

INSIGHTS INTO FORMULARY DECISION PROCESSES

Findings from a National Survey of Health Plans



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INSIGHTS INTO FORMULARY DECISION PROCESSES: FINDINGS FROM A NATIONAL SURVEY OF HEALTH PLANS

HIGHLIGHTS FROM THE SURVEY

- Three-fifths of health plan pharmacy directors are extremely familiar or familiar with the AMCP *Format*.
 - Among the largest plans—those representing more than 500,000 covered lives—almost ninety percent of plan pharmacy directors are familiar with the *Format* and over half indicate that they are extremely familiar with it.
 - Across all plans, 90 percent of all covered lives represented by sampled health plans are in plans familiar with the *Format*.
- The overwhelming majority of health plans maintain formulary decision-making responsibility, though a large number use input from PBMs and GPOs to guide their decisions.
- The health plans that conduct their own reviews and make their own formulary decisions tend to be more familiar with the AMCP *Format* than those plans that rely either completely or partially on the services of PBMs or GPOs for formulary decisions.
- Over one-third of all health plan pharmacy directors request information from drug manufacturers in a form that is consistent with the *Format*.
- Plans accept information as delivered by a PBM or GPO, which may limit familiarity with and use of the AMCP *Format*.
- With regard to safety and efficacy for labeled use, health plans were more likely to perceive information provided in the *Format* to be *complete* and *clear or easy to understand* than information in other presentations.
- Information related to off-label use and costs and benefits was frequently perceived by plans to be incomplete, lacking in clarity, and biased, regardless of the presentation.

INTRODUCTION

In recent years, health policymakers have worked to standardize and improve formulary processes, with the goal of grounding decisions in strong clinical and economic evidence. *The Academy of Managed Care Pharmacy (AMCP) Format for Formulary Submission* (hereafter, the *Format*) is a set of guidelines intended to improve the quality of formulary decision-making by standardizing the content of information submitted to health plan and pharmaceutical benefit managers (PBMs) pharmacy and therapeutics (P&T) committees for review. The *Format* represents a shift in perspective and approach for U.S. formulary committees which, until recently, have been more passive than proactive in requesting information from drug manufacturers.¹ Prior to the

¹ Neumann PJ. Evidence-Based and Value-Based Formulary Guidelines. *Health Affairs*. January/February 2004; 23(1): 124-134.

introduction of the *Format*, pharmaceutical manufacturers were more likely to submit drug information in multiple forms—such as journal reprints, product labeling, and formulary kits—which do not necessarily facilitate useful drug-to-drug comparisons or encourage submission of complete and comprehensive information.² The *Format*, in contrast, provides health plans with a method to request a standardized ‘dossier’ from drug manufacturers that contains detailed information on drugs’ intended use, effectiveness, and safety as well as potential for non-labeled use and economic value compared to similar therapies.³

Information is lacking on whether the guidelines contained in the *Format* have the potential to improve information exchange and the quality of decision-making by formulary committees. Although small-scale surveys and analyses reported in the literature have examined these issues to some degree, little is known regarding to what extent health plans nationwide 1) are familiar with the *Format*; 2) specifically request that drug manufacturers submit product information in *Format*-structured dossiers; 3) rate the completeness, clarity, and understandability of drug information contained in dossiers versus other methods used by drug manufacturers; and 4) believe that the *Format* streamlines the drug review process and helps inform formulary decision-making relative to other methods used by manufacturers for submitting product information. Thus, this study is the first to examine in a systematic and large-scale fashion how those participating in health plan formulary decision-making processes perceive the utility of the AMCP *Format* compared to other methods used by drug manufacturers for submitting product information to health plans.

BACKGROUND

As mentioned above, only small scale or single-health plan analyses have been conducted on these issues to date. Consequently, the ability to generalize the findings gleaned from these studies to health plans nationwide is limited, however, these findings provide a useful starting point from which the results of this and perhaps other future large-scale studies can be interpreted and expanded. Since its introduction by the AMCP in 2000, a number of leading health plans, PBMs, and state Medicaid programs as well as the Department of Defense have adopted the *Format* or a variation of the *Format*. Pharmaceutical manufacturers, in turn, are willing to submit dossiers that follow the *Format*, especially when specifically requested by formulary committees. A study of one large mid-Atlantic health plan found that pharmaceutical manufacturers submitted dossiers with drug product information in the AMCP *Format* for approximately three out of five products when requested by the P&T committee of the health plan.⁴ Interviews with 20 managed care organization (MCO) representatives, however, demonstrated that although both drug manufacturers and health plans are familiar with the *Format*, the

² Spooner JJ, Gandhi PK, Connelly SB. AMCP Format Dossier Requests: Manufacturer Response and Formulary Implications for One Large Health Plan. *Journal of Managed Care Pharmacy*. 2007; 13(1): 37-43.

³ Neumann, Evidence-Based and Value-Based Formulary Guidelines.

⁴ Spooner et al. AMCP Format Dossier Requests: Manufacturer Response and Formulary Implications for One Large Health Plan.

MCO representatives believed they received product information in dossiers following *Format* guidelines for less than half of all products reviewed.⁵

For those organizations adopting the *Format*, the potential of the guidelines to improve formulary decision-making depends, in large part, on the quality and completeness of dossiers submitted by drug manufacturers as well as the extent to which health plans and PBMs have the resources available to interpret and evaluate dossiers to ensure informed decision-making. Among the studies conducted to date, the results are mixed regarding whether *Format*-structured dossiers improve formulary decision-making processes. Among the dossiers reviewed by the 20 MCO representatives mentioned above, a little more than half included budget-impact models and even fewer included cost-effectiveness or cost-benefit analyses.⁶ Another study that audited 115 dossiers submitted by 28 drug manufacturers to a large health plan demonstrated that less than half included any economic analysis. When economic analyses were included, the analyses complied with recommended *Format* standards only occasionally.⁷

Results also are mixed regarding whether *Format*-structured dossiers increase the likelihood of product acceptance by formulary committees. One recent study found that drug products for which dossiers were submitted were assigned preferred formulary status much less often than products for which dossiers were not submitted.⁸ Other studies have shown that more than half of products submitted with dossiers achieved preferred formulary status⁹ and, more specifically, that inclusion of disease-based pharmacoeconomic models according to *Format* guidelines can improve formulary decision-makers' ability to judge the value of drugs and, therefore, promote inclusion in health plan formularies.¹⁰

Thus, it appears that the frequency with which drug manufacturers submit product information in dossiers following *Format* guidelines can vary considerably, as can the comprehensiveness of clinical and economic drug information included in the dossiers themselves. The current study aims to achieve a better understanding of these issues, which would aid policymakers striving to improve the value of investments in health care, and likely will provide useful information as private health plans broaden their role under the Medicare drug benefit.

⁵ Nichol MB, Knight TK, Epstein J, Honda DH, Tretiak R. Opinions Regarding the Academy of Managed Care Pharmacy Dossier Submission Guidelines: Results of a Small Survey of Managed Care Organizations and Pharmaceutical Manufacturers. *Journal of Managed Care Pharmacy*. 2007; 13(4): 360-71.

⁶ Ibid.

⁷ Colmenero F, Sullivan SD, Palmer JA, Brauer CA, Bungay K, Watkins J, Neumann PJ. Quality of Clinical and Economic Evidence in Dossier Formulary Submissions. *The American Journal of Managed Care*. 2007; 13(7): 401-407.

⁸ Spooner et al. AMCP Format Dossier Requests: Manufacturer Response and Formulary Implications for One Large Health Plan.

⁹ Fullerton DS, Atherly DE. Formulary development at Regence BlueShield—a formula for success. *Value Health*. 2002; 5: 297-300.

¹⁰ Watkins JB, Minshall ME, Sullivan SD. Application of Economic Analyses in U.S. Managed Care Formulary Decisions: A Private Payer's Experience. *Journal of Managed Care Pharmacy*. 2006; 12(9): 726-35.

TECHNICAL APPROACH

Description of the Pilot Study

Prior to implementation of the full study described in this report, a pilot study was conducted to test the feasibility of surveying a nationally representative sample of health plan pharmacy directors to assess use of the AMCP *Format*. The need for a feasibility survey was based on potential concerns that respondents would view the data being collected as confidential and/or proprietary. A draft study questionnaire was initially developed by members of the study team. This questionnaire was then reviewed prior to the AMCP's 18th Annual Meeting and Showcase by a technical advisory panel consisting of pharmacy directors, several of whom were employed by health plans where the *Format* was being used to aid formulary decision-making. Panel members were asked to complete the questionnaire, and then participate in a guided discussion regarding the survey content and administration. Following the panel discussion, revisions were made to the study questionnaire to reflect the Panel's critique and insights.

The revised survey instrument was field-tested on two groups of health plan representatives – purposively identified representatives with some experience with the *Format* ('adopters') and representatives of randomly-selected health plans. Response rates to the survey were 61 percent overall, and 73 percent and 50 percent for the adopter and random sample groups, respectively. Pilot survey response rates were very respectable for surveys of establishment-based professionals and suggested that a large, national study of use of the *Format* and other presentations of information by insurers would have a high likelihood of success. A by-telephone de-briefing was conducted with two survey respondents on the survey's design and whether it was effective in soliciting the requested information.

There was no evidence from pilot survey data collection activities that non-responders to the survey believed that the survey information could not be provided for confidentiality reasons or because requested information was deemed proprietary. In addition, pilot data suggest that questions designed to solicit perceptions on comparative advantages of the *Format* over other presentations of materials from drug companies were effective insofar as they reveal differences in perceptions between *Format* and non-*Format* presentations. A report describing the pilot study in more detail was submitted to FMCP in December 2006. The remainder of this section discusses the national study.

Sample Design and Selection

The listing of health plans for the national study was obtained from a database of health plan information purchased from HealthLeaders-InterStudy. Information included in the database was up-to-date as of July 2006. The universe of managed health care plans that provided prescription drug coverage was included in the sample.¹¹

¹¹ Three plans from this list were determined to be Out of Scope before the project began.

TABLE 1. SAMPLE STATUS	
Status	# of Plans
Number of Plans in Initial Sample	520
Out of Scope	28
Total # of Associated Plans*	235
Total # of Contacted Plans	257
Returned Questionnaires	134
*These are all of the state or local level plans associated with a national or regional health plan that are represented by one plan in the sample.	

Plans were determined to be ineligible (“out of scope”) during the follow-up phone call phase of the study if they did not meet criteria for participation. That is, if the interviewer discovered that the plan no longer existed or if the organization contacted was actually a PBM instead of a health plan, it was removed from the survey sample.

Within the sample there were a number of national or regional managed health care organizations with multiple plans at the state or local level, all of which operate by using the same formulary. For these plans one questionnaire was completed to represent all of the plans using the same formulary; it was completed by a representative at the location where formulary decisions are made for the organization. Determinations of which plans should be associated were made through the follow-up phone calls by field staff. Table 1 above shows the breakdown of the sample status.

Survey Design and Data Collection

Data collection efforts for the Formulary Decision Study were led by the National Opinion Research Center (NORC) beginning in mid-May and finishing in early November of 2007. Data were collected through self-administered questionnaires sent to respondents. The questionnaire took approximately 15-20 minutes to complete. All information about the sampled managed health care plans and records of call from contacting the plans were managed in a Microsoft Access database.

In order to maximize response rates, NORC utilized a Dillman-style approach to contacting respondents.¹² Table 2 displays the events for communication with respondents.

TABLE 2. EVENTS FOR COMMUNICATION

¹² Dillman, DA. Mail and Internet Surveys: The Tailored Design Method. (2000). Wiley & Sons. NY.

WITH SURVEY SAMPLE	
Respondent Contact	Date
Pre-Notification Letters Sent	5/14/07
Follow up Calls Begin	5/18/07
First Questionnaire Mailing	6/12/07
Thank You/Reminder Postcard	6/21/07
Second Questionnaire Mailing	7/10/07
Prompting Calls Begin	7/16/07
Third Questionnaire Mailing	9/7/07

Before the questionnaires were mailed, a pre-notification letter was sent out notifying the respondent of the study and letting them know that someone from NORC would be calling them. Six Field Managers (FM) were trained to make the follow-up calls after the advance letter to verify that we had contacted the correct individual at their organization. If the name listed in the sample was not the correct individual to contact or was no longer there, the FMs were trained in how to identify the correct individual to be the respondent. Once respondents had been identified through the follow-up calls, preparations were made to mail out the questionnaires to the respondents.

The first questionnaire mailing was sent out in mid-June and consisted of a letter of support from the Foundation for Managed Care Pharmacy (FMCP), a copy of the questionnaire, and a postage paid business reply envelope for the respondent to mail their completed questionnaire back to us. The materials were sent out using First Class U.S. Mail. A week and a half after the initial questionnaire mailing a postcard was mailed to the respondents gently reminding those who had not yet done so to complete the questionnaire and thanking those who had already sent their completed questionnaire back.

For those respondents who had not yet sent in a completed questionnaire a second copy of the questionnaire was mailed out. The second questionnaire was sent out approximately 4 weeks after the first questionnaire mailing and included the same materials as the first questionnaire mailing. However, the second mailing was sent out using Priority mail. After the second questionnaire mailing the Field Managers began making calls to prompt the respondents to complete and mail in the questionnaire. In talking with respondents, additional mailings were sometimes requested by the respondents, which were sent by Priority mail as well. During the prompting calls FMs were also able to determine if any of the managed health care plans were out of scope. The Field Managers continued to make prompting calls throughout the data collection period. However, as the number of viable plans decreased during the field period, the number of FMs making the prompting calls was reduced.

By the end of August several respondents had mentioned that they were unable to complete the questionnaire because they did not have enough time. At this point a shortened version of the questionnaire was created and offered to respondents who had mentioned time as a barrier for completing the questionnaire. The shortened

questionnaire consisted of the background information questions about the plan and a select number of important questions within the main section of the questionnaire about the respondent's opinions in regards to the formulary format(s) that they use.

A third questionnaire mailing was sent out at the beginning of September. For most respondents it was very similar to the first and second mailings. However, an updated letter of endorsement from the FMCP and a new handout with a brief message of why the study is important were included. A smaller number of respondents identified by the Field Managers were sent the shortened version of the questionnaire. In order to distinguish it from previous mailings, and in hopes of catching the respondent's attention, the shortened questionnaires were sent by FedEx.

In the final stages of the data collection effort a respondent incentive of \$50 was offered to all remaining plans. Eleven respondents completed the questionnaire in return for the incentive. Offering an incentive not only seemed to encourage respondents who were interested in the money, but it also encouraged a handful of others to participate even if they did not want the incentive. Respondents who ultimately refused to participate in the survey often cited that it was a company policy not to take part in any study. Others mentioned that they were too busy to find the time to participate.

Once a completed questionnaire was received at the central NORC office they were receipted and sent to an outside vendor to be data entered. Data were sent back to NORC in a password protected file and all hard copies of the questionnaire are kept in a locked drawer when not in use. A total of 135 questionnaires were completed for a response rate of approximately 52.5 percent.

Analysis of Survey Data

We present univariate and bivariate statistics, tabulated using a standard statistical programming computer package¹³. Because our frame includes the universe of health plans, rather than a sample, we have not computed standard errors or conducted tests of statistical significance. In the tables provided in the report, data are often provided by plan size, measured in terms of covered lives. This 'covered lives' measure is taken from the survey as reported by respondents. Survey respondents were asked to report on the number of covered lives served by their health plan's primary formulary. The questionnaire specified that if their plan used more than one formulary during the past year, e.g., if the plan covered employers who used different formularies, the respondent should report on the formulary that applied to the largest number of covered lives.

The number of covered lives reported by survey respondents for their plan's primary formulary ("survey covered lives variable") was compared to the number of covered lives provided in the InterStudy database used as a sampling frame for the study ("database covered lives variable"). We looked to see whether the two figures fell into the same grouping, i.e., <100,000; 100,000-500,000; or >500,000. The covered lives variable in

¹³ SAS® Version 9.1. Copyright (c) 2002-2003 by SAS Institute Inc., Cary, NC, USA. All Rights Reserved

the InterStudy database represents enrollment in PPOs and HMOs, excluding Medicare and Medicaid lives. For those health plans responding to the survey, the survey covered lives variable and the database covered lives variable fell into the same grouping in the vast majority of cases. For 18 of the 134 respondents, or 13 percent, the category varied. In the case of eight plans, the sampling frame information indicated a larger number of covered lives than the respondent reported and for ten plans it was the reverse. With the exception of the comparison below between responders and non-responders, all tables in the report were generated using the sampled lives variable from the survey rather than from the database.

In Table 3 we provide a comparison of the distribution of plan size for responding and non-responding health plans. Of the 257 pharmacy directors, medical directors, and chief executive officers of managed care plans sampled, 135 returned completed questionnaires (52.5 percent response rate). This represented over 125 million covered lives, or 74.2 percent of covered lives accounted for by all contacted plans. Responding plans included a substantially higher proportion of larger plans—23.7 percent of

TABLE 3. SAMPLING FRAME CHARACTERISTICS BY RESPONDER STATUS, USING INTERSTUDY COVERED LIVES NUMBERS				
	Responders		Non-Responders	
	n	%	N	%
Total Plans	135	52.5	122	47.5
Covered Lives	125,578,623	74.2	43,735,191	25.8
Plan Size in Covered Lives		% of Responders		% of Non-Responders
Less than 100K	64	47.4	59	48.4
100K-500K	39	28.9	47	38.5
More than 500K	32	23.7	16	13.1

responding plans were in the largest size category compared to 13.1 percent of the non-responding plans. This is likely due to the concerted effort made by the survey field team to reach these large health plans; the success in reaching the largest plans is also evident in the proportion of covered lives represented—almost three-quarters of the covered lives represented by the sampling frame are covered by the responding plans. The proportion of plans falling into the smallest category (less than 100,000 covered lives) was relatively similar across responders and non-responders.

Study Limitations

This survey represents the most ambitious effort yet to learn about health plans and their experience with the *AMCP Format*. Like all studies, however, the data have limitations and an understanding of those limitations is important to appropriate interpretation of the data as well as to the development of future efforts to improve the *Format*.

The study obtained a response rate of 52 percent; responders cumulatively were responsible for covering about 75 percent of all covered lives. While 52 percent is a

relatively high response rate there is always a potential for response bias unless the response rate approaches 100 percent. We can compare responders and non-responders in terms of size of plan, but we can not speculate about how non-responders would have answered the survey questions. Most survey researchers believe it is advantageous to obtain high response rates although the implications of non-response on any specific survey are unlikely to be known.

The quantitative analysis that is presented does not include information on use of the *Format* as reported by PBMs, though it does include health-plan-reported information on the role that PBMs play in supporting health plan formulary decision-making. The study was not specifically designed to make estimates that include both PBMs and health plans nor to make statistical comparisons between PBMs and health plans. On the one hand, because they are different types of organizations, they can not easily be grouped together nor are there a sufficient number of PBMs to support comparisons. However, a small number of qualitative interviews are being planned to be conducted with PBMs. Information gathered in these interviews will be used to describe how perceptions of and use of the *Format* by PBMs may differ from those health plans surveyed.

Because this survey targets an ‘elite’ population of extraordinarily busy professionals, the questionnaire must focus on the subset of issues considered most important. Thus, some topics were, by necessity, omitted. While respondents were asked about their familiarity with and use of the *Format*, there is no information on why health plans that report requesting information in the *Format* appear to use other presentations as well or why health plans that do not report requesting information in the *Format* use the *Format* in addition to other presentations—e.g., do manufacturers sometimes submit information in one presentation or another regardless of the request? or do plans sometimes request it in one presentation and sometimes in another? Without additional information regarding this phenomenon, some of the data gathered remain difficult to interpret.

Finally, the field of health technology assessment is rapidly evolving and the structure and quality of information that drug manufacturers provide may change substantially over time. As improvements are made to the *Format* as well, stakeholder perceptions may evolve and it will be important to track such changes.

FINDINGS

Characteristics of Respondent Plans

The characteristics of the responding health plans are shown in Table 4. The survey asked plans to answer questions based on the health plan’s primary formulary—that formulary covering the largest number of lives. Using the reported number of covered lives served by the plan’s primary formulary, plans were grouped into three categories – small (100,000 lives or less), mid-size (100,000-500,000 lives) and large (500,000 lives or more). In the final sample, about 45 percent of plans were defined as small, 31 percent as mid-size, and 24 percent as large. In total, these plans’ primary formularies

covered 96,202,751 lives, or almost one-third of lives in the U.S.¹⁴ Large plans accounted for nearly 90 percent of the covered lives reported in the survey, though these plans represented only 24 percent of the plan respondents. The majority of plans –44 percent--

TABLE 4. CHARACTERISTICS OF RESPONDENT HEALTH PLANS			
	Number of plans	Percent of plans	
Plan size in covered lives^a			Covered lives represented
ALL	134	100%	96,202,751
100,000 or less	60	44.8	2.5%
100,000 - 500,000	42	31.3	10.6
500,000 or more	32	23.9	86.9
Line of business for primary formulary^a			
HMO	60	44.4%	
Both HMO and PPO	44	32.6	
PPO	18	13.3	
Other	12	8.9	
Respondent job title^a			
Pharmacy Director or Administrator	89	66.4	
Medical Director/ Clinical Affairs Personnel	26	19.4	
Clinical/Staff Pharmacists	10	7.5	
Executive Director	2	1.5	
Other Personnel	7	5.2	
Respondent job responsibilities*			
Review other information for formulary review	119	88.2%	
Review information from PBM/GPO	107	79.3	
Direct pharmacy services	100	74.1	
Review info from drug manufacturer	98	72.6	
Staff P&T committee	95	70.4	
Voting responsibility on P&T committee	87	64.4	
Number of persons on P&T Committee with reviewer responsibility^a			Percent Employees
0	4	3.1%	-
1 – 9	50	38.8	59.1%
10-19	56	43.4	42.5
20-29	15	11.6	39.0
30 or more	4	3.1	60.8
Number of formulary decisions in which respondent was involved in last 12 months regarding chronic conditions^b			
1-10	27	23.9	
11-20	44	38.9	
More than 20	42	37.2	

*Responses are not mutually exclusive

^a Item missing for some respondents

^b This item only answered as part of full questionnaire

¹⁴ Note that the 96 million covered lives is the number reported by plans in the survey and refers to the plans' primary formulary. This number is smaller than that reported in the previous section obtained from the InterStudy database, which refers to all of the plans' covered lives rather than only those covered by the primary formularies.

reported their primary formulary to be in the HMO business; fewer plans –13 percent— were in the PPO business, and nearly one-third of responders’ formularies were in both. Plans that responded “Other” had primary formularies in the managed Medicare, Medicaid, POS, Indemnity, and ASO lines of business.

The population of survey respondents largely comprised pharmacy services managers and pharmacy directors (66 percent). A notable proportion of respondents were clinical services managers or medical directors (19 percent). Smaller proportions of respondents were non-directorial pharmacy staff (7.5 percent) or executive directors of plans (1.5 percent). Other types of survey respondents included directors of information services, operations and quality improvement. A small number of respondents held formulary-specific positions, such as chair of the plan P&T committee, head of plan drug list development, and formulary manager.

All respondents reported reviewing some type of information for formulary decisions as part of their job responsibilities. About 80 percent reviewed information submitted through a Pharmacy Benefits Manager (PBM) or Group Purchasing Organization (GPO), and 73 percent reviewed information directly from a drug manufacturer. A large number of respondents, 88 percent, reviewed other information for formulary review. Among respondents’ other job responsibilities related to formulary decision-making, 74 percent were responsible for directing pharmacy services, 70 percent serve on their plans’ P&T Committees, and 64 percent have voting responsibility on those committees.

When asked to report on the number of persons who typically serve on their P&T committees and have responsibilities for reviewing materials submitted by drug manufacturers prior to a formulary decision, most plans reported fewer than 20 persons (39 percent) had between 1 and 9 persons, and 43 percent had between 10 and 19 persons. Only four plans reported no such committee members. About 12 percent of plans had between 20 and 29 persons, and only 3 percent had 30 persons or more. The percentage of committee members with reviewer responsibilities who were employees of the health plan varied. Plans with the largest number of persons on their P&T committees with reviewer responsibilities were the most likely to have those persons be employees (60 percent), followed by the plans with the fewest number of persons (59 percent).

Respondents were asked to report on the reviews they had conducted on drugs used to treat chronic conditions in the twelve months preceding the survey. These responders appear to be relatively active reviewers: more than 75 percent of responders had reviewed more than ten drugs, and nearly 40 percent had reviewed twenty drugs or more in the twelve months preceding the survey.

One of the study goals was to learn how plans that have a PBM or GPO administer their formularies differ from plans that self-administer. In order to characterize the sample, plans were asked to describe how drugs are reviewed for inclusion under their primary formulary. The results are depicted in Table 5. The overwhelming majority of health plans maintain formulary decision-making responsibility, though a large number use

input from PBMs and GPOs to guide their decisions. A significant proportion of health plans (47 percent) conduct all reviews and make formulary decisions internally. Among large and mid-size plans, this is the most common review process (69 percent and 50 percent, respectively). A large proportion of plans (42.5 percent) rely on services and recommendations from a PBM or GPO, but these recommendations are subject to internal review and approval. This review process was the most common among small plans (60 percent). A small proportion of health plans contract out to PBMs or GPOs to make all formulary decisions (5.2 percent). Mid-size plans appear to be slightly more likely to depend entirely on PBMs and GPOs than small plans or large plans (9.5 percent of mid-size plans vs. 3 percent each of the other groups). Health plan representatives that reported using a method not listed described their review process as mostly internal, but supported with input from PBMs and GPOs.

	PBM/GPO administers & makes decisions	Relies on PBM/GPO but subject to review & approval	All reviews & formulary decisions based on internal review	Other
Plan size in covered lives	Percent of plans			
ALL	5.2%	42.5%	47.1%	5.2%
100,000 or less	3.3	60.0	33.3	3.3
100,000 - 500,000	9.5	35.7	50.0	4.8
500,000 or more	3.1	18.8	68.8	9.4

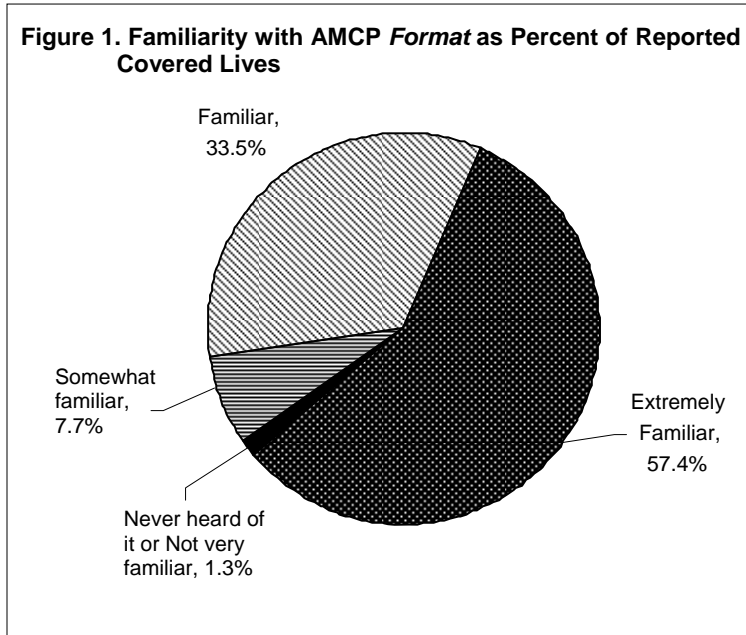
Familiarity with the AMCP *Format*

As shown in Table 6, most survey respondents appear to be at least somewhat familiar with the AMCP *Format*. Three-fifths of health plan pharmacy directors, medical directors, and CEOs are extremely familiar or familiar with the AMCP *Format*. Among the largest plans—those representing more than 500,000 covered lives—almost ninety percent of plan pharmacy directors are familiar with the *Format* and over half indicate that they are extremely familiar with it. Mid-size plans—those representing between

	Extremely familiar	Familiar	Somewhat familiar	Not very familiar	Never heard of it
Plan size in covered lives	Percent of plans				
ALL	35.3%	27.1%	13.5%	8.3%	15.8%
100,000 or less	20.3	20.3	8.5	18.6	32.2
100,000 - 500,000	40.5	33.3	21.4	0.0	4.8
500,000 or more	56.3	31.2	12.5	0.0	0.0

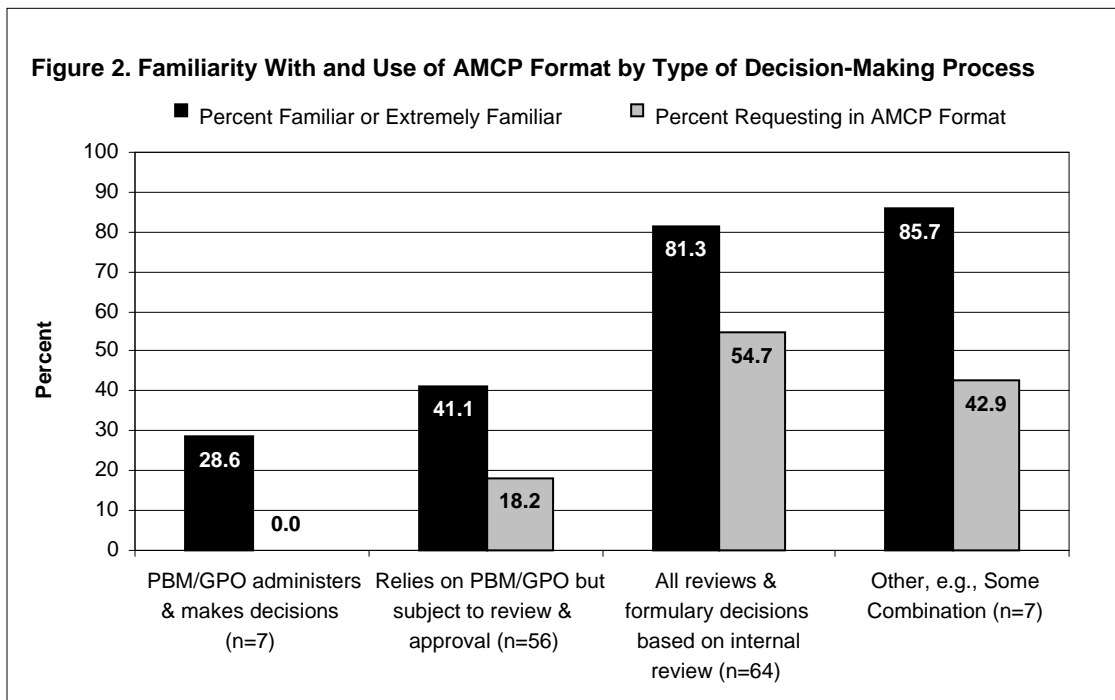
100,000 and 500,000 lives—also report a high level of familiarity: nearly three-fourths are familiar or extremely familiar with the *Format*. Among small plans – those representing 100,000 lives or less—about forty percent report familiarity with the *Format*. Small plans appear to be more likely to report never having heard of the

Format (32 percent) compared to mid-size plans (less than five percent) and large plans (none).



The difference by plan size with respect to familiarity with the *Format* is even more dramatic when shown by the number of covered lives, rather than the number of plans. Figure 1 displays the percentage of covered lives in plans by degree of familiarity with the *Format*. In terms of covered lives, 90 percent are represented by plans where the responding plan representative is familiar or extremely familiar with the *Format*.

Differences in plans' familiarity with the *Format* may vary by the type of formulary decision-making process used (as defined in Table 2). Analyses of the survey findings show that the health plans that conduct their own reviews and make their own formulary



decisions tend to be more familiar with the AMCP *Format* than those plans that rely either completely or partially on the services of PBMs or GPOs for formulary decisions (see Figure 2). The vast majority of plans (81 percent) that conduct their own reviews are familiar or extremely familiar with the AMCP *Format*. Among health plans that use PBMs for help with formulary decisions and ultimately approve or revise PBM or GPO recommendations internally, 41 percent are familiar or extremely familiar with the AMCP *Format*. Less than one-third of the health plans that contract out all formulary decisions were familiar with the *Format*.

Also shown in Figure 2 is the variation in *Format* usage by the degree of PBM or GPO involvement; it shows how familiarity with the *Format* compares to its actual usage. The survey results suggest that the way in which the health plan’s primary formulary is administered and whether or not a PBM or GPO is involved in formulary decisions may have an impact on use of the AMCP *Format*. More than half of the plans that conduct their own reviews (55 percent) request information in a form consistent with the *Format*. However, among health plans that use PBMs for help with formulary decisions and ultimately approve or revise PBM or GPO recommendations internally, only 18 percent request information in a form consistent with the *Format*. None of the plans that rely completely on their PBM/GPO to administer their primary formulary and make formulary decisions report use of the *Format*.

Adoption of the AMCP *Format*

Though in some cases familiarity with the *Format* has not translated into use, over one-third of all health plan pharmacy and medical directors request information from drug manufacturers in a form following the *Format*. As shown in Table 7, mid-size and large health plans tend to be more likely to request information in the AMCP *Format* structure than are small plans. About half of the mid-size plans and more than half (56.3 percent) of the large plans surveyed compared to 15 percent of the small plans surveyed requested *Format*-structured information. In terms of lives, nearly half (47.4 percent) of those covered by responding plans were represented by plans that use the AMCP *Format*.

TABLE 7. PLANS REQUESTING INFORMATION FOLLOWING AMCP <i>FORMAT</i> STRUCTURE			
Plan size in covered lives	Number of plans requesting <i>Format</i>	Percent of plans requesting <i>Format</i>	Covered lives represented
ALL	48	35.8%	44,658,000 (47.4% of all covered lives)
100,000 or less	9	15.0	561,000
100,000 - 500,000	21	50.0	4,992,000
500,000 or more	18	56.3	39,105,000

Health plans that reported requesting information in the *Format* structure also reported the year in which they adopted its use (Table 8). Not surprisingly, the data show that adoption was slow in the first few years of the *Format's* inception, but gradually increased as the guidelines underwent further revisions. More than one-third of the responding health plans adopted the *Format* in 2005, the year of the last *Format* revision.¹⁵

Year	n	Percent of Users
No date reported	5	10.4
2000/01	4	8.4
2002/03	6	12.5
2004	7	14.6
2005	17	35.4
2006	6	12.5
2007	3	6.3

Respondents were asked to report on the reviews they had conducted that involved information provided by drug manufacturers in the AMCP *Format*. (Note this question was not completed by those using the shortened questionnaire.) Plans were asked specifically about reviews conducted in the 12 months preceding the survey on drugs used to treat chronic conditions. As shown in Table 9, more than half of these pharmacy directors, medical directors or CEOs (60 percent) reported that at least one of their reviews for drugs used to treat chronic conditions involved information provided in a form consistent with the AMCP *Format*. Four plans reported that all of their reviews for such drugs in the past 12 months involved information from drug manufacturers in the AMCP *Format*.

Percent Reviews	Number	Percent of Responding plans
0	42	40.0%
1 - ≤25	21	20.0
25 < - ≤ 50	16	15.2
50 < - ≤ 75	13	12.3
75 < - < 100	9	8.6
100	4	3.8

As shown in Table 10, the main reason for not requesting information in the AMCP *Format*, given by one-third of study plans, was because they accept information from PBMs/GPOs. Fewer respondents reported that their reason for not using the *Format* was because it was too time-intensive (13.3 percent), does not meet their needs (8.9 percent), or requires expertise beyond that of their staff (5.9 percent). A number of respondents listed additional reasons, which included finding it difficult to find information in *Format*-structured presentations and believing that “information from manufacturing is

¹⁵ Foundation for Managed Care Pharmacy. The AMCP *Format for Formulary Submissions*. Version 2.1. A Format for Submission of Clinical and Economic Data in Support of Formulary Consideration by Health Care Systems in the United States. Alexandria, VA: Academy of Managed Care Pharmacy; 2005.

too variable”. Some plans reported requesting the *Format* presentations on an as-needed basis or expecting their PBM/GPO that makes recommendations or decisions to request in the *Format*.

TABLE 10. REASONS FOR NOT REQUESTING IN AMCP <i>FORMAT</i>(n=84) *		
	Number	Percent of Plans
Accepts information as delivered by PBM/GPO	46	34.1%
Review of <i>Format</i> is too time-intensive	18	13.3
AMCP <i>Format</i> does not meet its needs	12	8.9
Staff does not have expertise to use information provided by AMCP <i>Format</i>	8	5.9
Not familiar with <i>Format</i>	8	5.9
Use own format and resources	6	4.4

* Responses are not mutually exclusive

Impressions of Information Provided by Drug Manufacturers

In order to gauge health plans’ experiences with *Format*-structured and non-*Format* presentations, the survey asked a series of questions regarding three types of information provided by drug manufacturers —information on the safety and efficacy for labeled use, safety and efficacy for off-label use, and costs and benefits of drugs for the population served by the health plan. Table 11 displays the frequency with which respondents thought that information was *complete* “Most of the Time” or “Always”, the frequency with which they thought the information was *clear and easy to use* “Most of the Time” or “Always”, and the frequency with which they perceived drug company *bias in the conclusions* presented “Most of the Time” or “Always”. If all of a health plan’s reviews are conducted using information in the AMCP *Format*-structure, it only provided its impressions of the *Format* information. Likewise, if a health plan never uses information in the *Format*-structure, it only provided its impressions of Other Presentations. If a plan uses all forms, it provided its impressions of *Format* and non-*Format*-based presentations.

Therefore, information in the first two columns of Table 11 represents those plans that used the *Format* exclusively as well as those that used the *Format* along with other presentations, while information in the right-hand columns represents those plans that never used the *Format* as well as those that used a mix of presentations. The column “All” represents the responses for any plan that used either a *Format* presentation or other presentations. In addition to this information for the overall respondents, the columns called “Adopters” shows the impressions for individuals who specifically reported requesting information in a form consistent with the AMCP *Format*, either from drug companies or from their PBMs or GPOs. Though they request *Format* presentations, adopters do not necessarily use these exclusively for their reviews. Thus, thirty-seven adopters also provided their impressions of other presentations of drug information.

TABLE 11. IMPRESSIONS OF INFORMATION PROVIDED BY MANUFACTURERS*†				
	Format Presentations		Other presentations	
	Percent Most times/Always		Percent Most times/Always	
	All (n=59)	Adopters^a (n=46)	All (n=97)	Adopters^a (n=37)
How often was information provided by drug manufacturers complete?				
Information on safety and efficacy for labeled use	72.9%	75.6	67.0	64.9
Information on safety and efficacy for off-label use	14.0	13.3	11.6	18.9
Information on costs and benefits of the drugs for the population served by your plan	17.5	17.8	21.9	21.6
How often was information provided by drug manufacturers clear or easy to understand?				
Information on safety and efficacy for labeled use	74.1	80.0	60.8	67.6
Information on safety and efficacy for off-label use	26.8	29.6	22.6	36.1
Information on costs and benefits	22.8	20.0	29.2	27.0
How often were drug companies biased in drawing conclusions from evidence?				
On safety and efficacy for labeled use	34.5	33.3	39.8	31.4
On off-label use	25.5	27.9	31.2	28.6
On costs and benefits for the population served by your plan	46.4	48.9	48.4	38.9
	Percent "Yes"		Percent "Yes"	
Were materials prepared by the drug manufacturers important sources of information on costs and benefits for the population served by your formulary?	33.3	35.4	38.1	35.4
Are reviews for Medicare Part D formulary inclusion more time intensive than other reviews?	21.6	20.8	21.1	16.7
<p>* Responders could answer in both categories (presentations consistent with <i>Format</i> and other presentations)</p> <p>† The number of respondents varies by question. The n reported represents the largest number of respondents for any of the questions in a given column. Percentages were calculated based on the actual denominator for the question (row).</p> <p>^a Adopters are defined as health plan respondents who specifically request information in a form consistent with the AMCP <i>Format</i>, either from drug companies or from their PBMs or GPOs.</p>				

According to health plan pharmacy directors, medical directors, and CEOs surveyed, AMCP *Format*-structured information provided by drug manufacturers on labeled use is more frequently complete (73 percent) than the information provided in other presentations (67 percent), though the difference is not large. While the subset of *Format* adopters share this view, the difference in their perceptions of the two presentations is somewhat greater--75 percent of Adopters feel that the *Format* presentations they use are frequently complete compared to the 65 percent of Adopters who feel that non-*Format* presentations they use are most of the time or always complete. Responses show that neither *Format* nor non-*Format* presentations provide complete information on the safety and efficacy of off-label use very often; in fact, the vast majority of plans did not feel that they were frequently receiving this information from manufacturers regardless of presentation. For all responders and the subset of adopters, information on the costs and benefits of drugs also appears to be infrequently complete in either presentation.

Responses regarding impressions of the clarity and ease of use of information provided by drug manufacturers show the same trends as impressions of information's completeness, though the differences for safety and efficacy of labeled use were somewhat more substantial. Among all respondents, 74 percent reported that they found the *Format* presentations of information on labeled use clear and easy to use most of the time or always compared to 61 percent for other presentations. Plans also indicated a very slight preference for the information delivered in the *Format* presentation with respect to safety and efficacy for off-label use, though the difference between the two presentations was quite small and, overall, most plans report that this information is not clear or easy to understand.

Respondents found information on cost and benefits provided by drug manufacturers to be clear or easy to understand more often using non-AMCP *Format* presentations than using the *Format* presentations; however, as with off-label use, the differences were small and most plans indicated that they were not usually getting information that was clear or easy to understand. Regardless of the type of presentation used, only 33 percent of *Format* users and 38 percent of Other Presentation users indicated that materials prepared by drug manufacturers were important sources of information on cost and benefits for the populations served by their formularies. Adopters of the AMCP *Format* find information on off-label use and cost and benefit information to be more often clear or easy to understand in other presentations than in *Format* presentations; however, they concur that information on safety and efficacy for labeled uses in *Format* presentations is clearer and easier to use than information in other presentations.

Between one-quarter and one-half of health plan respondents report that presentations include biased information from drug manufacturers most of the time or always. Regardless of presentation, the perception of bias seems to be most common with respect to information on costs and benefits and less frequent for overall information on off-label use. For labeled use and off-label use, respondents were slightly more likely to find biased information "Most of the Time" or "Always" in non-AMCP *Format* information than in *Format* presentations. The perception with respect to information on costs and benefits was similar across presentations. However, results provide some suggestion that *Format* adopters believe conclusions based on evidence for cost and benefits is more frequently biased in the *Format* presentations than in other presentations (49 vs. 39 percent).

Table 12 shows how health plan representatives responded to a series of questions probing their impressions of information provided by manufacturers on drugs used to treat chronic conditions. In general, both responders who used *Format*-structured information and those who used other presentations agreed that clinical information on labeled use improved formulary decisions for their organizations (90 and 89 percent, respectively). Health plans also agreed, though to a substantially lesser extent, that information on costs and benefits of the drugs had improved formulary decisions; non-*Format* users more often agreed on this point than did *Format* users (73 vs. 63 percent). Among adopters, however, the *Format* presentations appeared to elicit a positive response slightly more often.

There is a lack of consensus on whether information on off-label use improved organizations' formulary decisions; approximately half of plans agreed information improved their formulary decisions. For all respondents, a slightly higher proportion agreed that other presentations of off-label information had improved decisions (54.5 percent) compared to *Format* presentations of information (50 percent). *Format* adopters' responses for their impressions of the impact of *Format*-structured information and other presentations of off-label use information on improving formulary decisions did not differ. This lack of consensus is most likely due to the fact that information on off-label uses is not readily available and is not likely to be included in *Format*-based dossiers as indicated in Table 11.

TABLE 12. IMPRESSIONS OF INFORMATION PROVIDED BY DRUG MANUFACTURERS FOR DRUGS USED TO TREAT CHRONIC CONDITIONS *†

	Format Presentations Percent Agree		Other presentations Percent Agree	
	All (n=60)	Adopters^a (n=46)	All (n=102)	Adopters^a (n=37)
Information improved formulary decisions of my organization				
Clinical Information on labeled use	90.0	93.5	89.2	91.9
Clinical information on off-label use	50.0	54.4	54.5	54.1
Information on cost and benefits of the drugs	63.3	69.6	72.8	64.7
Health plan staff have sufficient expertise to evaluate this information				
Staff who review <i>safety and efficacy</i> information	86.7	84.8	88.9	86.5
Staff who review <i>cost and benefit</i> information	83.0	84.8	81.2	86.5
Information submitted by drug manufacturers makes the review process easier to manage.	64.4	73.9	53.1	65.7
Information submitted by drug manufacturers should include more rigorous economic models.	72.9	71.7	84.7	82.9
Drug manufacturers should present information more concisely.	89.8	89.1	88.9	86.1
Drug manufacturers should submit information in a more organized way.	69.5	63.0	75.5	72.2
* Responders could answer in both categories (presentations consistent with <i>Format</i> and other presentations)				
† The number of respondents varies by question. The n reported represents the largest number of respondents for any of the questions in a given column. Percentages were calculated based on the actual denominator for the question (row).				
^a Adopters are defined as health plan respondents who specifically request information in a form consistent with the AMCP <i>Format</i> , either from drug companies or from their PBMs or GPOs.				

Overall, health plan representatives believe that their health plan staff has sufficient expertise to evaluate safety and efficacy information as well as cost and benefit information. Health plan representatives reported nearly equal ability of their staffs to critically evaluate *Format*-based presentations and presentations from other sources.

Additional survey findings shed some light on views of other presentations compared to views of *Format* presentations. Overall, responders agreed more often that *Format* presentations compared to other presentations make the review process easier to manage—64 percent of *Format* users felt this way compared to 53 percent of other

presentation users. Responses indicate that health plan pharmacy directors, medical directors, and CEOs uniformly agree that information from drug manufacturers should contain more rigorous economic models, be more concise, and be more organized. *Format*-based presentations appear to do slightly better than other presentations in terms of rigor of economic models—of those who use *Format*-based presentations, 73 percent believe the models should be more rigorous compared to 85 percent of those using other presentations. *Format*-based presentations may also be slightly better organized – 69.5 percent of *Format* users compared to 75.5 percent of other presentation users suggested improvement. There was no difference between *Format* users and other presentation users with respect to perceptions about the need for drug manufacturers to present information more concisely—about 90 percent of both groups agreed that this should be done. These trends are consistent between all users and adopters of the *Format*.

When asked whether the FDA should screen information before submission to health plans for review, the majority of plans (58 percent) indicated they disagreed or strongly disagreed (Table 13).

	n	Percent of plans
Strong Agree	22	17.3%
Agree	31	24.4
Disagree	61	48.0
Strongly Disagree	13	10.2

* Missing responses from 8 plans.

Conclusions

Through this study, the FMCP sought to fill a gap in the research on the formulary decision-making processes of managed care health plans nationwide by assessing their familiarity with, use of, and impressions on the utility of the AMCP *Format*. The survey captured information from just over half of managed care organizations in the U.S. that cover about three-quarters of the nation’s privately insured lives. It should be noted that PBMs were not included in the survey sample and, thus, the findings do not account for adoption of the *Format* by PBMs.

The results from the survey clearly indicate that the AMCP *Format* has had a substantial impact and familiarity with it is high; however, there is a substantial difference by size of plan (as defined by number of covered lives) in plans’ familiarity with the *Format* and the extent to which they request information from manufacturers consistent with it. Pharmacy directors, medical directors, and CEOs of larger health plans are substantially more familiar with the *Format* than their counterparts at smaller plans. However, of importance to those interested in furthering the adoption of the *Format*, though plans appear to be quite familiar with it, health plan P&T committees have not universally been requesting that information from drug manufacturers follow the AMCP guidelines. Throughout the study findings we see that P&T Committees commonly rely on their

PBMs in the formulary decision-making process and may defer to the PBM to make decisions regarding use of the AMCP *Format*.

The data show somewhat mixed responses and generally only small differences in plans' perceptions of *Format*-structured presentations and non-*Format* presentations in terms of completeness of information, clarity and usability of information, and degree of drug manufacturer bias in the information. As found in smaller-scale studies, results in this study are mixed regarding whether *Format*-structured dossiers improve formulary decision-making processes. In part, the findings may be explained by variability in the quality and consistency of information submitted by drug manufacturers who claim to be following the *Format* guidelines. As found in studies conducted by Nichol et al. and Colmonero et al. on small samples of managed care organizations and on submitted dossiers, only half or fewer of *Format* dossiers included required information on budget-impact, cost-effectiveness, and cost-benefits.

Other factors may be in play as well. There appears to be fairly strong consensus that information on safety and efficacy for labeled use is both complete and clear or easy to understand, regardless of presentation. However, for off-label use as well as information on costs and benefits, this is clearly not the case. That plans perceive information in these domains to be so weak in general may make it more difficult to assess how they perceive the *Format*.

As part of the questionnaire, health plan respondents were asked for suggestions for improvements to the AMCP *Format* as well as to other (non-*Format*) presentations; their recommendations fell into several categories: bias, content-related improvements, and structural or organizational changes. With respect to bias, plans urged manufacturers to more explicitly present negative aspects of drugs and suggested that content be more reliable and evidence better documented. In terms of clinical information content, responders want to see more comparative data, more detailed information on clinical trials and head-to-head trials. Health plan representatives expressed a desire to see more than FDA-approved information and more information from non-published studies. Pharmacoeconomic information, plans suggested, could be more realistic and the conclusions drawn less redundant. Furthermore, plans would like to see the *Format* presentations provide better summary information and, in general, be more concise and simple. Plans requested more timely information on drugs from manufacturers and potentially making dossiers available before product launch.