Priorities for pharmaceutical policies in developing countries: results of a Delphi survey

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The use of the Delphi method as a systematic and logical approach to establishing consensus among international experts on the priorities for interventions in national drug policies in developing countries is described. The Delphi survey showed a high degree of reliability, as evidenced by the high response rate, the quality of respondents, and the high standard for consensus. In addition to creating consensus on key issues and key components for priority intervention, the study identified six components that could constitute a basic framework for designing drug policy in developing countries. The study’s conclusions have important implications for decision-makers within international development agencies and national governments.

Introduction

In the 1970s the lack of basic drugs at prices that the poor could afford became a major concern for health officials in the newly independent states of the developing world. In response, the World Health Assembly passed a resolution (WHA28.66) in 1975 that mandated the World Health Organization “to develop means by which the Organization can be of greater direct assistance to Member States in advising on the selection and procurement, at reasonable cost, of essential drugs of established quality corresponding to their national needs”. WHO published the first model list of essential drugs in 1977 (1). Based on another World Health Assembly resolution in 1979 (WHA32.41), the Organization established the Action Programme on Essential Drugs and Vaccines in 1981 to develop a strategy which embraced all aspects of national drug policies.

In the 1980s, a large number of countries adopted essential drug lists with support from development agencies and nongovernmental organizations (NGOs) and began operating active programmes. Several countries, including Bangladesh (2), Philippines (3), and Nigeria (4), developed national policies and carried out major changes in the pharmaceutical sector.

Despite these efforts, however, serious problems remained in many developing countries, due in part to ad hoc, ineffective, and contradictory pharmaceutical policies. In 1988, according to WHO, more than 1300 million people had little or no regular access to the most essential drugs (5).

At the international level, the pharmaceutical industry and many developed country governments voiced strong opposition to WHO’s efforts to promote policies on essential drugs. At the national level, conflicts arose over the design of pharmaceutical policy and such issues as the role of the private sector and the priority for local production. Conflicts also emerged among international development agencies over where to intervene first in the pharmaceutical sector and over which strategies were likely to be cost-effective (6).

Numerous efforts to resolve these controversies have achieved only limited success. The Conference of Experts on the Rational Use of Drugs, held in Nairobi in 1985, was a concerted attempt by WHO to create agreement on what should be done (7). Since then, conflicts of opinion have persisted on priorities for action, reflecting the divergent views and interests of the different actors (8). A new approach is therefore required to help formulate drug policies that will meet the challenges of the next decade. This article reports the use of the Delphi technique as a systematic and logical approach to establish consensus among international experts on the priorities for interventions in national drug policies.

Methods

The Delphi technique is a method for structuring communication in a process that allows a group of individuals to deal with a complex problem and
reach consensus (9). The process involves the use of a series of questionnaires designed by a monitor group and then sent by mail in several rounds to a respondent group of experts who remain anonymous (10). After each round, the results are summarized and assessed by the monitor team and used to develop a questionnaire for the next round. The assessment document and new questionnaire are then sent to all members who responded. A Delphi survey is considered complete when a convergence of opinion occurs or when a point of diminishing returns is reached (11).

A major advantage of the Delphi technique is that it avoids problems commonly encountered in face-to-face group meetings. These problems include the influence of key persons on the responses of other panel members as well as the geographical constraints and costs of bringing together a group of experts. The anonymity of answers allows Delphi participants to express their personal views freely. The method is particularly useful for a subject with strong differences of opinion or high levels of uncertainty. The reliability of the Delphi method depends largely on the selection of panel members, the size of the group, and the number of rounds (11).

The Delphi method was developed as a forecasting tool at the RAND Corporation in 1948 (10), and has been widely used in defence studies and business strategy. The first studies in the health field were published at the end of the 1960s (12). In the pharmaceutical field, the Delphi technique has been used for conceptualizing the future of the pharmacist profession (13), for standardizing terminology (14) and prescription practices (15), and for exploring policy options (16). The pharmaceutical industry has applied the Delphi technique to forecast the evolution of important markets (17), although most of these studies are proprietary and not publicly available. Our review of the literature did not identify any use of the Delphi technique to assess or design drug policies in developing countries.

**Study design.** The study was designed by a monitor group, set up at the Harvard School of Public Health in Boston, USA, who received support from academic specialists and public health experts originating from developing countries. The study was based on a three-step logical approach and was completed over a six-month period. The first step sought to define the main problems faced by developing countries in the pharmaceutical sector, which have been called “key issues”. The second step was to identify for each of the key issues those elements of the pharmaceutical system that have a major impact on performance; these have been called “key components”. The third step was to rank both the issues and the components, in terms of importance for intervention, to establish priorities.

**Respondent group**

A list of 54 persons with substantial expertise in pharmaceutical policy in developing countries was prepared to serve as the respondent group. As shown in Table 1, the group included persons from different types of institutions: multilateral donors, such as the World Bank and European Economic Community; the United Nations system, such as WHO and UNICEF; nongovernmental organizations; research and consulting groups; pharmaceutical companies; universities; and consultants. Half were pharmacists or physicians, and half were economists, managers, policy analysts, anthropologists, or statisticians. The group of experts represented people from 12 countries on four continents.

**The questionnaires**

As shown in Fig. 1, the first questionnaire was developed after a review of the literature related to pharmaceutical policy in developing countries, including unpublished reports and documents from more than 50 countries. The monitor group proposed a preliminary set of five key issues and 40 key components.

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**Table 1: Evolution of the Delphi respondent group by categories: Initial and final compositions**

<table>
<thead>
<tr>
<th>Development agencies</th>
<th>UN system organizations</th>
<th>Drug industry</th>
<th>Nongovernmental organizations</th>
<th>Consultants</th>
<th>Academics</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physicians, pharmacists</td>
<td>(5)/4</td>
<td>(5)/4</td>
<td>(1)/1</td>
<td>(5)/5</td>
<td>(6)/5</td>
<td>(3)/3</td>
</tr>
<tr>
<td>Other (e.g., economists, managers, policy analysts, statisticians, anthropologists)</td>
<td>(3)/2</td>
<td>(3)/2</td>
<td>(7)/4</td>
<td>(4)/1</td>
<td>(3)/2</td>
<td>(6)/5</td>
</tr>
<tr>
<td>Total subgroup*</td>
<td>(8)/6</td>
<td>(8)/6</td>
<td>(8)/5</td>
<td>(9)/6</td>
<td>(9)/7</td>
<td>(9)/8</td>
</tr>
</tbody>
</table>

* The initial composition is shown in parentheses. The final composition of respondents in Round No. 3 is shown to the right.

* The size of each initial subgroup was nine for a total of 54. Three experts declined the invitation to participate, giving a total of 51 in the survey.
Respondents were asked to review the preliminary lists, indicate their agreement or disagreement, rephrase the proposed formulations, and propose additional issues and components. Three members of the initial group declined to participate in the study.

In the Round No. 2 questionnaire, respondents were asked to select the formulation that best defined each key issue, review additional key issues proposed in Round No. 1, rank the key issues according to feasibility of intervention and likely impact on the expected outcomes, and select five priority components for each key issue.

In the Round No. 3 questionnaire, respondents were requested to select the best formulation of two key issues not yet decided, rank the major structural constraints confronted by efforts to improve drug sector performance, and rank the key components according to the priority of intervention for solving each key issue.

**Results**

**Key issues**

A strong consensus was obtained in Round No. 1 on the five key issues proposed by the monitor team: “Structural constraints in the country” (91.1% of respondents), “Lack of government commitment” (86.7%), “Structural weakness of the drug public sector” (84.4%), “Limited drug affordability” (82.2%), and “Irrational use of drugs” (100%). The initial formulation of two key issues was accepted with strong agreement: “Structural constraints in the country” (61.9%) and “Irrational use of drugs” (73.3%). New formulations were proposed in Round No. 2 for the remaining three, taking into account the suggested rephrasing and comments from respondents.

A total of 40 additional key issues were proposed by the respondents, along with 10 comments regarding alternative key issues. Those most frequently mentioned were: the behaviour of the private sector (17.8%), the role of the multinational pharmaceutical industry (13.3%), the underestimated role of traditional medicine (8.9%), the lack of foreign exchange (6.7%), and the poor efficiency of international aid (6.7%). These five were proposed in Round No. 2 as possible new key issues or components.

In Round No. 2, 59.0% of respondents accepted the formulation “Limited affordability of essential drugs in both public and private sectors”. New formulations, reflecting comments from respondents, were proposed for the remaining two key issues in Round No. 3. The proposal to add a sixth key issue was rejected because none of the proposed additional key issues received more than 20.5% agreement. A majority (62.5%) responded that the first key issue to address for improving drug sector performance is the problem of government commitment (with a mean rating of 5.38 out of 6). Respondents ranked the weakness of the public drug sector as the second priority issue (with a mean rating of 4.23) (Table 2).

In Round No. 3 a consensus emerged on the formulations that best defined the remaining two key issues: “The lack of government commitment and capacity to design and implement a rational drug policy” (97.4%), and “The structural weakness and poor performance of the public drug sector” (57.9%).

**Key components**

In Round No. 1, the respondent group added another 119 items to the preliminary list of 40 components prepared by the monitor team. Those mentioned at least three times were included on a revised list, resulting in a total of 46 key components.

In Round No. 2, respondents were asked to select five priority components for each key issue. Across key issue categories, six components were mentioned as priorities by more than 70% of the respondents: the establishment of appropriate legislation and regulation, the selection of essential drugs, the allocation of sufficient funds for drugs in the health budget, the improvement of procurement procedures, the establishment of a drug pricing policy, and the organization of continuing education programmes in drug use (Table 2).

In Round No. 3, a consensus emerged that the major constraints for achieving the objectives of availability and affordability of essential drugs for the majority of the population are the public sector’s capability, the health human resources availability, and the country’s socioeconomic level. A consensus also emerged for each key issue on the three top-ranked key components for intervention (Table 2).

**Discussion**

The study’s results are discussed below from three perspectives: the reliability in establishing consensus, the priority issues for policy, and the priority components for action.

**Reliability**

The high rate of agreement obtained on most questions in this survey indicates that a strong consensus emerged on the priorities for intervention in national drug policies. Systematic application of the Delphi
Fig. 1. The Delphi method: summary of major actions taken by the monitor group and the Delphi participants.

**ACTIONS BY MONITOR GROUP**

**Round No. 1:**
- Propose key issues and key components
- Prepare first questionnaire and background papers on Delphi method

**Round No. 2:**
- Analyse responses
- Prepare assessment document No. 1
- Prepare second questionnaire

**Round No. 3:**
- Analyse responses
- Prepare assessment document No. 2
- Prepare third questionnaire

**Final review:**
- Analyse responses for three rounds
- Prepare final paper

**ACTIONS BY DELPHI PARTICIPANTS**

**Round No. 1:**
- Take position on key issues, propose additional issues and write comments
- Propose additional components

**Round No. 2:**
- Select key issues
- Rephrase and rank key issues
- Select key components

**Round No. 3:**
- Rank major structural constraints
- Rank key components for each issue
- Select priority components for action

**Final review:**
- Comment on final paper

[45/51 = 88.2% response]

[40/45 = 88.9% response]

[38/40 = 95% response]
(overall 38/51 = 74.5% response)
Pharmaceutical policies in developing countries

Table 2: Selection and ranking of key components in Round No. 2 and Round No. 3. All components mentioned as a priority in Round No. 2 by more than 50% of the respondents are listed for each key issue. The top three components are ranked according to the results of Round No. 3.

<table>
<thead>
<tr>
<th>Key issues/key components</th>
<th>Mean rating for ranking of each key issue*</th>
<th>% of respondents in agreement with key components:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>&lt;50%</td>
</tr>
<tr>
<td>A. &quot;Lack of government commitment and capacity to design and implement a rational drug policy&quot;</td>
<td><strong>[5.38]</strong></td>
<td>**</td>
</tr>
<tr>
<td>1. Legislation/regulation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Essential drug selection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Drug allocation in the health budget</td>
<td></td>
<td></td>
</tr>
<tr>
<td>— Drug control authority</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B. &quot;Structural weakness and poor performance of the public drug sector&quot;</td>
<td><strong>[4.23]</strong></td>
<td>**</td>
</tr>
<tr>
<td>1. Procurement procedures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Essential drug selection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Health human resources development</td>
<td></td>
<td></td>
</tr>
<tr>
<td>— Distribution/logistics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C. &quot;Irrational use of drugs&quot;</td>
<td><strong>[3.61]</strong></td>
<td>**</td>
</tr>
<tr>
<td>1. Continuous education (drug use)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Prescribing practices</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Essential drug selection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>— Pharmaceutical firms marketing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>— Public information/education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D. &quot;Limited affordability for essential drugs in both public and private sector&quot;</td>
<td><strong>[3.23]</strong></td>
<td>**</td>
</tr>
<tr>
<td>1. Essential drug selection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Drug pricing policy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Procurement procedures</td>
<td></td>
<td></td>
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<tr>
<td>— Drug financing policy</td>
<td></td>
<td></td>
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<tr>
<td>— Generic drugs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E. &quot;Structural constraints in the country&quot;</td>
<td><strong>[2.97]</strong></td>
<td>**</td>
</tr>
<tr>
<td>1. Public sector capability</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Health human resources availability</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Country socioeconomic level</td>
<td></td>
<td></td>
</tr>
<tr>
<td>— Foreign exchange</td>
<td></td>
<td></td>
</tr>
<tr>
<td>— Transport facilities</td>
<td></td>
<td></td>
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</tbody>
</table>

* In Round No. 2 respondents ranked the key issues on a scale of 1 to 6, with 6 representing the key issue considered most important according to feasibility of intervention and likely impact on the expected outcomes.

** The six key components (that received more than 70% agreement and were top-ranked for key issues A, B, C, and D) could constitute a basic framework for designing pharmaceutical policy.

method by the monitor group circumvented controversies that have long affected this field. A review of several factors suggests that the consensus obtained is reliable.

The survey was designed to meet the criteria of the classical Delphi method (9). The monitor team carried out three rounds of questionnaires, which is standard in most surveys and considered to be sufficient (9). Members of the respondent group were all well informed on the subject, and the size of the group reached acceptable standards for a Delphi survey (18). The literature reports that once an adequate size is reached (generally around 30 well-informed and motivated experts), few new ideas result from increasing the group's size (19). The response rate for the three rounds was very high (74.5% of the initial group), compared with figures reported in other Delphi surveys. Finally the survey used a high cutoff rate, compared with other Delphi surveys, to signify the achievement of consensus.

The respondent group was selected to represent diverse disciplines, various countries and social environments, and constrasting views on pharmaceutical policy, and the proportions remained reasonably con-
sistent through all three rounds. The group remaining at the survey’s end (after removing the 25.5% of dropouts) had approximately equal representation among the subgroups, which strengthens the survey’s reliability. The higher rate of responses among physicians and pharmacists could reflect a greater involvement in pharmaceutical questions (Table 1).

The three rounds of questionnaires allowed respondents to propose their own key issues and components, which were used by the monitor team for proposing alternative choices. The comments from respondents and their proposals for 40 additional key issues and 119 additional components suggest that the group used the questionnaires to express divergent opinions. These factors, combined with the high rate of agreement, suggest that overspecification of the initial issues was not a serious problem.

The monitor team used the assessment documents to present disagreements and minority views expressed by respondents, and these documents were sent to respondents in Rounds No. 2 and No. 3. The continuing high rate of responses, which reflects the lack of discouraged dissenters who would otherwise have dropped out, also contributes to the reliability of the consensus.

Priority issues

The key issues identified by the Delphi survey have been previously described in the literature on pharmaceutical policy as important problems faced by developing countries. This study makes an important contribution in establishing the following five key issues as priorities.

(1) Lack of government commitment and capacity to design and implement a rational drug policy. A majority of respondents ranked this key issue as top priority for attention. This result emphasizes the critical role of government in defining a drug policy, setting objectives, and implementing strategies. Agreement on this key issue supports the idea that a comprehensive drug policy is necessary to achieve significant progress. A WHO situation analysis of more than 30 African countries in 1990 reached a similar conclusion.\(^a\)

(2) Structural weakness and poor performance of the public drug sector. In the past ten years, many aid projects have attempted to improve the performance of the public drug sector. But repeated failures have convinced some agencies to decrease the public sector’s role and to advocate a greater role for the private sector in the poorest countries (20). This study’s consensus suggests that the public sector still needs to be strengthened in order to ensure drug availability.

(3) Irrational use of drugs. The survey’s 100% agreement on this key issue reflects growing awareness that the impact of cost-effective procurement and logistics systems will be significantly undermined if drugs are not prescribed and used correctly. To date, only limited action has been taken in a few countries to address problems of irrational use.

(4) Limited affordability for essential drugs in both public and private sectors. Consensus on this key issue may reflect two broader concerns in the international community: first, that drugs in the private sector are often unaffordable for poor people in developing countries; and second, that recent efforts to promote cost-recovery schemes in the public sector through sales of drugs could similarly restrict affordability of essential drugs for many poor people and could have adverse distributional effects.

(5) Structural constraints. A strong consensus emerged that broader structural constraints in the country need to be considered, even though pharmaceutical policy cannot resolve such constraints. This consensus reflects increasing recognition that structural constraints contribute to the failure of many international aid projects (21). For those poor countries that are too weak to sustain an effective drug policy on their own, interventions are necessary not only on pharmaceutical matters but also on national conditions outside the drug sector.

Priority components

Six key components were mentioned as priorities for action by more than 70% of the respondents in Round No. 2 and were top-ranked as interventions for solving each key issue in Round No. 3. In the past, some countries and donor agencies have addressed several of these components but rarely in a comprehensive policy package. This study suggests that future efforts to design drug policy and improve pharmaceutical conditions need to include all six components as a basic framework (with other components added according to each country’s specific conditions).

(1) The establishment of appropriate legislation and regulation was ranked as the first priority for government action. Most developing countries and the donor community have underestimated the problems associated with implementation of national policies. By ranking this component first, the respondents acknowledged the importance of translating policy into legislation and regulatory structures.

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(2) The selection of essential drugs was identified as a priority component for four key issues, reflecting strong support from the respondent group. Essential drug lists have been recognized since 1977 as a major tool for improving the drug situation in developing countries, especially when combined with other policy elements. The results of this survey confirm that the use of such lists is still a basic element of appropriate drug policy in developing countries.

(3) The importance of maintaining a significant drug allocation in the health budget was also emphasized by the respondent group. In recent years, the combined consequences of economic crisis and structural adjustment programmes have frequently led to a decrease in drug budgets. The survey suggests that the state should remain financially involved in pharmaceutical provision.

(4) The improvement of procurement procedures was ranked as an important priority for addressing the poor performance of the public drug sector and for improving drug affordability. Small additional efforts in the area of procurement procedures can yield substantial improvements and savings. But most developing countries have few pharmacists with an expertise in purchasing low-cost drugs of good quality in the international market, and international aid projects have not generally focused on this problem.

(5) The establishment of a drug pricing policy was selected as a priority component for improving the limited affordability of essential drugs. This agreement suggests that pricing mechanisms should be introduced to ensure that everybody — even the poorest — has access in both private and public sectors to the drugs they need.

(6) Continuing education programmes have been recognized as an important intervention for promoting effective drug use, although they are often difficult to implement. The respondents’ selection of this component reflects a need for greater efforts to understand prescribing behaviour and identify measures to alter it in developing countries.

The strong consensus reached in this survey argues that decision-makers in both international development agencies and national governments should adhere to the six priority components in designing and evaluating projects concerned with pharmaceutical policy. It is important to note, however, that this Delphi study did not produce agreement on the policy content of each component.

These often difficult choices need to be made at the national level. Within individual countries, the Delphi technique could be used to specify the contents of national drug policy and create consensus among local interest groups (including consumer associations) involved with the pharmaceutical sector.

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Résumé
Etablissement des priorités pharmaceutiques dans les pays en développement: résultats d’une enquête Delphi

Dans les années 70, le manque de médicaments de base à des prix abordables pour les populations les plus démunies est devenu un grave sujet de préoccupation pour les nouveaux pays indépendants du monde en développement. En dépit des progrès réalisés par certains d’entre eux et du développement de l’aide internationale, l’accessibilité aux médicaments essentiels continue de poser un problème, notamment dans les pays les plus pauvres. Les désaccords qui ont persisté sur ces questions au cours des années 80 et l’absence de consensus international sur les interventions prioritaires ont contribué à freiner la conception et la mise en œuvre de politiques pharmaceutiques appropriées.

Cet article rend compte de l’utilisation systématique et logique de la technique Delphi pour dégager un consensus parmi les experts internationaux sur les objectifs prioritaires des politiques pharmaceutiques nationales dans les pays en développement. Le groupe interrogé initialement comprenait 54 experts internationaux appartenant à divers types d’institutions et ayant des vues différentes sur la politique pharmaceutique. L’enquête a été menée selon une approche logique en trois étapes. Elle visait à identifier les principaux problèmes auxquels sont confrontés les pays en développement dans le secteur pharmaceutique ("questions clés"), à déterminer, pour chaque question clé, les éléments du secteur pharmaceut-

tique qui ont une incidence majeure sur ses performances ("éléments clés") et à classer ces questions et ces éléments en fonction de l'importance des interventions, de façon à établir des priorités.

Le taux de réponse élevé, la qualité des participants et le degré de consensus exigé ont conçu aux résultats de l'enquête un haut degré de fiabilité. L'ampleur de l'accord atteint sur la plupart des questions montre qu'un consensus très fort s'est dégagé sur les priorités des politiques pharmaceutiques nationales. L'application systématique de la technique Delphi a permis d'éviter les controverses que l'on observe depuis longtemps dans ce domaine. L'étude a apporté une contribution importante en démontrant le caractère prioritaire des cinq questions clés suivantes: absence de volonté et incapacité des gouvernements à concevoir et à mettre en œuvre une politique pharmaceutique rationnelle; utilisation irrationnelle des médicaments; difficultés pour se procurer les médicaments essentiels, tant dans le secteur public que dans le secteur privé; contraintes structurelles. Plus de 70% des participants ont également mentionné six éléments clés qui, selon eux, justifiaient une intervention prioritaire: établissement d'une législation et d'une réglementation appropriées; choix des médicaments essentiels; maintien d'un poste "médicaments" important dans le budget de la santé; amélioration des procédures d'achat des médicaments; établissement d'une politique de fixation des prix; poursuite des programmes d'éducation.

Les conclusions de l'étude ont des implications importantes pour les décideurs au sein des agences de développement internationales et des administrations nationales. Cette étude offre en effet un cadre général pour la conception d'une politique pharmaceutique dans les pays en développement. Il importe toutefois d'observer qu'elle n'a pas permis d'arriver à un accord sur la place de chaque élément dans la politique générale. Il s'agit là d'un choix souvent difficile qui doit être fait au niveau national. Dans chaque pays, la technique Delphi pourrait être utilisée pour spécifier le contenu de la politique pharmaceutique nationale et créer un consensus parmi les groupes d'intérêts locaux (y compris les associations de consommateurs) qui œuvrent dans le secteur pharmaceutique.

References