. These figures are not absolutely typical as this organization markets OTC products which significantly inflate the marketing spend due to the need for expensive TV and other media advertising. While OTC is outside the scope of this study it is interesting to note that- in the view of this executive at least- a far higher proportion of revenue was allocated to sales and marketing for OTC versus Ethical. Based in the turnover of this company a figure of around 25% gives a deployment cost consistent with the estimate above. This company has a mixture of patented, branded generic and OTC products.

One factor pushing up the cost of promotion for all companies is the rapid turnover of promotional materials. Due to high call frequency rates there is a belief that MDs quickly tire of seeing the same material and new items are consequently developed on a quarterly or even bi-monthly basis. [In reality it is more likely that the sales force has become bored and the Product Manager needs to recapture their attention and enthusiasm but it is expedient to blame the customer]. Since important new data tend not to come out at such a pace most of these new materials are restatements of previously known data however the origination charges can be considerable.

Products Promoted: Patented branded, off- patent branded, branded generics and to a far lesser extent unbranded generics are promoted to Doctors. A top clinician noted that one noticeable effect of the newly introduced Cheaper Medicines Act had been a sharp increase in the number of representatives calling to promote branded generics.

A top Executive at a large organization promoting predominantly branded generics explained how selling and other resources were allocated to the various products. This company had several separate sales teams deployed; each carried six or seven products. On average each Representative carried three “Primary” products, 1 or 2 “Secondary” products and 1 or 2 “Harvest” products. [Harvest in this context denotes a product which is generally long established in the market with little further growth potential. It is therefore viewed mostly as a source of cash]. In general the primary product attracted around 40-

50% of the overall promotional budget and roughly the same proportion of sales force time. The specific Primary product during the current cycle was a branded generic.

A senior executive at a company marketing predominantly branded generics described the strategy to slow the encroachment of low cost generics in to the market. Rather than cut overhead cost and compete on price the plan was to maintain the sales team at full strength and use the relationships built up over the years with the Medical Practitioners to maintain loyalty to the company's products. While there was some concern over the future there was confidence that the company could "weather the storm".

Combining the information from Slides 1 and 2 it is apparent that branded generics are the most heavily promoted drug items. Local companies generally have no innovator products from their own research and MNCs continue to promote brands after patent expiry (when they may be considered a branded generic depending on the preferred definition of the term).

Number of Calls Made: Industry expectations of call rates for medical representatives are in the order of 15 to 20 calls per day. A senior cardiologist reported seeing 15 to 20 medical representatives per day. It is now quite common for more than one representative carrying the same product to be assigned to a given hospital thus the doctor may be detailed the same product multiple times within minutes.

A description of the use of the sales call by a former GM was to "shuffle the deck". The working assumption here is that the doctor will have perhaps three or four top of mind products for a given clinical situation and the name of the game is to get your card to the top of the pack. Certainly this is consistent with the extremely high repeat call rates seen in the Philippines. "Priority" doctors are visited as frequently as once every week.

A Senior Marketing Executive at a large local company explained that three separate sales forces were deployed to promote a total of around 20 products. While the products themselves were varied (almost all branded generics) the target customers overlapped considerably. This interviewee expressed the view that it was highly likely that an individual MD could see two or even three Representatives from the company during a single day.

The standard number of visits required of the sales force for both Local and Multi- National companies is 4 times per month for a high priority Doctor.

Time Spent per Call: The typical representative call lasts from 30 seconds to about 2 minutes with one to three products being "detailed". There is little scope for the transfer of helpful scientific information during such a truncated exchange according to one industry observer. This was underlined by a senior Physician who gave the average duration of a call at 90 seconds.

Observations at hospital clinics in Metro Manila have consistently given a call duration of 30 to 120 seconds. In all cases much of this time is consumed by the requirement for the Representative to obtain the Doctor's signature for management internal control purposes.

Call Content: A leading Physician with a large clinic practice observed that the scientific content of the call was generally zero and that the perceived purpose of the call was twofold (i) To enhance brand name recall in the hope of generating branded prescriptions and (ii) to develop a social bond between representative and doctor. Reps able to successfully achieve this social relationship generally then proceeded to develop it through dinner invitations etc. These meetings were entirely social in nature with no scientific discussion taking place.

A former GM noted that there is a significant social aspect to the representative call; the goal is to build a positive relationship with the MD. The area of concern is therefore not so much the regular sales call, which is too brief and public to create much space for questionable practices but what happens once a social relationship has formed and company supervision falls away. An example was quoted of representatives being ordered by their district managers to provide transportation services for doctors in the interest of relationship building. It is hard to see how this would benefit a patient however it is not uncommon.

Promotional Items Left: PHAP sets clear rules on the nature and value of promotional items to be given to doctors. Items should be relevant to patients' health and of nominal value (under P1,000). This limit can be circumvented by paying the doctor to participate in a post marketing study. One Medical Director talked of a study commissioned by marketing to "investigate" a known property of the drug. The fee paid to the investigators (who were selected by the field force) was ten times the usual consultation fee prevailing at the time. Patients were given a starter pack of drugs but were then required to purchase further supplies. This individual observed that whereas trials of chronic medications are commonplace studies of acute therapies were rare. In the opinion of this Medical Director the reason for this discrepancy was that a successful investigation of an anti- biotic will result in a cured patient who has no further need of the product. By contrast a patient taking an anti-hypertension drug would be expected to remain on treatment long after the formal study has concluded.

In another instance the Philippine arm a regionally coordinated study resulted in the investigators being paid "regional" (i.e. inflated) rates and equipment used to conduct the study was gifted to the investigators after the study was completed. In this manner the company was able to circumvent both the rules on making direct payments to doctors and the limits on the value of gifts although it must also be noted that the equipment was clearly linked to patient outcome thus it would have met that criterion had it been applied.

In the opinion of a Regional Compliance Director, gift giving was less of a problem in the Philippines than in many Asian countries; values were modest and the items generally had at least some connection to the practice of medicine or patient welfare.

According to a Senior Executive at a large local company the management of gift giving to individual MDs was partially devolved to the Medical Representatives. Mid level sales and marketing managers developed a "menu" of items or activities which could be offered. The Executive noted that the company had a specified objective of meeting the Doctor's Personal needs as well as Medical needs. An example given of the former category was the giving of wine to recognize a birthday; examples of the latter included stethoscopes, sphygmomanometers and journal subscriptions. The company monitored the monetary value of such gifts through a hierarchical system of approvals (i.e. authority to approve cash amounts was linked to company rank) but the decision of what to spend the money on was largely left to the Representatives. It should be noted that this particular organization offers no explicit training in gift giving ethics to its Representatives. The executive noted that in recent times the absolute value of items given had declined. High value goods such as refrigerators and air conditioners were no longer offered but had been in previous times.

Company "G" has a guideline of P25 per item for giveaway items- significantly below the PHAP limit. Due to the high frequency of Representative visits to Doctors the need is felt to develop fresh materials at a very fast rate. One Executive stated that on average the company produced one giveaway item per promoted product per month. During any one promotional cycle an allocation of promotional items was given to the Representatives based on 70% of their expected calls for the period. While the total cost of this in terms of goods purchased was relatively modest the exercise consumed a lot of time and, by extension, money. All items, no matter how basic, were subject to the full approval system including Medical Department oversight.

Samples Given: Samples are given for most solid form products however the sample size is very small- normally only a single tablet contained within a catch cover (similar to a match book) which generally has some promotional content. This is not sufficient for meaningful assessment of the product in any but the most exceptional circumstances none the less the practice is almost universal. There is a case of a local general manager who unilaterally decided to discontinue distributing samples. Unfortunately sales were severely adversely affected and the individual was removed from his position after a few months.

The industry practice of distributing a single tablet for "evaluation" was questioned by one prominent clinician. Over time the quantities build up and this doctor admitted to not knowing what happened to unused samples. This lapse in custodianship (previously not considered but surfaced during interview) could lead to medicines falling into the wrong hands.

It is not uncommon for (especially junior) doctors to collect and sell samples. This is most prevalent in government hospitals. They them prescribe the medicines sampled in order that their pharmacy partner

can make sales and move the stock. All doctors interviewed so far in phase one have admitted to selling samples at some stage in their careers. One executive of a distribution company with wide experience of operations in the industry has estimated that 5- 10% of medical representatives sell their samples to bolster their income. Strictly speaking this is not promotion but it can impact availability of products at smaller store with limited range.

Perhaps one of the more egregious uses of samples was in the early days of the statins (mid 90's). According to a Physician then practicing Cardiology the representatives of one major multinational were equipped with simple cholesterol screening kits. They were stationed at a large government hospital and approached potential patients directly. In the event that the patient tested positive for elevated cholesterol they were given a sample of the company's product. Effectively these representatives were practising medicine without medical training or a licence.

One local company bucked the trend of giving single tablets as samples. A top manager took the view that a proper trail was needed even thought the products in question were all branded generics. Generally a strip of ten tablets (which could be 3- 10 days of treatment) was given on request. Repeat sampling was the norm which called into question the true nature of the evaluation. At core, the purpose was to encourage switching to that company's brand according to the manager.

When asked about the need for samples of branded generic presentations of well established medicines one senior physician noted that the central issue was one of equivalence and (by extension) a lack of confidence in the regulatory system to establish this parameter. This effect is also seen at the scale of specific hospitals where the therapeutic committee requires data beyond that deemed sufficient by the FDA. This has been noted at both private and government hospitals.

A head of Sales and Marketing explained a two step system by which samples were allocated. After allocating samples to the sales force according to the expected number of calls to be made in the cycle their customers were then categorized into three types: "Prospect" "Acquisition" and "Retention". Prospect customers were defined as non- prescribers who may ultimately be of interest but perhaps with limited potential (e.g. because of specialization they may have a limited number of patients requiring a specific drug). Acquisition customers were non- or low- prescribers who had a significant potential to use the drug in their practice. Retention customers were existing prescribers who used the drug regularly. Samples were allocated to the three types as follows: Prospect- one sample every second visit; Acquisition- one sample every visit; Retention- two samples every visit. The quantities involved were adequate for two days of treatment which was insufficient to produce a clinical end point. This executive claimed a very clear link between sampling and sales.

A Marketing Manager described the chain of custody applied to the distribution of samples. Each month an allocation was made to the members of the field force based on their planned calls for the cycle. Representatives were responsible for maintaining control of inventory under the supervision of their first line managers. The quantity of samples left per call was partially at the representative's discretion

but an MD's signature had to be obtained confirming receipt. The samples themselves were clearly stamped "Sample not for Commercial Sale" as a measure against leakage into the normal distribution system. The individual samples (which were for a chronic therapy) comprised a strip of 7 tablets.

Entertainment: Entertainment of MDs by sales and Marketing staff is accepted standard practice industry- wide however standards and constraints vary.

At one end of the scale company "D" only allowed pre- planned and approved meals with doctors at limited cost and providing there was a business discussion. An alternative approach was described by a high level executive at company "F" a local concern not affiliated with PHAP. According to this correspondent entertainment was encouraged and restrictions were few. Girlie bars were off limits and could be grounds for dismissal but no effective monitoring process was in place to systematically uncover such transgressions. The rationale was straightforward enough: Face to face time at a clinic call is extremely limited- why not change location and environment and have 2 or more hours of access.

A similar logic applied to golf. Representatives are encouraged to play golf with the Doctors on their territory in order to build personal relationships and enjoy 4 hours of access. The correspondent did point out that the company did not reimburse the representatives for their own green fees and that Doctors frequently (but not always) paid for themselves either entirely or partially. If golf was not to the Doctor's taste ballroom dancing and bowling were popular alternatives. The selection of MDs to participate in these leisure events was left entirely to the individual sales person.

At a more elevated level at least one local company regularly organizes a golf tournament for Doctors. This would not be permitted under the PHAP code.

In direct contrast to the above an interviewee at a PHAP company made it very clear that Golf was a forbidden activity and would invoke the disciplinary system.

Services Provided: Provision of transportation services is offered by a number of companies both local and multi- national. This may involve ferrying a Doctor to the airport (often in association with the requirement to catch a flight to attend a company sponsored event or convention) or – as one executive put it- being the "designated driver" when an MD travel between clinics. In this latter instance the case was again made that extended face time was the motive behind this service. A rep who would have got 90 seconds with the Doctor 15 minutes earlier in the clinic now has that person's undivided attention for perhaps an hour (or longer if Manila's notorious traffic makes a contribution).

Payments for Privileges: Representative detailing is becoming subject to restrictions at certain hospitals. As explained by a Marketing Executive some Doctors are taking advantage of this by implementing a bond scheme. The MDs of one unit at a hospital which does not permit Medical Representatives on the premises have set aside a weekly schedule where they are all present at a (modest) local restaurant. If the Representative or his/ her company pays an amount of money they are granted leave to detail to the Doctors. Any Representative who happens by the location without having paid the bond is not

entertained and sent away in a rather humiliating manner. The sum involved is quite large and it is not clear whether it is donated to the Department or not. With the growing trend towards restricting access to MDs it is possible that this could become more widespread.

Another practice related by this interviewee was the habit of a Senior Physician of demanding tribute on the occasion of his birthday. Once informed that PHAP regulations proscribed the giving of lavish birthday gifts and alcohol to support a party this MD set up a system for generating bogus receipts which appeared to have been issued in connection with *bona fide* CME activities. By coercing the Representatives to join this fraudulent scheme the likelihood of the whistle being blown was remote. Non participants would find their products blacklisted for several months.

Meetings

Locations and Venues: A senior Industry Executive explained that there are different kinds of meetings depending on product life cycle. Pre- launch there may be investigators' meetings which may or may not be organized by the local subsidiary. These meetings are exempted from PHAP rules on promotional sponsorship (7 delegates outside ASEAN/ China/ Korea, 12 delegates within). Since investigators are generally senior and influential MDs- Opinion Leaders in the marketing argot- this is a loophole which could be exploited by research- based Pharma companies (i.e. multi nationals in the Philippine context). This can start happening up to 3 to 4 years before a product is introduced.

Post launch meetings tend to be more marketing oriented and organised by the sales and marketing team. They are a counter to the brief and informationally sparse regular sales call. The subject matter varies. On some occasions there may be presentation slides prepared by marketing (and with medical clearance) on others the agenda- such as it is- is more social.

A former executive of a multinational described a "menu" of overseas conferences which was offered to influential doctors early each year. In a similar vein a senior executive at a large local company described a promotional budgeting process whereby a list of target MDs was drawn up together with a cash amount the company was willing to spend on that particular individual. Once the budget was settled the trips to be offered were agreed by the management team and executed by the sales force. The likely scientific content of the various meetings was not a focus of discussion during this process.

A physician with long industry association recalled a division of a large local company which arranged luxury cruises in the Baltic and Mediterranean for doctors. Brazenly the sales and marketing team adopted the moniker "Cruises Я Us".

Even legitimate overseas travel can be hijacked. A senior cardiologist with wide experience of sponsored overseas travel explained the diversion process. A doctor who may have been given funding to register for every day of an overseas convention may opt to attend only a single session and use the money for personal expenses. In this he or she may be aided and abetted by company booth personnel who arrange sightseeing and other diversions during the course of the day while the scientific sessions are in progress. Manufacturers will send staff to prestigious overseas conventions to make sure that "their" doctors are not diverted by employees of other companies. This defensive, sheparding, role adds to the cost of overseas sponsorship.

A top cardiologist stated that a large local company had recently taken large groups of doctors to Dubai and Jordan. In both cases the 5 day trips included only one hour of CME in the form of a lecture delivered by one of the group. The subject of the lecture was one of the sponsoring company's own products.

Restaurants and Hotels remain the default locations for meetings according to a Product Manager at a Multi National. This executive, who was responsible for a mixture of recently introduced brands and longer established products estimated that around 40% of the marketing budget would typically be allocated to launch meetings. These would ideally be in the form of RTDs either with or without KOL participation. Venues were selected carefully to remain in conformity with PHAP ethical guidelines. A further 25% of the marketing budget was allocated to symposia for older products (which may or may not be off patent). This means that almost two thirds of the marketing spend is directed towards meetings.

Non PHAP members have great latitude when is come to both location selection and the number of participants involved. As a Corporate Executive at one such company explained destinations were mostly within Asia but the Middle East, Europe and the US were also recent choices. No limit was placed on the number of attendees of these overseas events and the attendance numbers would often climb into triple digits. About 20 to 30% of the marketing budget was allocated to this type of promotion.

Scientific Content: For PHAP members at least in recent years the trend has been towards greater scientific content according to a senior Academic Doctor. In the early part of the decade sponsorship of parties and sporting tournaments was more prevalent. Even after this type of activity was outlawed Multi National "E" - a PHAP member- sponsored a bowling tournament with zero scientific content. In modern times there are guidelines for scientific content which are observed by PHAP members.

Speaker's fees for local speakers range from P10,000 for a short meeting in the speaker's home town up to P30,000 for a longer out- of- town event. Given that the speaker may have to cancel clinic in order to attend the meeting this is not an unrealistic figure. As was pointed out by one Sales and Marketing Director, speakers tend to be better known doctors and therefore tend also to have a large patient base and consequently significant consultation and other fee income.

Speakers typically present slides prepared for them by the sponsoring company. It is usually the responsibility of a Product Manager to originate the slides unless they are created centrally (which is usual practice for multi- nationals with "blockbuster" trials to promote. The sponsoring company will take care to ensure the speaker stays "on message"; speakers judged to be negative in their delivery do not get asked again.

A senior official of a leading Medical Society noted that training in critical appraisal of scientific papers is not a part of the curriculum at medical schools. According to the PCP it is now being incorporated into residency training programs. In addition there is no clear or systematic way for industry sponsored

content to be identified as such when a large convention schedules scientific sessions of mixed sponsored and independent research.

A member of the PHAP ethics committee provided documentation of a junket trip to Paris. In an excursion lasting 5 days the total scientific information consisted of a two hour lecture on the second day. Participants were treated to a Seine river cruise, a Louvre visit, a trip to Versailles and the Eiffel tower among other distractions. If this were not egregious enough the invitation/ schedule had a footer asking "Where would you like to go next? Allow us to take you there" a clear statement of future intent plus the logo "Tours R Us".

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One medical representative trying to arrange for a company presentation was informed by the head of department that such presentations were only allowed if the company involved sponsored an "outing". It was very clear that this outing was intended to be recreational.

As noted elsewhere in this paper, the exchange of executives among local and international companies is sometimes bringing a new ethical approach to previously less fastidious organizations. A top manager at a large non PHAP company reported that around 8% of the marketing budget was spent annually on meetings. This individual was under some pressure from a more senior executive who was regularly advocating more "junkets" as a means of promotion. While the respondent's tenure was not directly threatened by declining this advice there was a constant awareness that should sales slacken for any length of time the "old ways" may be invoked to address the issue.

Many companies both local and multi-national; PHAP and non- PHAP maintain speakers' bureaux in some shape or form. The size of these groups appears to correlate better with the market share of the sponsoring company rather than the quantity of scientific data likely to require dissemination. That said sponsored scientific meetings play a valid role in bringing information to many doctors. The normal operational mode is for the speakers to interact regularly with the company's senior Medical and research staff and attend scientific meetings on the disease area and/ or product profile. Once a level of expertise had been achieved these MDs were then invited to speak on the subject at group meetings. In general the sponsoring company provided the slides but all interviewees were clear that the speaker was at liberty to make any changes he or she saw fit.

The Outsourcing Industry is applying the same criteria as the traditional Pharmaceutical Companies; at least those outsource companies which are members of PHAP. As a top Executive at a leading Outsource Organization noted the expectation of the Principal was compliance with PHAP guidelines. A formal SOP

had been promulgated throughout the organization and the Medical Department had an oversight role in the development of the scientific program.

A PHAP MNC has implemented a comprehensive system to direct the scientific content of RTDs. All materials to be used must follow the same approval process as that used for promotional items i.e. sign off by the Medical Director. This system was applied even to the invitation which described the scope and objectives of the meeting. Standard modules, developed overseas with extensive Medical input, were presented by the KOL after being screened for local label compliance.

A Marketing Manager at a PHAP MNC stated that the expectation of the company for was mid level managers to entertain MDs around twice a month. These would be lunch or dinner get- togethers and entirely social in character. The interviewee claimed that MDs became upset if a product was mentioned.

There still remains one area where no attempt is made to provide scientific content and this is the graduation party sponsorship. One Senior Executive of a PHAP company noted that this was now the exclusive preserve of non PHAP members but was quite widespread none the less. Medical Students, Interns and Residents were provided with food and drink during post examination and other milestone celebrations.

For mainstream scientific meetings the code prescribes the proportion of any meeting which should be given over to scientific presentations at 60%. However as has been noted elsewhere there is no effective monitoring of the quality of the material. While the program may list a series of lectures the Ethics Committee does not have the resources or manpower to monitor if this is actually what happens or how the information is delivered. One long tenured Senior Executive noted that the practice of Doctors was to drift in and out of the meeting hall even during lectures. This means that the register taken can only indicate the maximum number of participants likely to have been present during the scientific discourse. In reality it is a much smaller percentage who will engage enthusiastically with the scientific debate. This is a behavioural issue and the interviewee noted that there was little that could be done to address it other than trying to minimize the amount of distractions on offer.

In former times it was common practice to schedule entertainment at the end of the meeting in order to keep the delegates in the room. This would frequently mean a “Starlet” would be contracted and this would feature on the meeting invitation. Since this is now frowned upon the invitations no longer provide this information but, according to one highly placed insider, the entertainment continues. Word of mouth is used to more discreetly inform attendees of the treats in store.

Sponsorships: According to a senior sales and marketing executive at a prominent local company around 20- 30% of the promotional budget was allocated to convention sponsorship. The manager noted that the company’s entire product range consisted of off- patent “branded generics” and that in general it was unlikely that new product data was likely to emerge during scientific sessions. On the one

hand this meant that the scientific information shared was decoupled from product considerations which would therefore not unduly influence prescribing of the company's brands. On the other it was expected that a "favour" would be returned.

A Senior Executive at a non- PHAP company explained how sponsorships were allocated among the various Doctors practicing on a given territory. At the top levels of Sales and Marketing a plan is created for individual Doctors (these are generally the higher- profile specialists) and the proposed investment levels matched against scheduled conventions. Form this exercise a plan is produced to sponsor specific individuals to identified conventions, either local or international. This Executive was aware of previous market research which demonstrated that Physician prescribing behaviour changes once sponsorship is agreed and not after the event (when presumably new knowledge will influence product selection). For this reason sponsorship arrangements tend to be made well in advance of the actual convention to maximize the commercial benefit of altered prescribing. There was also a sense of pre- empting the competition who may similarly wish to proffer an invitation; in other words there is active competition to sponsor leading MDs. This has led to the emergence of the popularly known "frequent flyers"; well known doctors who spend significant amounts of time attending overseas conventions as guests of various Pharmaceutical companies.

Post Event Expectations: A Corporate Executive described a sophisticated system for directing and monitoring the impact of sponsorship.

MDs were selected for sponsorship to local or overseas conventions based on their existing prescribing behaviour. A system was in place to decide whom to send to where. From this a total budget was matched against planned allocations and the plan operationalized. The amount invested was then tracked at the level of the individual.

The usual purpose of the intervention was to increase prescribing however "rewards" were also given for consistent supporters of a given brand in the absence of substantial growth (the reasoning being that a saturation point had been reached based on market share data). Pre and post sponsorship the company monitored the prescribing choices of the Doctor. From this an assessment of return on investment was made.

An additional level of sophistication was the very effective business intelligence unit which was capable of estimating the investments in identified Doctors made by competitors. Where necessary a second sponsorship opportunity would be given to overtake the investment made by a competitor.

A top manager at a larger local company explained how the selection of conventions was made on the basis of sales generated. The more business a specific MD was sending their way the greater the likelihood of sponsorship to a prestigious overseas meeting.

Arrangements to cascade data to local MDs not able to attend the various conferences and conventions were not very robust in one large local organization. A Sales and Marketing Executive stated that only

one or two attendees would be expected to act as local speakers to disseminate information to their colleagues. The rest were expected to simply increase their rate of prescription.

1. Journal Advertising
    a. Products Advertised
    b. Estimated Spend
    c. Message Compatibility with Label

Products Advertised: Professional Medical Journals are the only legitimate vehicles for advertising ethical pharmaceuticals however in many cases the space is taken up by food supplements, OTC products and even Real Estate advertisements. As had been noted by a Senior Executive responsible for a mixture of ethical and OTC products advertising is of lesser importance for prescription items. In this first overview of the ethical products advertised branded generics were the most common category and cardiovascular medicine the most common therapeutic area. No ads for unbranded generics were seen and no ad provided information on SRP.

Estimated Spend: Discounts and deals are part of the Media Purchasing environment and it is not possible to know with certainty what price is paid for any specific placement. An insight can still be obtained by looking at the published rates offered by leading Journals. Premier placements such as back cover, inside covers etc were quoted at P100K to P150K. Ad space sold within the magazine could be full, half, one or two thirds or quarter page in most cases. P25K appears to be about the minimum for a small ad, full pages can achieve P100K. Journals are very creative in preparing false covers (i.e. the advertiser wraps the publication with a "cover" of his own devising) which can climb into the P200- 250K range for a leading Journal.

In the context of the deployment cost of a typical Medical Representative advertising costs and budgets are not very significant. Promotion in the Philippines remains a highly labour intensive affair.

Message compatibility with Label: According to one former Medical Director, journal ads undergo the same approval process (with Medical oversight) as all other promotional communications.

A sample of 20 product advertisements was taken from a selection of Medical Journals. In all cases the claims made were consistent with the usage of the compound as described in MIMS. Pharsight did not attempt to review reference clinical papers supporting the copy. A sample will be taken for Slide 3.

One ad for a branded generic of a recently off patent cardiovascular drug used the term "More Affordable" but did not give a price. According to the PHAP code such unqualified comparatives should not be used but the copy is not clinically misleading.

Message Integrity Assurance

1. Message Integrity Assurance
    a. System for Assuring Compliance with Evidence and Label
        i. Role of Medical Director
        ii. Effect of PHAP code
        iii. Effect of FDA Regulation

Role of Medical Director: Multi- national "A" has a system of claims control based on a centralized process to match claims to the "world" label. Some minor deviations occur under the following circumstances: There are differences between the local label and the world label (local data sheet will prevail) or: Local management believes a specific claim to be of lesser relevance due to market specifics. In the latter case local management can reorganize priorities or delete entire claims without a burdensome approvals process however *adding* a claim attracts a far higher level of scrutiny and as a rule is not done.

Company "A" does not submit promotional materials for legal review taking the view that this is a scientific matter. All promotional materials are signed off by the Medical Director prior to issuance to the sales group

Company "B" has a similar system of Medical Department approval without legal overview. Company "C" requires Medical and legal review as does company "D". The budget for Medical Affairs is decided by the sales and marketing group in company "B" as a result the range of activities was restricted.

A former Medical Director and member of PCPI (the association for Medical Directors) stated that smaller local companies generally do not provide much training for the Medical Director outside of basic matters such as proper reporting of Adverse Events. The impact of this shortcoming is not particularly significant as the internal approval process in such companies may not involve input from Medical. One local conglomerate has 8 units operating of which only 2 have a full time medical director. Under Philippine law a pharmaceutical company must have a licensed pharmacist on the staff but there is no such requirement for a medical professional.

Both local and multinational companies conduct clinical studies of varying degrees of rigor. One former medical director stated that the purpose of studies for marketed products was to support marketing's desired claims. Studies with negative or unhelpful outcomes were "buried". This individual also pointed out that journals were reluctant to publish negative studies in his experience; studies with positive results were thought to be better for circulation figures.

Company "G" has an organizational structure which is specifically designed to promote a high level exchange between the company and KOLs. While most companies entrust the management of KOLs to the marketing department company "G" enhanced this approach by employing specialist Physicians to

act as scientific liaison with the Medical Professionals. These individuals are all qualified MDs and are under the supervision of the Medical Director. The Marketing group works closely with this team but ultimately the Medical Director has jurisdiction over what can be shared. This facility is especially useful pre- launch or when an extension to the label claim is planned as it permits privileged Physician to Physician communication. These officers are also involved in the approval process for Promotional Communications.

Effect of PHAP code: The PHAP code is modelled on international standards and has undergone significant development in recent years. The falling number of ethics violations pertaining to promotional activities may be viewed as a measure of the success of this initiative. It is important to note that not all pharmaceutical companies operating in the Philippines are members of PHAP. This includes some large, high profile multi nationals. Enforcement of the guidelines for promotion is more challenging for non member companies. For those which are members of IFPMA (or whose parent company is) there is the option for escalation. This applies to most but not all multi nationals. For local unaffiliated companies the IFPMA is not a factor.

Effect of FDA Regulation: By rule, every statement on a promotional piece must be consistent with the locally approved label. Compliance with this regulation is only passively enforced by the FDA, unless a third party (typically a competitor company) raises the issue there is no spontaneous investigation by the FDA.

Sales Management and Employee Policies

Incentive Scheme Parameters: Incentive programs for medical representatives are more or less universal in the Philippine industry. The proportion of the representative's income derived from this source varies widely and as a consequence the pressure to achieve the sales target. Depending on the business results a sales and marketing executive at company "D" estimated that during a successful year around 33% of representative income would come from the variable component. In another multinational the figure was closer to 50%. For more senior staff the sales component of variable pay was generally less with other defined corporate objectives forming an increasing proportion of the pot. None the less a sales element features in the compensation of all sales and marketing staff up to and including the general manager. At multinational company "D" even staff with no obvious link to the selling effort were reliant indirectly on the sales result as it was a key parameter in assessing overall corporate performance which then determined the total bonus pool available for distribution.

At the level of the representative in all cases where an incentive scheme operated territory sales was a factor in calculating the bonus payment. Some multi nationals include non- sales parameters as a component of the scheme to encourage ethical behaviour. Company "D" operated such a hybrid system; over the course of around 5 years the proportion derived purely from sales grew from 65% to 80- 90%. A senior manager at the company felt that this undermined efforts to support the "right way" of doing business.

Incentives for the field force at a large local company could be quite lavish. Based on a formula which weighted sales achievement at around 60% of qualifying criteria Representative incentives in one case included a one week luxury Asian cruise. While no-one outside the company was invited to this event and companies are free to decide how to treat their staff the message sent to the field force is extremely clear. Under normal circumstances few if any staff making a basic Representative's salary would be able to afford such a vacation.

Another hybrid sales force incentive plan is being implemented at a large local company. About 80% of the scheme is driven by sales; the remaining 20% is derived from parameters such as call rate, completion of administrative requirements and test scores on regularly administered product knowledge quizzes. There is a general trend towards broadening the parameters of the sales incentive scheme and providing staff with a basic wage sufficient for their daily needs. In the past the weighting was often such that without commissions from sales the lowest level sales staff would struggle to meet

their regular bills putting enormous pressure on them to generate sales. For this company the same basic division between direct sales measurement and other performance parameters applied to first level supervisors also.

Sales related parameters are included in the incentive schemes for departments other than sales and marketing. One large MNC with a significant PA/ PR department included a sales based component of 30% for the department head.

MRAP Participation per Company: Despite the evident de- emphasis on MRAP by PHAP several companies have had their training staff certified to deliver the curriculum over the years. One local company (a non- member of PHAP) boasted a 100% certification rate among its field force. A senior executive at this company observed that one of the problems with MRAP had been that Representatives' unions in some companies had viewed the requirements as a threat to job security and had threatened industrial action. Whatever the merits of this argument the effect on the pervasiveness of MRAP was tangible.

Data on Company participation rates are no longer kept.

Ethics Training: Where existent ethics training forms only a very small component of the curriculum. More data will be available in the next slide.

A former Sales Manager commented that the practice of prescription buying is believed to still be active although direct evidence is virtually impossible to obtain. In the past the system tended to be operated by individual district managers (first line supervisors of the sales force). The participating MD is given a special Rx pad and told to direct patients to a specific pharmacy where these prescriptions can be monitored. Because of the "entrepreneurial" nature of this activity it is hard to surface hard evidence either as a market researcher or a company manager. All corporate personnel interviewed for phase one were clear that this practice would not be tolerated and any employees involved in such activity would face severe disciplinary measures including immediate dismissal.

A senior Sales and Marketing executive at a local non- PHAP company stated that on average Medical Representatives were given one month's classroom training plus 3 or more weeks of "OJT" supervised by the training group. This is then followed by a further 3 months of OJT under the representative's line manager. Ethics training (excluding any that may be provided *ad hoc* by a line manager) comprised a 1-1½ hour session on truthful presentation the core of which is the prohibition of off- label promotion. No guidelines on gift giving (which the representatives subsequently have a role in managing) are included. A second component of the ethics training concerns the need for honest reporting of financial transactions and achievement of job- specific objectives such as calls made on Physicians.

CME Quality Assurance

1. Validation CME Quality Assurance
    a. Validation Process for Scientific Content
        i. By Industry
        ii. By Medical Society
    b. Participant Selection Criteria

Validation Process for Scientific Content by Industry: An executive at a multinational noted that for major events the agenda and content were closely controlled by the region however for smaller, territory level meetings (e.g. RTDs) the sales and marketing group worked with a local speaker with a moderate to high degree of independence. PHAP members would be expected to adhere to the prescribed standard but this measures only the quantity of time allocated not the quality of the information disseminated.

A Corporate Executive at a large local company explained the CME strategy and how it was implemented: One key component was a pure science meeting, sponsored by the company but with no product promotion either in the scientific presentations or peripheral to the meeting. The speakers at these sessions were drawn from across the spectrum and included Medical Directors of competitor companies. Content was therefore subject to fair peer review with preliminary evaluation for agenda inclusion being conducted by in- house experts.

At the other end of the scale were the company promotional meetings and product introductions (NB all products being introduced are “branded generics”). Meetings designed to support the marketing of in-line products were customarily held within the Philippines although resort locations were often selected. According to this respondent hundreds of doctors would attend such events. At a rather higher level were the new product launches (again “new” in this context means newly added to the product range rather than new pharmaceutical entity). These meetings were generally held outside the country and often functioned as “consolation prizes” for Doctors who did not qualify for sponsorship to overseas medical conventions.

Validation Process for Scientific Content by Medical Societies: According to a senior official of PCP there is no drive for improvement of scientific content of CME events coming from the Medical Societies. When discussing a new clinical study for example speakers will commonly present slides made by the sponsoring company. One reason given for the lack of leadership shown by the medical societies was their desire to maintain good relations with the industry in order to attract sponsorship for their various conventions (typically two per year). Booth space sold to Pharma companies provides significant funding for the society.

Participant Selection Criteria: Company “D” operates a sophisticated system for selecting participants at CME events based on the perceived networks of the MDs in a specific area. Informal “Opinion Leaders”

are identified and prioritized for early exposure to new information. The physician network then disseminates the information with or without further input from the company. Before this system was in place typical selection criteria were size of practice and existing level of business. The notion of CME being viewed as a "reward" for good customers is actively discouraged by this firm. A manager at the company noted that while the program had been quite successful the fact that such an intervention was needed in the first place was indicative of a misconception among the rank and file of the true purpose of CME.

: A Marketing Manager at a large PHAP member company explained how Doctors were chosen to participate in RTDs. The selection methodology was based upon nominations by the sales force from a list provided by marketing, In this way marketing sought to control the total number of attendees around the country and thereby the costs of the project. The scientific content of the discussion was the responsibility of the KOL assigned to be the discussion group leader. KOLs were compensated for this work being paid a fee of P8,000 to P15,000 depending on the location of the event (higher fees recognized travel and other logistical issues). Ten to Fifteen MDs would normally attend one such round table session.

On the basis of the discussions so far with both local and multi-national organizations Pharsight estimates the total annual number of overseas trips sponsored by the Pharmaceutical Industry to be in the order of 3,000 plus. This represents a significant proportion of the total number of MDs practicing in the country (note that a top MD may contribute several trips to the total).

KOLs are regularly used as speakers at scientific meetings. A marketing manager at a Multi National explained how a KOL would generally be identified. Criteria applied would be status within a specialist Society (ideally an officer or recent past officer); Position held (Department Head at a large hospital for example) and links to Training Institutions. The KOL's publication history or academic qualifications were not assessed separately by the company; rather it was assumed that these would be consistent with the Doctor's rise through the hierarchy. Once selected as a speaker the MD would often be given communications training (including handling the media which was usually very well received) and then provided with a slide deck. Marketing would normally point out the highlights and items for emphasis however speakers are at liberty to amend slides. The Q&A session which follows most presentations is an opportunity for a less structured discussion of the subject matter to take place. The interviewee was clear that speakers who appeared less than enthusiastic or supportive would not be dropped from the program but further efforts would be made to convince them of the merits of the company's product.

FDA Influences

1. FDA/ Government
    a. Role in Monitoring Promotional Activity
    b. Guidelines
    c. Enforcement
    d. Internal Constraints
    e. New regulation

Role in Monitoring Promotional Activity: The DoH and FDA (formerly BFAD) have regulatory authority over the Pharmaceutical Industry as a whole including oversight of promotional activity. The Legal department has the specific task of policing promotional practices. The FDA has an active discovery capability in the shape of a small team of inspectors and will also receive complaints from third parties such as consumers or health care professionals. The active capacity is extremely limited with only 4 to 5 inspectors full time in the Metro Manila area and nothing in the provinces. The efforts of the inspectors are supported by an informal network of regular employs who are encouraged to look for potentially illegal practices. Once a transgression is identified it is passed to the Legal Group for assessment and processing. Again, this is a small team with only 3 qualified lawyers being available at FDA.

On average the monitors detect around 30 violations per year with ads for ethical products to the public being the main area of focus. Since these are by definition violations they are easy to spot and there is little room for interpretation or negotiation.

All of the above are after- the- fact responses; there is little done proactively. For example there is no requirement to submit materials for approval pre- publication. This contrasts with general commerce where ads are reviewed by the ad board prior to publication or screening. In the past there was FDA (BFAD) representation on the ad board for non- Rx products but this participation was withdrawn due to lack of resources.

Awareness of the PHAP code is patchy at the FDA and few if any are intimate with the details. As one interviewee put it there is some contact with the industry and industry associations but no process for formal alignment or exchange of codes (in any event the DoH would have primacy). Interestingly this official noted that there was virtually no contact with the Medical Profession or Medical Societies.

Guidelines: The local FDA requirement for post marketing surveys does not set the bar sufficiently high in the opinion of one Medical Director. It is possible to satisfy the safety protocol with as few as 30 patients which is far too small a number to produce useful information.

The consumer acts, FDA 3720- now 9711 FDA act 2009 form the legal basis for regulation of the Pharmaceutical Industry. The Implementing Rules and Regulations (IRR) for the governing acts are promulgated by the FDA and DoH. The FDA is not involved in providing specific guidance before the fact

and is not consulted prior to the instigation of a promotional campaign. As a senior official pointed out there were no resources available to undertake the work if it were required.

Another area for improvement which could impact promotional practices was the requirement for a Pharmaceutical company to have a Medical Director. A DoH official noted that this is in the guidelines but again, enforcement is lacking. Given the role that the Medical Director could potentially play in the quality control of marketing collaterals this interviewee saw a significant missed opportunity.

The Internet is considered a vehicle for promotion to patients and is therefore subject to the same regulations are apply to printed mass media. DoH officials however recognize that it is next to impossible to effectively monitor this medium.

The FDA does not routinely consider issues of excessive entertaining. According to one official the approach was to determine whether a category of promotion (e.g. a dinner discussion) was permitted or not. If permitted the magnitude was not normally considered although if a violation was found to have occurred it may be a factor in determining the penalty. This individual was aware of only one single case where a delegate to a conference or convention raised a concern over the amount of money spent. In sum, FDA does not see its role as policing absolute marketing spending.

Enforcement: A direct quote from a senior marketing executive at a large organization: “FDA/ DoH don’t impact my marketing decisions”. The only concern is the reaction of competitors who may report transgressions to PHAP. For non- PHAP companies the risk of meaningful punishment is effectively zero.

By rule, every statement on a promotional piece must be consistent with the locally approved label. Compliance with this regulation is only passively enforced by the FDA, unless a third party (typically a competitor company) raises the issue there is no spontaneous investigation by the FDA. A PHAP ethics board member observed that the FDA never spontaneously investigated promotional issues. A review of ethics cases going back to 2005 confirmed this observation.

An academic physician formerly in industry commented that the supervisory regime at the FDA was inadequate to guarantee the quality of generics. While this is not directly related to promotion it is a key concern and public relations efforts by the industry have in the past hinted at these shortcomings (the interviewee opined that the industry would not risk antagonizing the regulator with overt public criticism).

It is also apparent that the FDA/ Government has not been successful in stamping out corruption in its own ranks. One GM stated that the devolution of purchasing had led to an increase in corrupt practices due to the large number of individual players. Although the promotion (i.e. marketing) platform may be consistent with the approved program the sales element was riddled with requests for off- invoice discounts and other anomalous practices. The interviewee noted that there were significant regional variations depending on the priorities and morality of the local decision makers. The question raised was

the degree to which industry is actively engaged in initiating corrupt practices versus varying level s of resistance to extortion.

Until recently the penalties for violations in promotional practices were extremely mild with fines of P1,000 to P5,000 being levied. These do not represent a deterrent to even the smallest commercial enterprise. Recently the range of the fines has been increased to P50,000 to 500,000 with an additional P1,000 per day of continuation.

In addition to the system of fines there exists on the books the sanction of suspension of the Certificate of Registration for a specific product also exists as does the option to cancel the offending company's LTO (License to Operate). No one interviewed at the FDA/ DoH was able to give a single instance of this penalty having been invoked. The option to revoke the LTO is also available in cases where there is no Medical Director but again no instance of this penalty being handed down was given.

One FDA official noted that the normal first step was to issue a "Cease and Desist" order. Generally these orders produced the desired result and court cases were rare.

Much of the work done by the inspectors was to intercept and eliminate direct to consumer promotions of prescription drugs (see note below) but there was one interesting deviation from the FDA's restrictions on promotion of prescription medicines to the general public at the Generics Fair. At this event, held in a shopping mall with free access for the general public BFAD specifically permitted the promotion of generics.

Internal Constraints: There are several areas where the effectiveness of FDA/ DoH in the monitoring and control of promotional practices could be improved according to insiders. The biggest obstacle appears to be volume of work/ shortage of resources. There are 30,000 licensed establishments and 40,000 to 50,000 registered drugs. FDA is accountable for monitoring label compliance of printed materials which are commonly distributed at retail pharmacies and to prevent the promotion of ethical drugs to the general public. With minimal presence outside Metro Manila and few resources even in the capital FDA has little hope of discharging this responsibility effectively.

In addition to the workload/ staffing dynamic insiders at FDA also pointed out poor internal communications as a source of concern. According to one senior officer by the time the paperwork on a violative piece reached qualified personnel the campaign was frequently already over. This interviewee also noted that under these circumstances no further action was taken. This means that companies have a good chance of never being penalized and even those that do get fined have presumably reaped the benefit of the program in terms of increased sales.

Another example was the subject of violative prescriptions (including those not prescribing generically as per the law). The internal procedure here was for DoH to endorse the case to FDA but FDA is not the competent authority. Given the intent of the generics act and the large amount of effort and money behind the promotion of "branded generics" this is a key control which is not functioning.

Another concern expressed during an interview and subsequently raised again at the MeTA workshop was the risk of being sued. Drug companies had filed cases against specific individuals rather than the institution. This was a source of considerable concern to FDA professional staff.

New Regulations: For companies marketing to the paediatric market there is a sense that the cheaper medicines act will have muted impact. A top Marketing executive stated that parents were very reluctant to take risks with the health of their children and therefore would stick to tried and trusted brands (including branded generics) regardless of price.

MDs and Medical Society Influences

1. MDs/ Medical Societies
    a. Number of Representatives Seen
    b. Products Promoted
    c. Existence of Guidelines for Interfacing with Industry
    d. Existence of Parameters to Assess Industry Provided CME

Number of Representatives Seen: This figure varies widely. In certain hospitals Medical Representatives are banned completely so the number is close to zero (although the same MDs may be seen elsewhere should they have other clinics). One hospital controls the number of Medical representatives by issuing a limited number of ID's each day; representatives without proper documentation are not permitted inside the hospital. The director of a large hospital in Makati lamented the large number of Medical representatives who were overwhelming the elevator system.

An MD with a well established practice can expect between 10 and 15 calls after clinic. All Doctors interviewed were accommodating of Representatives but equally all expressed a desire for the number to be reduced. The author of this study is involved with a generics company which has specifically set out not to deploy a field force and instead interact through the Internet. On every occasion this concept has been introduced the reception has been very positive.

The observation previously made by a Practicing Physician that the Cheaper Medicines Act had paradoxically increased the number of Representatives calling was mirrored by a comment made by a Marketing Manager at a diverse MNC. Since the act came into force extra resources had been given to the field and patient program investment had increased. Again, one driving force behind this was to generate brand loyalty for off patent products. That said, in some cases the discounts offered under patient rebate schemes exceeded the mandated 50% applied by the government to competitor products.

The observation previously made by a Practicing Physician that the Cheaper Medicines Act had paradoxically increased the number of Representatives calling was mirrored by a comment made by a Marketing Manager at a diverse MNC. Since the act came into force extra resources had been given to the field and patient program investment had increased. Again, one driving force behind this was to generate brand loyalty for off patent products. That said, in some cases the discounts offered under patient rebate schemes exceeded the mandated 50% applied by the government to competitor products.

Products Promoted: A GM explained that Medical Societies are exposed to new products in some cases pre- launch in order to build support and provide a vehicle for MD education. This takes place starting from around 12 to 18 months prior to launch. The acceptance of the registration dossier by the FDA is

often the trigger for this activity as the registration process can take 12 to 14 months despite official claims and targets.

Branded generics or “me too” products are the most heavily promoted according to all practicing physicians participating in the study. Originator brands are also well represented, particularly to specialists. One MD described the level of promotion for unbranded generics as “zero”.

A Medical Student discussed another form of promotion with a representative of the PHAP Ethics board. Immediately after qualifying this individual noticed that the Consultants habitually “promoted” certain drugs for use in specific clinical situations. While it seems appropriate on the surface for an experienced Physician to offer guidance, the practice was to specify the brand rather than the generic molecule. This is a curious intervention since by law Physicians should prescribe by generic name only. In the opinion of this particular newly qualified Doctor the Consultants were in hoc to the drug companies, hence their behaviour.

Existence of Guidelines for Interfacing with Industry: An ex- board member of a leading Medical Society observed that most such societies lacked any code of conduct for dealings with the industry (PCP is an exception) and as a result much of the interaction dynamic was being shaped by PHAP. Over time (since the 80s) many of the excesses had been trimmed but non- PHAP members continued to exploit the willingness of the Medical Societies to indulge in social rather than scientific events.

A senior officer of the PCP advised that the official Code of Ethics covering relations with industry had been introduced 5 years previously due to a consistent campaign by the then President. Since then this interviewee was not aware of any of the specialist societies having followed suit; something he felt was linked to the short (one year) tenure of elected Presidents. While the PCP ethics committee does have some teeth- it can expel a violator- its mode of operation is purely reactive, convening only when a complaint is raised.

Individual cases of misappropriation of industry funds do reach the ethics committee. In one case a fellow who had been granted funding to train at the Mayo clinic in the US was found to have diverted the money for his personal expenses. This discovery was made several months after he was supposedly in the US, pointing to weak oversight practices.

The PCP called a meeting with industry CEO’s in January 2010 to discuss the issue of sponsorship. At this meeting the CEO’s admitted that the practice was ultimately unsustainable but when challenged as to why in that case it was so persistent some were forced to confess that there was no “plan B”. In other words the provision of sponsorship had become so endemic to the marketing group that it had crowded out other, potentially more constructive, ideas.

According to a senior officer of PCP overseas sponsorships are now being offered to quite junior doctors. In previous years the “frequent flyers” were almost always senior consultants but now even residents are being approached. This individual opined that such activity inculcated a sense of entitlement and a

culture of quid pro quo obligation very early in the doctor's career. This entitlement mentality was the biggest hurdle to introducing code of conduct for industry relations more widely in this observer's opinion. There is only limited cooperation between the PCP and PHAP on the subject of ethics. One senior PCP officer admitted ignorance of the PHAP rule on scientific content for industry sponsored meetings (60%). This respondent was aware of the PHAP rule limiting the number of MDs allowed to travel to any specific event but commented that this knowledge was only becoming widespread as the restriction was being used as an excuse by pharma companies when pressured for sponsorship.

The same MD also recalled a convention held by a Visayan chapter of the PCP which had been sponsored by a number of pharma companies. The major sponsor, a large local firm, obtained exclusive rights to an extravagant gala dinner at the end of the affair. The company then proceeded to convert the event into a launch meeting for a new product they were bringing to market; effectively hijacking the meeting. The officers of the society reacted negatively to this and imposed a one- year ban on the company sponsoring their events. The management of the parent company replied in kind by disengaging all subsidiaries for the same period.

Sponsorship of medical Society events is commonplace and the societies regularly solicit Pharma companies for support. Controls are patchy here. While the size of the donation can be managed the beneficiary of the bank account to which the money is transferred may not be known or even knowable. Company "A" only gives money to societies- never individuals but is obliged to take the recipient's word for the final destination of the funds. There is also the situation where a society has budgeted for e.g. 5 sponsors to cover its costs but then attracts 7 or 10. Where the extra money goes or how much of it there may be is not known to the sponsors.

Another chapter of a large medical society attempted to extort the industry by threatening to blacklist any company which failed to purchase booth space at their upcoming convention. While in this specific instance this plan was intercepted and overturned it is illustrative of a perhaps extreme example of a mindset of dependency.

Local Medical Societies actively seek out sponsorship from Pharmaceutical companies and individual Doctors do the same. Over time a widespread practice has evolved of Pharmaceutical companies sponsoring selected MDs to premier conventions. As one Marketing Executive explained the company budgeted for a specific number of sponsorships as part of its marketing plan and then "slots" were allocated to Representatives to sponsor Doctors from their territories. As international travel is not involved the PHAP regulations on number of participants do not apply.

Medical Societies have become adept at securing sponsorship and various packages are available to suit the Company's budget. Higher level "Platinum" sponsors may be granted the opportunity to hold their own satellite meeting at the convention location during lunch or dinner. No society officer interviewed was able to give an example of guidelines governing this process outside of purely financial objectives.

As has been noted earlier, there are no clear guidelines for interaction. One outcome of this is the extremely low rate of complaints received by the PHAP ethics committee from the Medical Profession. According to a member of the ethics team only one or two complaints were received per year. While it may be said that the PHAP ethics committee may not be the first or most obvious choice for Doctors with concerns over Industry practices it is self evident that large numbers of MDs are present at the various events sponsored by the Industry. It is therefore surprising that so few find a reason to complain about the industry's promotional practices.

Existence of Parameters to Assess Industry Provided CME: A senior Industry Executive stated that where meetings were sponsored by Industry the sponsoring company will have significant impact into the society meeting agenda; the societies themselves do not exert much effort in agenda control.

A serving officer of a leading Medical Society noted that there is no drive from the medical societies to address the issue of scientific balance or completeness at company sponsored scientific meetings. The society's officers are keenly aware of the need to keep the drug company money flowing in terms of sponsorship of conventions and purchasing booth space.

Generally the Society does not seek to influence the topic or content of the presentations at satellite symposia attached to the main convention.

PHAP Influences

1. PHAP
    a. Ethics Committee Enforcement System
    b. MRAP Compliance Management

Ethics Committee Enforcement System: Company "A" follows the PHAP guidelines on meeting location (business type venue, no resorts). All expenses associated with promotion must be receipted for reimbursement- this would also apply to regular field force activity. Since the control is applied after the fact a single transgression may not be prevented by the system; repeat offenses would be detectable.

PHAP provides clear guidance on ethics and operates an effective, independent ethics committee which is responsible for investigating complaints. The source of the complaint is invariably a competitor company which feels itself disadvantaged by the actions of the alleged transgressor there is no instance of an ethics issue being brought to the attention of the committee by a medical practitioner.

A review of ethics cases going back to 2005 revealed a trend towards fewer cases. In 2005 there were 44 cases reviewed plus 4 carried over from 2004. Of the 2005 cases 11 resulted in punitive action of some kind on the transgressor company with a further two cases of individual employees being disciplined. In 2006 the number dropped to 12 cases with 4 punitive outcomes. In 2007 the number of cases dropped further to 9 of which on l one resulted in a fine. The downward trend was reversed in 2008 with 21 cases however closer inspection reveals that 14 if these were proactive requests for clarification/ permission/ exemption so the total number of ethics violations handled fell to 7. In 2009 there were only 4 cases of which 2 were proactive requests for clarification of rules.

While this is superficially encouraging one GM observed that the documentary requirements for proof were a hindrance in surfacing issues since both parties have an interest in maintaining a clandestine relationship; the true level of malfeasance can only therefore be underestimated by case review.

It should be noted that more than one company resigned from PHAP over the period due to disputes over the application of the ethics code. In one case a major US multinational resigned during the review process however it is not possible to causally link the two events.

A senior cardiologist averred that it was possible to discern PHAP members from non PHAP by the nature of the interaction and enticements offered. PHAP members were perceived to be more restricted however this interviewee noted that often the differentiating feature was the convoluted way in which the member company sought to circumvent the association's restrictions.

A former GM recalled an ethics case where a PHAP member company had exceeded the limit on participants' travel by a factor of 7. The limit within ASEAN is 12 doctors, the sponsoring company sent 86. The offending company's (unsuccessful) defence when the complaint was filed was that the event

had been organized by the region and therefore the local limit did not apply. This would seem to support the observation of the doctor in the above paragraph.

It is interesting to note that the influence of PHAP extends beyond its membership. A top Sales and Marketing executive at a non PHAP company who had previously worked at a PHAP member related how the impact of the code had been carried over to the new environment. While the code was not being applied *in toto* (restrictions on travel numbers being the prime exception) the concept of ethical promotion was gaining traction and such things as medical oversight of materials and meeting agendas were becoming an established norm. Additionally, while numbers sponsored to overseas events were out of code the entertainment and accommodation were less lavish than in previous times. The encouraging thing here is that it may not be necessary for PHAP membership to be universal to positively affect the environment.

An interviewee with long experience of the PHAP ethics committee noted that the primary source of complaint was competitor companies that felt disadvantaged by the actions of the alleged transgressor. While this process is quite effective at surfacing issues it is not always successful in prosecuting the offender. The reason for this is the (natural) requirement for documentation. A particularly challenging scenario is when individual Medical Representatives complain about the actions of competitor reps on their territory. It is very hard to differentiate between a legitimate complaint and a bogus charge created to explain away poor performance on the part of the complainant. Hearsay and simple accusation cannot be sufficient for establishing guilt but there is little doubt that many detected transgressions go unpunished.

The PHAP code compares favourably with other such codes elsewhere and in comparison with WHO guidelines. Attached to this document is a point by point analysis recently completed by S Lazo MD, a member of the MeTA research team. This should not be a surprise since the code has to be consistent with the IFPMA constitution with necessary modifications to accommodate local legal requirements. The local law is regarded as the baseline or minimum requirement and there is no “upper limit” imposed. The most recent iteration of the PHAP code was drafted by an independent body with no representation from the industry on the team. It should be noted however that the draft had to be approved by the industry prior to its adoption. The code is also amended incrementally from time to time. While this study was being conducted two premier hotels in the Visayas region were removed from the list of acceptable venues for CME. In previous times the two hotels (both 5 star and at resort locations) had been exempted from the general ban on the use of resort hotels due to the lack of alternatives in the area. With more development business hotels had recently become available and the exemption was no longer valid. While this shows leadership from the top it is worth noting that a Product Manager, on learning the news, lamented that it would be very difficult to get good attendance at future CME events in the district.

As one member of the Ethics Committee noted the big issue is not minor weaknesses or inconsistencies within the PHAP code. These are quite easy to fix. The problem is that there is no umbrella code which

applies to the entire industry. PHAP has around 50 members who account for about one half of the market (value sales); its reach and influence are correspondingly limited.

This interviewee noted further that until there is balance from the MD side of the equation the situation will not improve. In this case fixing at least part of the supply may be more straightforward than addressing demand.

MRAP Compliance Management: MRAP (Medical Representatives Accreditation Program) was introduced in the early 2000's with the objective of setting a minimum standard for representatives. In recent times it has lost impetus and there currently is no active MRAP committee operated by PHAP. No data for enrolment rates are centrally held. A PHAP board member who served at the time recalled that participation varied greatly from company to company with enrolment rates between 30 and 80%.

MRAP has also influenced the outsource industry which has used the program partially as a marketing tool to assure potential Principals of the quality of their Representatives. An interviewee at a leading outsourcing organization stated that some 70 to 75% of its sales tram was MRAP certified at the height of the program and that its training group were still all qualified to teach the curriculum.

As has been noted previously MRAP is adrift at the time of writing. One member of the PHAP board was clear in that this must be remedied since this was the first line of defence against unethical promotion by PHAP members (non members may take the course but are not obliged to). There would still remain issues with the curriculum however in the opinion of the interviewee. The specific problem lay with over- specialization of the technical modules. These were generally written by specialist Physicians and, while appropriate for Medical Representatives who had products to promote in the related field, they were too detailed for Medical Representatives who did not. For example, a Representative selling a hypertension medication to Cardiologists would be expected to understand at least the basics of the Renin- Angiotensin system but a Representative discussing topical steroids with a Dermatologist would have no need for such knowledge. The curriculum would serve better if redesigned to have a baseline of general knowledge for all and specialist modules based upon the individual's product assignment. Of course this is still not perfect as the assignments often change but with many companies' training departments still qualified to deliver the program that could be addressed. The Ethics Module would then be common to all and the more specialized segment would help prevent misleading statements being made when Representatives are in a less structured detailing environment.

Trade Level Promotion

One effect of recent legislation to encourage substitution has been a shift in marketing focus to the pharmacy. One medical representative reported that a large local generics company was offering pharmacy clerks an incentive of a P100 mobile phone load for every three empty boxes of the company's products they could produce. The purpose of this intervention was to ensure that company's generics were the first to be recommended to patients asking for a cheaper option. Patients are commonly told that alternatives are out of stock. The program was run without the consent or knowledge of the staff pharmacist. It should be noted that most pharmacy clerks are poorly trained and few if any hold degrees in pharmacy. Generics substitution is increasing but has significant barriers to overcome key of which is the low level of public and physician trust in unbranded drugs.

One physician discussed the behavior of dispensing doctors and the types of commercial opportunities put to them by the industry (Note that the Philippines is a prescribing market, dispensing is only permitted if there is no pharmacy within the area. This clearly is not the situation obtaining in Metro Manila yet there are several hundred MD's dispensing. One common- and perfectly legal- work around is for a doctor to own a pharmacy across the street from his office). One large local manufacturer of (mostly) branded generics operated a quota system. In addition to volume discounts which can be looked upon as normal practice across many industries this company offered non medical equipment as an incentive for MDs reaching the consumption target. A popular choice given the hot climate was an air conditioner.

Rebates to trade and "loading"- the practice of offering a special limited period discount in exchange for abnormally high trade purchases continue although the latter is now less common in part due to legislation passed in the USA which impacts local subsidiaries of American companies. Again, it is not unreasonable to offer price advantages to large purchasers but choice can be affected due to the ultimate limitations of customers' warehouse space. One Operations specialist commented that since the price roll backs the calculation had changed in that the value of the discount on rolled- back products was now far less in absolute terms and the cost of warehouse space was therefore correspondingly higher this the trade was becoming less willing to accept high inventory levels.

The same manager noted that even with lower prices- which should translate into broader usage as more people are able to afford medicine- there has been little obvious investment in market expansion. At the time of writing there has been little unit growth except for anti- biotics. A senior manager at a large distribution company noted that since the price reduction has squeezed budgets it is not surprising that companies are backing away from more indirect means of promotion however the unintended consequence may be an intense fight over the existing patient pool which will retard the spread of newly affordable medicines to the less affluent.

A GM reported that a sales representative attempting to get the company's products listed at a mid- size hospital in Metro Manila was told by the hospital director that a donation of 20% of the value of sale

would have to be made to that individual in person as a condition of approving the listing. The products involved were low cost generics.

A senior executive at a large outsource/ agency business commented on the increasing rates of substitution and the measures that were being taken to address this. This company had recruited a specialist team of around 15 persons to visit Pharmacies and engage the pharmacy staff. The materials presented covered the importance of Bio- Equivalence and the need for properly conducted clinical studies to establish effectiveness. Since the FDA does not generally require BE studies and generics companies have no incentive to conduct clinical research (this having been done by the originator during the patented period) a typical purveyor of generics will not meet these criteria. The message is clear therefore that generics lack critical elements vital to establish trustworthiness. This project has been running for 3 years; before its inception substitution rates were as high as 30% even in high- end outlets catering to wealthy clients. Following the introduction of this program the rates at key drug store chains dropped and the results have been sufficiently encouraging to extend it to independent drugstores (which often cater to the C2 and poorer demographic).

The initiative above is supported by a feature of the drug store chains' compensation schemes. Like many businesses drug stores provide their retail outlets with sales targets which are generally based upon previous levels of business. The Cheaper Medicines Act has upset this system by reducing the value of the products dispensed (there has been little sign of any compensatory increase in volumes). This means that the Pharmacy staff have been losing money as their incentives have not been paid. As a consequence they are receptive to messages which will help them promote higher priced medicines. A top executive at a major Pharmaceutical company which actively promotes a message of non-substitution reported that shortage of income was perceived to be an important behavioural factor among Pharmacy staff. It is important to remember that much of the dispensing done in Philippine Pharmacies is by clerks on the minimum wage.

One loophole in the PHAP code can potentially be exploited by less scrupulous companies. The PHAP code concerns itself with professional communications i.e. communications between representatives of the industry and Physicians, Pharmacists and other healthcare professionals. Technically it could be argued that a pharmacy clerk is not a healthcare professional since they generally lack the necessary educational background and therefore communications with them would not be covered by the code. On the other hand this could also be interpreted as discussing prescription medicine with a member of the general public which is banned (even though this specific member of the general public spends the working day dispensing pharmaceuticals). If, as some trends in the industry seem to indicate, trade level promotion is going to become a more significant feature of the landscape it seems sensible to be specific about acceptable communication in the code.

While the generics law encourages substitution it seems reasonable to suppose that those framing the regulation had envisaged such substitution being made either by, or under the close supervision of, a properly qualified pharmacist. In reality this is not the case. As one long experienced executive pointed

out many pharmacies do not have a pharmacist on the premises for most of the time. It is a well established practice for pharmacists to “rent out” their licenses to provide legal cover for unqualified personnel to operate a retail pharmacy without ever setting foot in the premises themselves. This means that much of the substituting is being done by unqualified staff who may have a financial stake in promoting one branded generic over another. This is not well regulated by the ethics code and recent changes in the industry point to a sharply growing need to address this. This phenomenon has been characterized as an emerging issue by several interviewees.

As the use of generics becomes more widespread the role of trade level promotion (as opposed to MD detailing) is likely to increase. A Director of a local generics company who had previously worked for a large MNC noted that the trade was compensating for lower Suggested Retail Prices by demanding bigger margins. A second factor in the margin discussion is that the trade is passive with regard to patented products where there is no generic competitor and demand is driven by MD prescription. Research companies therefore focus promotion on the MD and do not see the need to woo the trade with large discounts. With substitution becoming more prevalent there is a transfer of power to the Pharmacist which is impacting strongly on margin negotiation forcing drug companies to compete on price but the retailers are not necessarily passing these savings on to the consumer. To give a sense of the market dynamic a large MNC would expect a retail chain pharmacy to apply a margin of around 10% on a patented product. For unbranded generics the margin would be 40% to 50%. For reasons of anti-trust the PHAP code is perforce silent on pricing and ultimately economic considerations will result in some stability but discounting practices could be an emerging issue depending on how they are executed.

Negative Promotion

A senior practicing physician observed that historically the attraction of cheaper generics had been mitigated by trust issues. The Medical Profession had low confidence in the quality of these medicines and, by extrapolation low confidence in the capability of the FDA to guarantee standards. This negative perception of the FDA was also noted by a senior academic physician.

The effectiveness of the FDA in QA is outside the scope of this study however in earlier times the industry was able to sow fear of substandard medicines. While a degree of skepticism is reasonable given the prevalence of counterfeit drugs in some pharmacies a Public Relations executive stated that there was a deliberate communications policy to draw the public's attention to the subject. The morality if this is for others to judge. It may be viewed as an altruistic endeavour to protect the population from dangerous counterfeits or a cynical attempt to instill fear and position brands as the only safe choice. The consensus view of both industry and physician interviewees was that this negative publicity had diminished considerably in recent times.

For companies marketing to the paediatric market there is a sense that the cheaper medicines act will have muted impact. A top Marketing executive stated that parents were very reluctant to take risks with the health of their children and therefore would stick to tried and trusted brands (including branded generics) regardless of price. Messages were being geared to undermine confidence in unbranded generics.

While not strictly Negative Promotion the research based industry does expend time and money on publicizing the need for tests such as Bio Equivalence whenever a generic copy is introduced or competes for a hospital tender. Whatever the scientific merits of this requirement the fact is that the competent local authority has already issued guidelines on which molecules do and do not require BE.

Whether due to this activity or otherwise a number of Hospitals have taken it upon themselves to insist on BE studies for compounds not on the FDA list for such testing. Again, it could be argued that this is being done to enhance patient safety but the action results in usurpation of the FDA's authority and constitutes a significant barrier to entry, especially for smaller generics companies.

International Comparisons

A regional Compliance officer with many years experience both in Asia and other developing and developed countries agreed to share perspectives on the practices in the Philippines compared with other countries in the region.

The interviewee who is responsible for 14 countries from Pakistan to New Zealand explained that there were three general clusters unto which the various territories fell. Cluster one is highly regulated with strict, effective controls. Typical examples would be Australia, New Zealand and recently Korea. Cluster three is at the other extreme with no effective regulation and a culture highly tolerant of corruption. China and India were examples of this grouping. The middle cluster included Malaysia, Thailand and the Philippines where some effort is being made to tackle ethical issues but the status is clearly a work in progress. This executive noted that due to the decentralization of health care there was less government corruption in the Philippines, as another interviewee noted however this most likely means that the problem has been pushed down a couple of levels rather than being eliminated.

Elsewhere the problems varied from designed underfunding in China leading to corrupt practices in order to balance the budget to a warehouse full of designer goods from which Indian doctors were invited to make their selections.

When compared to other countries in the same “cluster” the interviewee assessed the PHAP regulations as being well drafted and in terms of enforcement the Philippines was leading the group. There are a couple of areas where the Philippines stood out:

Call rates and representative productivity: The Philippines is unique on the region in the frequency with which doctors are visited by medical representatives. Call frequencies of one or more times per week are not unusual and this has led to very low field force productivity.

Marketing Costs: The absolute level of expense was in the high side on the Philippines but perhaps of more interest were the drivers of these costs: meetings and meals. These are expenses closely associated with social “relationship” marketing and where supervision of the agenda is difficult. By contrast gift giving was modest in the Philippines compared with other countries and the gifts themselves tended to have at least a tenuous link to the practice of medicine or patient welfare.

MD Loyalty: The interviewee noted that the result of long term relationship building has been a high degree of MD loyalty to specific companies and/ or drugs. This manifests in the extreme longevity of brands which often continue as unit market leaders long after patent expiry when far cheaper generic alternatives are already available.

Overall in terms of issues raised relative to the size of the organization and the market the Philippines fell in the middle of the 14 nation pack with a subjective estimation of the level of corruption of 5 to 6 out of 10.

Note that in the specific case of this section only a single position holder was available to interview. This individual, while having wide experience, is obviously more acutely aware of the situations occurring in the company of employ. While there is no reason to doubt the veracity of these statements the perspective is perforce constrained.

Patient Promotion and Compliance Management

Initiatives directed at improving patient compliance post- prescription have been in place since at least the mid 1990s. According to one of the early innovators in the field the objective was to improve compliance (and thereby sales volumes) by providing patients with incentives to continue treatment. For perspective it should be understood that at the time of introduction the average prescription size for chronic medication (e.g. anti- hypertensive treatment) was less than 20 days and the average number of tablets purchased was around 10.

Early designs featured a discount card which patients could present to participating pharmacies in return for which they would be able to purchase the medicine at a discounted rate. The discount cards were provided via the patient's Doctor and the Pharmacy was reimbursed for the lost revenue by the Drug Company. One reason for implementing this process was the observation that manufacturers' price discounts often were absorbed by retailers as additional profit with the sales price to the patient remaining the same. The card was intended to prevent the trade from benefitting and provide the patient with a lower price. In addition to discounts, patients were sometimes provided with educational materials or other collaterals to support improved adherence to therapy.

In recent times the use of patient cards has declined in popularity, issues of universality of access and patient confidentiality being among the prime areas of concern (not all MDs were given cards by the Representatives therefore not all patients had an equal opportunity to benefit). There remain some in circulation however and a Senior Marketing Executive explained how one such scheme worked.

A number of cards is first allocated to individual members of the sales force. The Representatives are responsible for identifying which Doctors on their territories will be offered the cards. Marketing does not specify selection criteria. Obviously doctors of low interest to the company (due to being difficult to reach; having a small, poor practice or specialists in a field of medicine for which the company does not have a product option) would be excluded by default since they would not be on the representatives' call list in the first place. Once the initial allocation is consumed the Representative can request for more. The Representatives distribute the cards to the Doctors and report to marketing to whom the cards have been given. The cards themselves are machine readable and readers are installed (not by the company) at participating Pharmacies. The cards are activated by a third party agency and, once accepted will entitle the patient to a discount which can be anything from 20 to 50%.

While this company blinds itself to patient data MD uptake of the cards is monitored and more active participants can expect to receive further stocks.

An alternative benefit under one scheme is generated by the reader which maintains a running total of tablets purchased against the card. Once a target number is reached the machine prints out a coupon entitling the patient to further supplies for free. It could be argued in this case that the machine is

therefore practicing medicine since it is effectively issuing a repeat prescription however the interviewee stated that participating MDs were informed of this and presumably stand behind the"Rx".

The usage data is monitored by the third party which also holds patient information (i.e. the Pharmaceutical Company does not have access to patient data). The Pharmacy is then reimbursed for the discount and also is paid a data handling charge. For logistical and data processing reasons it is generally large chain Pharmacies which participate in these programs rather than small independents although the ubiquity of readers (which tend to be specific to a given company) varies according to which company is running the scheme. Some programs have national coverage; others are focused mostly in Metro Manila,

The cards do not carry brand names due to local restrictions on patient communication but the programs themselves will typically have a "brand name" [Note that some Pharmacies also run schemes for regular customers which are similarly branded]. The cards may be accompanied by other materials produced by the company which address "FAQ's" associated with the use of the product. One example would be the enrolment form which the doctor gives to the patient on initiation. Since this happens post- consultation the intention is to support the dosing and other instructions given by the Doctor to the patient.

As mentioned above the penetration of electronic readers varies according to the design of the scheme and the sponsoring company. A Marketing manager at a large MNC stated that one competitor had installed machines on a national basis in almost every available pharmacy. While this infrastructure could be a potentially valuable resource the readers were dedicated to the individual company programs. The interviewee noted that this meant they were idle for much of the time and perhaps other data processing tasks could be assigned to improve general health.

Post Marketing Survey

All Senior Managers interviewed stated that there had been a sharp decline in “experiential” trials. These are relatively informal studies which may or may not have protocols developed with proper scientific oversight and are designed to increase uptake and usage of a drug. The overall concept is straightforward. A number of tablets (say 5 strips of 10) are provided to a practicing MD. This Doctor is then asked to find 5 suitable patients each of whom is given a free starter dose (these trials almost universally apply to chronic medications and the 10 tablet course is not therefore expected to be curative). Patients are responsible for purchasing further quantities of medicine and the Doctor performs an evaluation (usually of an already well- established product parameter) at say 4 and 8 weeks. There would normally be a fee for service paid after all 5 patients have completed the study. The data are then collected and processed by the Drug company and the results used for production of marketing materials which would note that the compound had been now tested locally. The data were not submitted to the FDA under normal circumstances nor were they submitted for publication in a peer-reviewed journal.

The ethical shortcomings of this device are obvious and do not need to be discussed here. The positive message is in the reduction of such activity and several Multi- Nationals have now completely abandoned the practice. It is still occasionally employed by non PHAP companies however.

A more representative picture emerges from an interview with a top industry executive. In this PHAP member company all research protocols are developed with regional/ HQ approval and inputs from local Medical staff. Studies may be pre- or post- marketing but in both cases the data are submitted to the local FDA (often as part of the regulatory submission). All materials are supplied and physician compensation is calculated on the basis of level of effort, complexity, burden of documentation and other relevant parameters. Relative to a standard consultation fee (say P500 to P700 for a top Manila Hospital) the compensation is generous with P5,000 per patient being unexceptional. For more intensive investigations with extensive lab and other work that fee could rise to P20,000. The interviewee also noted that investigators were equally keen on the exposure given by having their names on the final paper. Occasionally with trans- national studies an investigators’ meeting would be scheduled outside the country. PHAP has in the past been lenient about granting exemption from attendee limits on the grounds that these meetings are not convened by the local entity and do not feature marketing presentations.

Structural Adjustments

Over the years the Industry has sought to protect sales of its off- patent brands at lower cost by developing an outsourcing strategy. Under this arrangement a third party is contracted to maintain the sales performance of one or more older products while the originator concentrates on building the newer, patented brands. While not a new strategy this has developed in to a significant feature of the landscape since the mid 1990's when the concept began to take off. In fact a top Executive at an Outsourcing company observed that the Cheaper Medicines Act had been positive for certain parts of the business as clients looked for lower cost ways to promote products; this organization was looking to expand.

Outsourced capacity is used in a number of different ways by Originators:

1. To extend field force capability and reach during the launch phase of a new product
2. To act as a local agent where the business is too small to support a direct presence
3. To extend the life of older, low- priority brands (usually post- patent)

There are a number of companies operating in this market segment from the very small (sometimes marketing only a couple of products from a single company with which there may be some shared history) to the very large. The biggest player fields 900 Medical Representatives although this particular business is diversified and also handles a number of compounds on its own account along with several agency agreements. Around 550 of the Representatives are assigned to contract selling activities. Whether acting as a contract sales force or operating as a *de facto* local branch these staff are generally motorized unless the principal wishes otherwise.

Of the three main business models listed numbers 1 and 3 are of most interest to this study.

In scenario 1 the 3rd party supplier typically supplements the sales force of the originator company by reaching customer groups of lesser priority or where the principal's relationships are weak. An example of this would stem from the tendency of Multi- Nationals to focus on specialists (this is not a universal tactic but quite commonplace). The 3rd party sales team would then be expected to promote to GPs and Family Medicine practitioners for example. Alternatively the tendency for the coverage plans to overlap (i.e. the same MD would appear on the call decks of both Principal and Outsource sales forces) may be deliberately exploited to increase the exposure of a group of Doctors to the brand. It would not be unusual for a high priority MD to be visited 6 times in a month (4 times by the Principal and twice by the Outsource) under this arrangement. High frequency calling is occasionally referred to as a "Show of Force" in the industry and is used to increase awareness among the Medical Profession and intimidate competitors. Of the GMs interviewed for this study most had employed this tactic from time to time, generally for a limited period due to high cost.

In scenario 3 the target compound is generally at the opposite end of its life cycle. It may be off- patent, off- strategy or simply have been overtaken by competitors or an in- house discovery. Overall the

intention of outsourcing is to slow the rate of sales decay for an older compound- often long after patent expiry. A top executive at one large outsourcing company explained that a "cost plus" model was offered to Multi- Nationals under which the outsourcing company would recruit, train and manage a contract sales force to promote a compound or compounds. A typical sales objective would be to either maintain existing sales (improving margin for the Originator as Outsourced sales staff are lower cost) or to grow at a 10 to 20% annual rate. This particular organization handled only branded products. There were no plain generics in the portfolio although by configuration this would be easy to do.

There is a potential moral hazard in outsourcing. Although Sarbanes Oxley constrains the US companies from "outsourcing" bad behaviour a third party may have more degrees of freedom than its principal to indulge in questionable practices. According to a Senior Executive at one large Outsourcing company this risk had been turned on its head to generate a marketing platform.

Conscious of the environment in which its principals are operating this 3rd party Contract Sales company had joined PHAP and followed the promotional guidelines assiduously. In those cases where the production of promotional materials was delegated to the Outsourcer the procedure for quality control was closely modelled on Multi- National standards and involved qualified Medical staff in the approval process. The interviewee reported that the Principals frequently conducted audits of the company and adherence to ethical practices was one of the key points of emphasis.

In scenario 2 above the outsource company is functioning as a local branch of the Principal. Many foreign manufacturers employ this strategy to facilitate a lower cost entry in to the Philippine market and there are many local organizations actively pursuing this line of business. In general the local company will develop the business to the point where it becomes attractive for the foreign entity to establish a direct presence at which time the business is spun off (effectively purchased back by the Principal). During the build- up phase the local agent is responsible for the development of marketing materials and quality control over this process is varied. Most Western Multi Nationals have already established themselves in the Philippines; some smaller ones and MNCs from other nations are still in the agency stage. According to one executive at a well- established agency the Western companies generally played an active role in the production of marketing materials with guidelines being produced regionally/ from HQ and some degree of direct supervision. Asian Multi- Nationals (Chinese, Indian being the dominant group) tended to be more relaxed and granted more day to day autonomy.

The local agent makes its money on the transfer price mark- up. The study of transfer pricing is not within the scope of this research however the general margin available is relevant as it sets an upper limit on investment (local agents who know the business will ultimately be taken away tend not to tolerate long term losses in the interest of building the business however they may be in a negative P&L situation from time to time). Margins would be in the neighbourhood of 70- 75% (i.e. the agent would buy at $25- 30 and sell at $100) although this was not always delivered entirely through pricing as free goods and promotional support grants were used to support local initiatives. For example the transfer

price may be $40 but 10% free goods may be provided plus a cash allowance of 5% of sales for promotion.

It is also not uncommon to outsource a single part of the business. A Director of a local generics company noted that outsourcing was used to service market segments which are not covered by the larger distributors. In most cases this refers to smaller drugstores that deal on a cash basis but may also include Dispensing Doctors. This executive noted that there were outsource agencies employing pharmacists as salesmen to supply products to these accounts. The outsource agent acted as a passive supply chain component and did not promote one brand over another but the principals were able to negotiate discounts and other terms directly with the MDs which were then fulfilled by the outsource company. This arrangement opens the door to some moral hazard as physicians may be influenced by profit motive rather than clinical outcome expectations.

Another potential area for moral hazard is in the incentive program provided to employees of outsource companies. A has been noted elsewhere in this survey incentives based purely on sales outcomes risk tacit approval of unethical practices and many companies have recognized this by including behavioural components into the system. Outsource companies also run internal schemes including when they are acting as contract sales organizations. As described by a top Executive at an outsource company these were similar to the schemes in place at the Principal and the Principal was encouraged to supplement the internal scheme with its own plan. This provided an opportunity for the Principal to direct the program and include non- sales elements.

As we have seen above the outsource companies are a growing and important feature of the Philippine Pharmaceutical Industry. The products they promote are therefore important to the make- up of the overall character of the market. One interviewee at a major player was clear on the parameters of product selection: they did not handle plain (unbranded) generics. The philosophy was to work with MNCs with a portfolio of off- patent drugs and form them into a branded generics unit. These branded generics would be priced at around 80 to 85% of the originator and promoted to MDs via a large sales force. The outcome of this is to disproportionately alert physicians to the availability of branded generics over unbranded.

Corporate Social Responsibility and Promotion

Pharmaceutical companies of all sizes are involved in CSR to varying degrees. PHAP Cares, a sister association of PHAP, provides a vehicle for donation of free goods on both a continuing basis and as a calamity response. PHAP members are expected to make available a quota of medicines on an annual basis.

While this charity can provide a degree of relief in the right conditions its scope is fairly limited and many companies have taken it upon themselves to do more. Since this often involves contact with the general public it is an area which needs to be monitored from the standpoint of promotional communications.

It is not universal that CSR is directed at communities, disease states or issues in which the company has some kind of vested interest. At least one company selected its program on the basis of criteria which included a complete absence of commercial interest in the sector. It is more common however for the chosen intervention to be related in some way to the company's area of portfolio interest. This is not inherently bad. Clearly a large commercial organization with an understanding and level of expertise derived from prior involvement will potentially have useful knowledge and contacts. On the other hand, what may appear altruistic could also be disguised market development. Again, enlightened self-interest is not a crime but disingenuous involvement and concealed marketing is not consistent with the highest principles of charity.

A largely neglected discipline until the mid 1990s many larger corporations have now developed sophisticated Public Affairs/ Public Relations capabilities aimed at both professional and lay audiences.

While some are more advanced than others the best- as described by a senior executive at a large multinational- provide product promotion, market development/ disease awareness, corporate image management, community outreach and CSR services. In recent times this has meant getting involved with access to medicines.

A top practitioner of Industry CSR pointed out that one important step in achieving access not normally thought to be under the influence of the industry is the availability of properly qualified medical and life science graduates. With this observation in mind this company had initiated a program of developing local scientists (some but not all were MDs) in order to build capacity in the country. The company organizes a "bio camp" and holds contests and competitions judged by an expert panel consisting of 3 third party academics and 2 company representatives. The chosen fields of study were not related to the product portfolio.

A more direct linkage was found with the same company's support of Heart Health (they were active in the anti- hypertension market). In this case a partnership had been formed with the Hypertension society and young people were invited to make videos promoting a heart healthy lifestyle. In recognition

of the role of family in decision making these videos took the form of messages from youngsters to parents and other older family members. Once again external adjudicators selected the winning entries.

In addition to the fairly obvious partners available within the healthcare community one multinational had found cooperative opportunities with the CSR efforts of other industries entirely. As a top executive explained industries such as oil and gas have developed extensive distribution capability in far flung areas often poorly served by the pharmaceutical industry. Using this external partner the drug company made available life saving medicine at cost to under developed provincial areas. This interviewee commented that true access for the poor meant more than pricing action. Affordable drugs are of no benefit if the nearest location from where they can be purchased is a day's travel away. Not only was this inconvenient but the cost of the journey would eat into the limited budget available to purchase medicine.

In neither of the above two cases was there any expectation that the sponsor would directly derive income from the activity. Another area of focus for PA/ PR has a better defined link to commercial objectives and this is market building. As a senior executive explained, this action can happen at any point in a product's life cycle depending on a number of parameters. If the product was intended to treat a disease that was not well known or previously had inadequate treatment options the objective was to raise awareness of the existence of the disease among potential patients and the availability of a new treatment among Physicians. If the disease state was already well understood and several treatments were on the market the expansion program would only be pursued if the company had market leadership (so that it would derive the most benefit from an increase in the rate of diagnosis). In either case the process was essentially the same.

In the first, awareness, stage Doctors are informed about what is about to happen. This has three effects according to the interviewee. Doctors do not appreciate patients coming to the demanding a treatment they themselves are unfamiliar with so the "warning" was important to maintain good relations. Secondly, the anticipated uptick in consultations meant that the Doctor's fee income would likely accelerate which was generally quite popular and again served to improve the Doctor/ Company relationship. Finally those doctors who already had diagnosed patients were made aware of a new alternative and were encouraged to try it out.

In the implementation phase the tactical execution can vary according to the specifics of the product and the nature of the disease. "Silent Killers" i.e. largely asymptomatic disorders with life- threatening potential are a popular target for awareness campaigns. The approach described by one top executive served as a good model. The PR department would work with Medical and Marketing to understand the patient population; for example elderly women would be the "target group" for osteoporosis. The PR team would then set about finding what media were popular with this cohort and develop a message to stir them to take action (normally this would be a very simple self- diagnosis questionnaire followed by an exhortation to consult a doctor if the questions were answered in a specific manner that could indicate either elevated risk or active disease). In all companies interviewed the preparation of patient

communication materials were subject to the same Medical oversight processes as Doctor- oriented materials. Interviewees were all aware of the PHAP and FDA regulations against promotion of ethical drugs to the public and took effective steps to comply.

The information was then released to the public in two ways: paid ads and press releases. In both cases company materials did not mention brand names although generic names were frequently used. This was compliant with the regulations but there was one loophole. Journalists writing health columns in the lay press had no difficulty in finding out brand names and frequently used them in their articles after a press conference. One journalist claimed rather unconvincingly that generic names were difficult for people to deal with and snappier brand names made for more legible copy.

Continuing the journey from the most indirect to the most direct forms of promotion undertaken by Public Affairs/ Public Relations teams the next in line is the support or sponsorship of screening clinics for disease states treatable with the company's products. This is a category of the "Market Building" discipline and is its most tactical manifestation. Often in partnership with a Medical Society or group of Physicians, mobile screening clinics offer free diagnostic services. Typically the doctors donate their time and the drug company arranges for publicity (before and after) and attends to most of the logistical requirements. In the event that a suitable patient is found through this endeavour the expectation is that the sponsor's drug will be the first line choice. Occasionally the sponsoring company will have an OTC medicine which can be used for treatment or perhaps adjunctively. In these cases sampling may occur which is entirely within the code.

Not all patient directed communication is designed to increase drug consumption. As a senior PR executive explained healthy lifestyle choices were frequently encouraged through a variety of media. These recommendations were developed in close coordination with professional Medical Associations and were intended to offer an alternative to drug treatment. Examples of this include publishing low sodium cookbooks for hypertensives and less targeted interventions such as promoting weight management. Obviously the same advice would be of value to support patients undergoing treatment with the company's products as well.

One top Executive with long experience of PR in the local industry was at pains to point out that all activities were compliant with the PHAP code and care was taken not to give the general public information on individual medicines. The Medical Community was very capable of discerning the product which was intended to benefit but not the layman.

Results and Conclusions

Introduction

The promotion of ethical pharmaceuticals in the Philippines is a complex and sensitive subject. For many years stakeholders have adopted largely antagonistic positions with little constructive engagement taking place. Agendas- hidden or declared- are abundant.

MeTA seeks to change this environment and one step in this direction was the commissioning of this study to survey the landscape and open the way for a rational debate based on facts. As is the nature of such investigations all sides will be able to find data to support "their" world view but this is not the most constructive use of the material. There are significant areas of alignment- or at least the potential for it- available to those willing to understand the objectives and concerns of others.

At core the issue breaks into two components: Lack of Universal Standards and Poor Enforcement of Regulations.

Universal Standards

Promotional Programs

For the industry as a whole the key dividing line is not research versus generic or local versus foreign, it is PHAP membership. While it is an oversimplification and something of a mischaracterization to classify members as "ethical" and non members as "unethical", there are behavioural and attitudinal differences between the two groups. Interviewing staff from PHAP member companies a consistent theme was a sense of being at a disadvantage relative to non members when it came to promotion due to the presence and enforcement of the PHAP ethics code. Talk to a Marketing executive at any level and you will soon hear him or her refer to the "level playing field". From these discussion is was the author's distinct impression that these marketers did not actually want to indulge in unethical practices- to the contrary many were proud of their ability to rise above it. This attitude is not all- pervasive; considerably energy and imagination is expended to exploit loopholes rather than adhere to the spirit of the code but it is fair to say that the overwhelming majority were trying to do the right thing. The problem was that all too often they had seen the results of trying to do the right thing in terms of mercurial customer loyalty and diminished market share and were frustrated that the "cheats" were prospering.

Why is this so and what forces are at work? First off, a little context; it is clear from the interviews of more seasoned marketers and Doctors that the situation has improved markedly in recent years. Oftentimes this has been the result of strict internal policies being handed down from HQ (especially for American companies) and has had little to do with the local situation other than a prescription to meet the higher standard of either local or corporate code. European companies tend to be a little more relaxed but are also moving uniformly in the direction of restricting promotional practices on a global

basis. Combine these drivers with the efforts of the PHAP ethics committee and there is a clear if uneven trend toward more ethical marketing practices. Both PHAP and non PHAP companies are moving in the same direction but the speed and end points contemplated by the two groups are not the same.

The portion of the industry outside of PHAP (mostly but not exclusively local) tends to see the PHAP regulations as overly constraining, driven by foreigners and out of touch with Filipino cultural norms. They claim that they are doing nothing illegal and appear satisfied with this argument. Without debating the specifics of certain programs which certainly would not meet international standards of "avoiding the perception of corruption" the constructive response has to be to challenge whether minimum compliance with the letter of the law is the standard against which an industry should be judged. A more robust reply could equally be that their behaviour makes a powerful case for more aggressive legislation. It is also well worth noting that PHAP has a large number of local companies among its members which rather undermines some of the cultural sensitivity defences.

What is beyond doubt is that two different standards are being applied in terms of what is permissible. What is also obvious is that the Medical Community has realized this and adapted accordingly. In several interviews respondents explained how Medical Societies or individual Doctors would approach different companies according to the nature of the need. For CME purposes (lack of QC notwithstanding) the research companies were the first port of call. For less scientifically oriented gatherings non- PHAP local companies would be approached first.

All of which brings us to the other partner in the deal- the Medical Profession. It is possibly controversial but not unreasonable to postulate that many of the ethical promotion issues would go away were it not for the fact that junket trips result in higher sales. At the end of the day the drug companies are spending their shareholders' money and would not make the investment if it didn't bring a business return.

For the Medical Profession the dividing line is less clear. Both individual MDs and Societies demonstrate the full spectrum of those who actively seek opportunities to participate in unethical practices, those who tolerate it and those who shun it. Perhaps unsurprisingly some younger Doctors have a tendency towards greater idealism but this is often tempered by financial considerations. Older practitioners have been conditioned by many years exposure to the bargain between the industry and the profession, have integrated it into their world view and are generally less questioning of the status quo.

What is apparent however is the number of missed opportunities for inculcation of ethical practices throughout an individual's career. Ethics training at Medical School is rudimentary at best and there does not appear to be any educational program in place post graduation. While it is true that the PMA has fairly recently developed a code of ethics, awareness and enforcement leave much to be desired. No MD interviewed for this survey was prepared to support the contention that the code was widely understood and followed. The continuing behaviour of some individual MDs, informal groups and societies in seeking to extract money and favours from the industry is evidence of how far there is to go.

Universal Standards

Messages

The foregoing section has concerned itself with the more accessible parameter of what is done. Of at least equal importance is what is said.

Simply put the Pharmaceutical Industry has got itself into a promotional arms race and its customers are either complicit or powerless to take action. The primary reason given for many of the interventions sponsored by drug companies is always increased access to Doctors and prolonged "face time". This has become necessary because sales forces are so huge and the number of Representatives queuing to see a Physician so large that the interaction time with the Doctor during routine clinic coverage has degenerated into a 90 second signature collection drive with attendant sample dropping. The sales force is essentially fulfilling the role of a brand reminder item and conveying minimal scientific information to the MD. As the number of Medical Representatives has steadily increased they find themselves competing for the Doctor's "memory space" with several other salespeople offering the same or a very similar molecule. Even if a scientific discussion were possible it is not obvious how multiple different brands of the same generic could be differentiated on the basis of clinical effect. These factors lead almost inevitably to high frequency calling (so that the Representative's brand is still top of mind when the next case presents) which further erodes the likelihood of scientifically relevant information being discussed (it is hard to bring four new discoveries a month to the doctor's attention- particularly when no research has been done on the molecule for several years). The only tool left in the hapless Representative's box is therefore relationship building and what better way to make friends than to offer free benefits?

Note however the use of the qualifier *almost* in the foregoing paragraph. The high frequency/ minimal scientific exchange model only prospers because Doctors tolerate it. Although some hospitals restrict Representatives access individual Doctors (including those working at those hospitals) continue to see Representatives on a regular basis.

Even when extended interaction is possible or a scientific agenda forms the basis of a meeting not enough effort is being made to monitor the quality and delivery of the information. Such Quality Control as exists resides exclusively within the drug companies themselves and not all are configured or equipped to fulfil this role in the first place. Some steps have been taken to involve outside experts in the development of educational material but the Medical Societies appear content to delegate this task to the industry. At a company sponsored event the proportion of the agenda given over to science is controlled by PHAP for members but the content is entirely at the company's discretion. For non- PHAP members both factors are under company control.

Enforcement

The competent authority regulating Pharmaceutical Promotion is the FDA. Unfortunately it is very clear from the interviews that the FDA is not effective in this role. Internal issues of communication, number of trained staff, work load and priority all seem to move uniformly in the direction of poor oversight. PHAP attempts to fill the void for its member companies and PMA has made a start from the Physician side but the level of coordination between the two is not great and much of the industry and the supply chain falls outside these organizations.

One interesting thing to emerge from the recent MeTA workshop session with representatives of the research industry was a common appeal for greater enforcement and a universal desire not to have this done by the Government. This was not born of a fear of over- zealous politicians but rather a concern that such enforcement would be ineffective. Whatever the merits of that argument it is fair to say that there is currently no effective enforcement body with the mandate to oversee the process of Pharmaceutical Promotion in its entirety. In the absence of such an authority cynical abuse of the rules will continue and the best one could hope for would be incremental change in a portion of the market; specifically local subsidiaries of foreign companies responding to Head Office mandates with the Philippines getting a free ride.

For enforcement to work the alleged transgression must be detected, guilt established and an appropriate penalty applied. None of these three stages is working efficiently in the Philippines. The FDA is not equipped to detect anything much beside errant point of sale material, has insufficient qualified staff to assess materials presented to it and has a clumsy schedule of penalties that are not an effective deterrent. PHAP does rather better on adjudication but its detection is limited and again the schedule of penalties is not a serious threat, at least to a medium sized company. PMA is only just getting started and has yet to demonstrate its capabilities. And nobody is looking at the content of scientific meetings beyond a mandate to set aside a certain amount of time. It is this feeble enforcement environment, overlaid with the easy success to be obtained through questionable promotional activities which is the root cause of the malaise.

Recommendations

The critical need is for effective regulation on both sides- Industry and the Medical Profession. It is important to recognize that no amount of action by any individual stakeholder (with the possible exception of the FDA) acting in isolation will remedy the problem. In order to bring Pharmaceutical Promotion in the Philippines into an ethically sound environment two things must change together: What is Done and: What is Said

What is Done is the most visible- Sponsorships, gifts and the other lightning rod activities of the industry as it promotes its products

What is Said is less visible and has been something this study has tried to bring into the light- what are the messages, who is controlling the conversation, are promotional statements based on real science?

Of the two, What is Done is potentially the easier to fix in the short term. A level playing field should be created and the level of that field (i.e. what is allowable) should be dictated by patient interest.

There are three components to this

- Universal rules governing the entire Pharmaceutical Industry
- Complementary and coordinated regulations for the Medical Community
- Efficient and Impartial Enforcement of the above

This in turn begs four key questions

- Who will write the rules?
- Who will detect transgressions?
- Who will enforce the rules?
- What sanctions will they have at their disposal?

Let us consider these last four questions in turn: They can be thought of in terms of the Legislature, the Police, the Courts and the Penal System.

Writing the Rules: The Legislature

The PHAP code may represent a starting point for a universal code for ethical promotion. As can be seen from the comparison made by Dr Lazo of MeTA (attached) the current iteration of the code is compatible with the WHO and forms a practical basis for regulating the Industry. [Note that the section covering advertising in this analysis needs to be read in conjunction with the overall standards for substantiating claims in section 2 of the code]. While there are understandable differences in areas of emphasis both the PCP and PMA codes also show a good level of compatibility.

As a first step the Industry- including representatives of non PHAP companies- should convene with the PCP and PMA to draft a set of universal principles. These could then be submitted for third party review by an independent ethics board with representation from FDA and other stakeholders as well as disinterested parties with appropriate qualifications to adjudicate matters of ethics (e.g. University Ethicists, Legal Experts etc.). A sub- cohort of this third party committee could then be invited to serve on a continuing basis to maintain the code as circumstances evolve. A standing committee would thus form the basis of an independent Ethic Committee.

Once the Rules and Regulations have been agreed FDA should mandate that any drug company operating in the territory must be a member of an Association which subscribes in full to these regulations and agrees to be bound by them.

At a recent workshop organized by MeTA in Makati there was willingness among stakeholders to adopt a multi- sectorial approach. [Disclosure: The author was co- facilitator at one of these sessions involving the Research Industry and received an honorarium for participating]. This should give encouragement to those seeking change.

Detection: The Police

From the industry standpoint at present the FDA has a very limited capacity to detect violations and within PHAP the majority of the sleuthing is done by companies believing themselves to be placed at a disadvantage by competitive activity. From the Medical Professionals' perspective there is next to nothing being done to combat complicity with unethical promotion or blow the whistle on junket trips.

A better approach would be to have a detection capability attached to an independent Ethics Watchdog. The watchdog could be paid for by a small levy on industry, the FDA or other legitimate 3rd party (such as MeTA for example) and would have the power to (anonymously) attend events as well as manage a team of investigators across the country collecting promotional materials and monitoring printed and other media. Inter- company complaints would be raised to this organ.

Enforcement: The Courts

Once a problem is detected there must be a consistent, transparent and independent body responsible for enforcement which would be able to act quickly on the evidence provided by the watchdog and possibly force suspension of a promotional program pending (expeditious) review by the Committee. For this to be effective the Committee would have to be willing to hear cases as they arose. This could mean the need for a small number of "on duty" adjudicators or a simple acceleration of the regular meeting schedule.

Without several supporting changes the power to suspend promotion would not be viable under the present system where Company A raises a complaint against Company B as there would be a perverse incentive to raise nuisance complaints in order to derail a competitor's activity. The current adversarial

mechanism could still exist alongside an independent committee to allow for “out of court settlements” so as not to overwhelm the committee with trivial matters but it would not have the power of injunction.

For proper balance the committee would concern itself with the attending Physicians as well as the sponsoring company. For this to function the committee would need to be comprised of well recognized independent experts with a broad range of expertise and sufficient time and resources to discharge their duties expeditiously.

Sanctions: The Penal System

A series of escalating penalties should be available and administered by either PHAP (or its universal successor) for industry, PMA for the Medical Profession and FDA where the law of the land has been broken. Again, the PHAP code has some ideas on the subject as does the FDA. However, as was noted at the MeTA workshop the FDA penalties tend to be either trivial (minimal fine) or draconian (loss of License To Operate). There is an evident need for a more granular system.

The option to “Name and Shame” is one seldom exercised. The Ethics Committee should in any case operate in the open and the logical step from here would be to publicize the results of its deliberations. Companies in violation could have their names published in the paper which would cause reputational damage and conceivably hurt other functions such as recruitment. A mechanism by which Head Office personnel could be notified of local ethical violations would dramatically increase the pressure on the MNCs.

For the Medical Profession a suggestion was to insist that Doctors declare any sponsorship on their tax returns since this is a form of income. For those Doctors able to convince the BIR (Bureau of Internal Revenue) that this was a legitimate business expense there would be no tax penalty but it seems likely that a large proportion of junketers would be dissuaded from accepting invitations.

Another possibility is a full disclosure of “who got what” as is done in the USA. MDs sponsored to meetings would have those details published and made available along with the identity of the sponsoring company. A proponent of this idea concedes that it may be a little too soon to implement this in the Philippine context but the threat alone may be effective* See Note 1.

Whichever combination of the above or alternative penalties are selected guidelines will need to be developed to ensure fair and consistent application of sanctions and the concept of escalation for repeat offenders should be built in.

Structures Required

Given the speed at which the system must operate in order to keep pace with the industry and its clients there is no room for a cumbersome bureaucracy.

Essentially there is a need for a Rules and Regulations Committee which would regularly review and update the regulations as circumstances demanded. There could be a need for a very nimble sub-committee to focus on the Internet.

There is also a need for a Standing Ethics Committee whose main focus would be on rapid adjudication and interpretation of the regulations. A subcommittee or with investigative powers should be one of the primary means by which issues can be detected and raised to this committee.

Finally a working group should be convened on an ad hoc basis to review the schedule of penalties.

The Standing Ethics Committee would be the master organ and should report to the FDA as well as the heads of the Medical Society Ethics Committee and Industry Ethics Committee (which should encompass all drug companies operating in the Philippines)

Monitoring Progress

Quarterly or annual reports from the various bodies recommended above would form the basis of a progress monitoring system but the first step is to decide what should be measured, how and against what standard. Some encouragement was given at the recent MeTA meeting when the research industry delegates were asked to envision an ideal environment and the give a score of one to ten to assess how close they were. Nobody is suggesting that this particular vision be adopted wholesale but it was interesting to note the scores (see attachment). At least denial appears no longer to be a problem.

An interesting exercise might be to extend this visioning session across all stakeholders in order to at least determine factors to be measured even if a common vision remains elusive.

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* Note1: The immediate impact of this may be mitigated in the Philippines by the fact that there seems to be little shame attached to accepting drug company largesse. [Indeed many senior MDs can readily identify their high profile colleagues as being connected with a specific company or companies and this generally attracts little opprobrium.]. This could easily change over time and in fact could form part of the metrics for assessing progress. There could additionally be the option to extend this disclosure to gifts which may increase the pressure to either discontinue the practice or restrict gift giving to such items as would be demonstrably of patient benefit. As with overseas sponsorship, it may be that the BIR would be harder to convince than some others.

Author's note: It has always been a mystery to me why these matters are never raised at shareholders' meetings. The purchase of a single share is enough to gain entry and no corporate boss wants to be harangued on the subject of the behaviour of a subsidiary he or she has almost certainly never visited in front of the board and pension fund managers.

Irrational Use

The key question of whether Drug Company promotion leads to irrational use of medicine can't be conclusively answered by a single study but there are some areas of concern.

Looking at the WHO definition of irrational use as published on their website we see the following:

"Irrational use of medicines is a major problem worldwide. WHO estimates that more than half of all medicines are prescribed, dispensed or sold inappropriately, and that half of all patients fail to take them correctly. The overuse, underuse or misuse of medicines results in wastage of scarce resources and widespread health hazards. Examples of irrational use of medicines include: use of too many medicines per patient ("poly-pharmacy"); inappropriate use of antimicrobials, often in inadequate dosage, for non-bacterial infections; over-use of injections when oral formulations would be more appropriate; failure to prescribe in accordance with clinical guidelines; inappropriate self-medication, often of prescription-only medicines; non-adherence to dosing regimes."

Whether drug promotion in the Philippines is leading to some or all of these issues is outside the scope of this study but one consistent pattern does emerge. The constant promotion of branded copies of off-patent medicines over their cheaper plain generic counterparts has limited the penetration of the market by plain generics to less than 10% of the total by value (source PHAP). [Since unbranded generics are generally cheaper they have a slightly higher penetration by unit.]

While this study is not designed to show a causal link between higher prices and larger promotional budgets what is clear is that the more expensive options are the ones most often promoted to doctors (if not to pharmacists). The fact that the largest local player in the market built its business almost exclusively on "Branded Generics" is a significant fact. Also of significance is the position taken by the rapidly expanding outsourcing industry. If they are successful at maintaining a price level of 85% to the originator brand they may be able to deliver on their marketing objective of crowding out much cheaper plain generics. Note however that this 85% price point will in some cases be applied to a reference molecule which has already been reduced in price due to the recent legislation. There has been significant convergence on the prices of originator, branded generics and plain generics over the past few months (source PHAP; drugstore survey).

The consequences for those in lower income groups are troubling. Medicines are not as affordable as they should be and the market dominance of higher priced products creates a significant risk of non adherence to treatment. As an illustration of this effect consider the following: One leading drugstore chain requires manufacturers to stamp the expiry date on every pocket of a blister of tablets. Why? Because the majority of patients do not purchase a full blister of (e.g.) 10 tablets for economic reasons. This practice means that the pharmacy clerk must cut the blister and dispense a proportion of its contents, hence the need for redundant expiry date data. The pharmacist notes the number purchased on the prescription form which is retained by the patient who may return in a few days to purchase

more. Clearly this carries a great risk of patients failing to complete a course of antibiotics as one example, or defaulting on long term treatments.

Most MDs interviewed for this study and many others with whom the author has interacted over the years state that they consider the patient's economic situation before prescribing. A wealthy hypertensive patient will often be given the latest patented ARB, the middle class perhaps an ACE and a Beta Blocker for the poor. This phase of the process is a rational response but it is undermined by the subsequent prescription of an expensive branded generic (at least in the last two cases). Again, the Doctors have a plausible reason for their behaviour in that they have little confidence in the quality of unbranded generics. This lack of confidence has received positive feedback from some sectors of the industry but at core the problem lies with the MD's trust of the FDA. If the FDA were effectively guaranteeing the quality of every compound on the market then no amount of propaganda would shake the confidence of prescribers. With wider adoption of generics this issue is gradually fading but confidence cannot be built overnight.

Regrettably the data available for the quantitative analysis was insufficient for the task of establishing a causal relationship between promotion and market distortion. However from the data available (PHAP presentation courtesy of RW Gloor) on the impact of MdRP the minimal participation of unbranded generics in the ARB, statin, ciprofloxacin, platelet aggregator inhibitor and glicazide markets is a consistent trend. High switch rates in the Philippines (Source: private conversation with IMS management) have also long been thought to be markers of the effects of promotion on patients undergoing maintenance therapy. It is also evident in the ARB market that the 2 leading molecules each had 2 companies promoting them (cooperatively in one case, competitively in the other). From the interviews conducted for this survey Pharsight estimates that approximately 500 medical representatives are or have recently been engaged in the promotion of this market sector.

GLOSSARY

OJT: On the Job Training. New hires or newly promoted staff are supervised under real world working conditions by either a direct supervisor or an experienced peer. The purpose is to translate the classroom knowledge into applied skill at the task.

PHAP: The Pharmaceutical and Healthcare Association of the Philippines. The Industry association; open to all manufacturers, marketers and distributors as well as service businesses.

MRAP: Medical Representatives Accreditation Program. A standardized curriculum for all industry representatives introduced by PHAP early in the new decade. Participation was/ is mandatory for PHAP member companies' sales forces but recently the project has lost momentum and there is no standing committee supervising the initiative. Originally the test was administered by a third party agency but in many cases company training staff have been accredited to teach the course and conduct exams.

MNC: Multi- National Company. A (usually) large Pharmaceutical company with its HQ outside the Philippines. The local operating unit may have one of a variety of legal personalities and the degree of local autonomy will depend on this and the prevailing management philosophy of the mother company. The Philippines does not have home- grown MNCs in the broad sense although UniLab does operate in other ASEAN countries.

P&L: Profit and Loss. A basic analysis of whether the business is making or losing money. Sales form the "Top Line" from which operating expenses are sequentially deducted until the "Bottom Line" remaining Profit or Loss is calculated.

SOP: Standard Operating Practice. A set of written procedures governing how specific tasks should be accomplished. Typically formulated at the very top of the organization to ensure compliance with legal and ethical guidelines (e.g. PHAP code). The internal disciplinary system is engaged for enforcement purposes.

KOL: Key Opinion Leader. A senior Physician or Researcher who possesses advanced knowledge about a specific medical or pharmaceutical topic and is recognized by the broader medical community for this knowledge. Often used as a speaker to relay the results of new research or introduce a new chemical entity to the general community but also used to add credibility to commercial messages.

RTD: Round Table Discussion. A meeting format wherein a small number of Doctors (say around 10) are gathered together to discuss some feature of a product or the results of a study. Often led by a KOL and with a delegate the marketing group in attendance; the objective is to allow for an in- depth consideration of the topic at hand.

CSR: Corporate Social Responsibility. A broad term used to encompass altruistic or charitable work done by the company as well as more commercially- oriented activities such as Public Relations and Image Management.