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# AIPM Guidance on Patient Support Programs

## Purpose of the Document

This document is intended to establish the key principles and approaches to organizing and implementing Patient Support Programs (PSP).

## Definitions

**Patient Support Program (PSP)** means any activity or system of activities initiated, organized, held and/or financed by pharmaceutical companies on their own or involving third parties/organizations in which financial aid and/or information on the disease and/or its treatment is provided to Patients, i.e. to individuals who have been properly diagnosed and prescribed treatment and/or to Caregivers, i.e. individuals who take care for patients (hereinafter, "participants").

Examples of PSPs aimed at providing financial aid to participants are: improved affordability of pharmaceutical products through compensation of a part of their price; financial support for patients in carrying out or providing free diagnostic and laboratory and instrumental examinations, physician consultations, and medicinal manipulations (these and similar PSPs hereinafter referred to as ***"financial PSP"***).

Examples of PSPs aimed at providing information to participants are: measures to raise participants' awareness of the disease, treatment, compliance with therapy, and prescribed pharmaceutical products; measures to familiarize participants with pharmaceutical product usage techniques, informing them about the need to take medical tests to specify a diagnosis, monitor and evaluate treatment results, and notify participants about the need to take pharmaceutical product as prescribed (these and similar PSPs hereinafter referred to as ***"informational PSP"***).

A Patient Support Program may be combined ***("combined PSP"***), i.e. it may consist of activities of an informational PSP and a financial PSP.

The explanations given below apply to all types of PSP, unless otherwise directly stipulated in the text of the recommendations.

To avoid any doubts, the type of a contract supporting the involvement of a pharmaceutical company in a PSP does not affect the qualification of the PSP according to these recommendations. For example, pharmaceutical companies may finance a PSP on the basis of a gift/donation/grant agreement, and such PSP shall also be governed by these recommendations to the applicable part.

The following activities are not considered to be PSPs and, therefore, are excluded from the scope of application of these recommendations:

- clinical research;
- observational studies, real clinical practice studies;
- programs for early access to pharmaceutical products;
- disease awareness programs;
- discounts for distributors;
- cost-sharing and risk-sharing programs (with legal entities or government bodies);
- screening programs for initial identification of the disease.

## Terms of PSP Implementation. Principles of Approval, Launch, and Conclusion

PSP shall be aimed at improving the patient's treatment outcomes. PSP shall not be aimed at encouraging the prescription or recommendation of a pharmaceutical product for patients by healthcare professionals (HCP). PSPs shall not be used to initiate baseless requests for a pharmaceutical product. PSPs shall not be used to promote pharmaceutical products.

A pharmaceutical company shall approve the PSP in accordance with its internal procedures. Each PSP shall have documented medical justification for its need.

Period and other main parameters shall be established for each PSP. These parameters can be changed subject to proper and advanced notification of the participants and, if applicable, of the third parties involved in the organization and/or implementation of the PSP.

Under implementation of each PSP there shall be registration of PSP participants in compliance with laws on protection of personal data. A participant makes a decision on participation in a PSP on his/her own. A participant may be included in a PSP only after giving consent to the processing of his/her personal data. If a PSP involves processing information on the patients' state of health, consent to personal data processing shall be obtained in writing and shall contain the information required by law.

The pharmaceutical company shall stipulate and ensure the procedure for collecting information on adverse events (AE) under the PSP.

A participant has the right to quit the PSP at any time. A participant's right to quit the PSP cannot be restricted. Unjustified exclusion of a participant from the PSP is not allowed. PSP documents shall provide for the procedure for a participant's quit the PSP.

A PSP may be terminated by a decision of the pharmaceutical company. Upon ending the PSP, it is recommended to consider the possible negative effects from PSP termination for its participants and take measures to reduce such effects.

## Support of Patient Schools

Patient schools (PS) are training activities held to raise patient awareness about their disease, possible ways to mitigate risk factors, and ways to use the prescribed therapy.

PSs are not always PSPs. PSs are considered to be PSPs when:

- the participants are the patients with a diagnosed disease and treatment prescribed by a HCP, which includes the medicine of the company which organizes/finances the PSP, and
- the pharmaceutical company initiates the PS as an integral part of the PSP, and provides financial support for the organization of schools.

The content of the PS shall be balanced, up-to-date, and include terminology that is clear for ordinary patients with the disease. The purpose of the PS shall not be to collect data on the efficacy or safety of pharmaceutical products or medicinal products by the pharmaceutical company, or to receive data on disease prevalence.

The PS cannot be associated with the promotion or advertising of the pharmaceutical company's products and shall not include medicines and/or indications which are not registered in the Russian Federation. The PS shall not encourage prescription of the pharmaceutical product by the HCP, whether explicitly or implicitly. The PS shall not be used to initiate baseless requests for a pharmaceutical product.

The procedure for registering of the participants in the PS must be organized.

The employees of the pharmaceutical company cannot take part in those parts of the PS that fall under licensed medical activity (e.g., giving consultations on treatment or diagnosis of the disease). The employees of non-commercial divisions of the pharmaceutical company may attend the PS as observers if this is allowed by the internal rules of the pharmaceutical company and occurs in full compliance with such rules.

Patronage visits may be considered as a special, patient-specific variant of the PS ("patient school at home"). If there are any free therapeutic or diagnostic procedures performed for a patient during the patronage visit (e.g., administration of a pharmaceutical product), such PSP shall be considered a financial PSP.

## Materials for PSP

During PSPs (including Patient Schools), materials with information relating to human health or diseases may be prepared. These materials shall meet the requirements of the *AIPM Code*, in particular:

- information in the materials shall not constitute the subject matter of licensed medical activity
- information in the materials shall be accurate, complete, ethical, and honest
- information shall not substitute for a physician's consultation or encourage self-treatment
- information shall not contain any elements of the medicinal product's brand (colors, graphic design, font, symbols, layouts, and any other elements related to brand design). Use of a company's branding elements, including its logo, is not allowed. Branding elements of the PSP are permitted for use

All documents shall be accompanied with the information on the pharmaceutical company organizing the PSP and include a reference to the need to receive medical advice from a professional. For example: *"This document was developed with the support of the Pharmaceutical Company (specify the name) to raise patient awareness about their disease. Information in this document does not substitute for a healthcare professional's advice. Please consult with your physician".*

## Use of Digital Channels in PSPs

Digital tools and communication channels may be used for the PSP, such as mobile applications, information support by phone, hotlines, websites, information posted on social networks, and electronic reminders about compliance with the treatment plan (SMS, e-mails).

All principles set forth in the section "Terms of PSP Implementation. Principles of Approval, Launch, and Conclusion" also apply to digital tools and channels. They are also covered by the requirements set forth in the section "Materials for PSP".

A participant may be included in a PSP that sends messages to participants via digital channels only after giving proper consent to receive such messages.

Digital channels containing information related to pharmaceutical products shall be available only to the HCP and patients who receive treatment with the respective pharmaceutical product.

Websites shall provide information only on the problem/disease and cannot be dedicated to a pharmaceutical product.

## Involvement of third parties, including healthcare professionals, in PSPs

Pharmaceutical companies may engage third parties in the organization and/or implementation of a PSP on the basis of respective agreements. The third parties involved in the organization of a PSP may also involve other third parties in the implementation of a PSP. In this case, the company may establish requirements that must be followed by the third parties engaged in the organization of a PSP.

If individual activities conducted by the third parties in connection with the PSP require a license (special permit), the pharmaceutical company shall ensure that the third party has the necessary license (special permit) before entering into a contract with such third party.

HCPs may be engaged in the implementation of a PSP as third parties only if their participation in the PSP is associated with their teaching and/or research activity.

HCPs shall be engaged by the company according to the standard process of HCP engagement (defining the topic, approval of the HCP's materials, categorization, determination of remuneration, etc.). A possible exception may be made for reporting on the activities — it is not recommended to include patients' personal data or use signature lists and individual photos of patients. It is permitted to submit a report with a reference to the total number of participants, signed by the representative of the medical treatment facility on the basis of which the school was held.

HCPs may be engaged to create materials (if allowed by company rules) based on the principles set forth above.

## Special Conditions for Financial PSPs

The exact period of a financial PSP is particularly important. The typical (average) duration of treatment (use of the pharmaceutical product) shall be taken into account. The period of the PSP may be changed by the pharmaceutical company subject to proper advanced notification of the interested parties on changing of the period. When making a decision to change the period of a financial PSP, it is necessary to consider the interests of patients with chronic diseases who need permanent treatment.

The pharmaceutical company has the right to change the list of pharmaceutical products (add/remove pharmaceutical products) covered by the financial PSP subject to proper and advanced notification of the interested persons on such changes to the list.

Within the framework of financial PSPs aimed at improving the affordability of a pharmaceutical product through compensation of part of its price, the amount of such compensation shall be determined by the pharmaceutical company at its sole discretion, taking into account the goals of the financial PSP, nature of the disease, specific features of pharmaceutical product use, treatment stage, and compliance with the treatment prescribed for the patient (e.g., the amount of compensation may be gradually increased for patients with a high level of compliance with treatment).

The following measures are aimed at mitigating risks associated with the implementation of financial PSPs:

- the contract for participation in such PSP shall be signed with the pharmacies and/or pharmacy chain, and may stipulate, apart from direct administration of the PSP, the distribution of informational materials about it to the participants;
- pharmacy and/or pharmacy chain remuneration shall not depend on the amount of distributed materials and their components;
- the criteria for choosing pharmacies and/or pharmacy chains involved in the PSP shall not be discriminatory;
- materials developed under the PSP shall contain a warning that the pharmaceutical company does not influence patients' decision on which pharmacy they buy the pharmaceutical product from;
- there shall be no obstacles to selling competitive pharmaceutical products by pharmacies (the pharmaceutical company shall arrange proper communication with the personnel of the pharmacies);
- no incentives shall be given to the HCP for giving an advantage to the company's pharmaceutical products and for promoting their prescription;
- no incentives shall be given to pharmacies and/or pharmacy chains for changing the prescribed pharmaceutical product to a pharmaceutical product taking part in a PSP, or for other actions that contravene the law.

## Notification of Participants and HCPs About a PSP

Information on a PSP and on joining the PSP may be provided to participants, patient organizations, and/or HCPs by a pharmaceutical company (including via medical representatives), or by a third party engaged by the latter.

HCPs (except pharmaceutical professionals) may be provided with information on informational PSPs; information on combined and financial PSPs may be provided in a strictly limited and generalized format (e.g., the amount of compensation on the price of a pharmaceutical product), provided that such information is secondary to the main informational materials on improving compliance with therapy to achieve the most effective treatment, and it always constitutes an integral part thereof.

Distribution of informational materials on financial PSPs and on the financial terms of combined PSPs to patients via physicians is not allowed.

Patient organizations and HCPs that are pharmaceutical professionals may receive information on all types of PSPs.

A pharmaceutical company or its representatives are not permitted to transfer discount cards and/or informational materials on financial PSPs or the financial terms of combined PSPs to HCPs for the purpose of their further distribution to the participants.

Participants can receive a discount card or a coupon for a free laboratory and instrumental test or visit to a professional only in one of the following ways:

- from a pharmacist in the pharmacy after presenting a prescription issued by a physician. To manage compliance with this requirement, the pharmaceutical company may use a registration form which confirms that the pharmacist has checked the availability of a prescription and which will be signed by the pharmacist and the patient
- by postal or courier delivery after registering in the PSP on the website or over the telephone hotline
- during a patient school or other educational activity within the framework of a combined PSP.