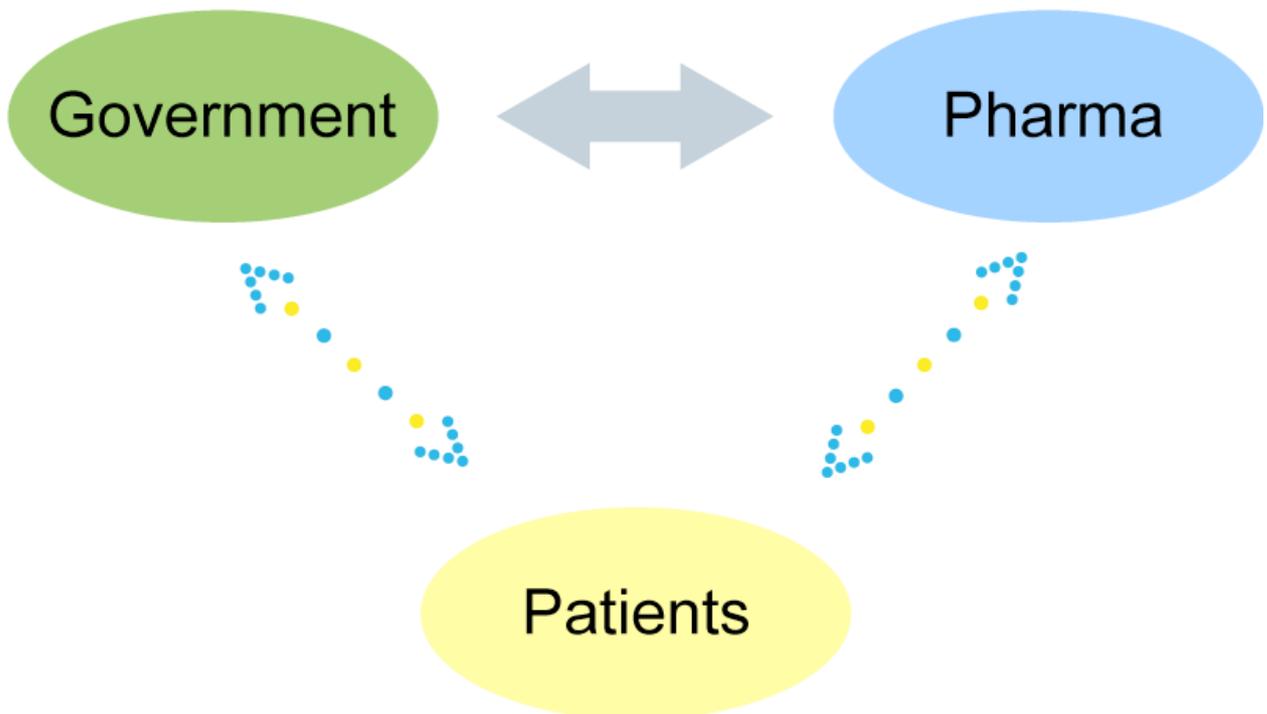


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Policy for Charitable Foundation “Ukrainian Community Advisory Board”

PREAMBLE

During 10 years of Ukrainian independence negotiation system between state and pharmaceutical sector has officially excluded patient. It concerns pricing and delivery processes, as well as quantity and quality of drugs present at the market of Ukraine. Usually, all negotiations of state – pharma – pharma – patient were held behind closed doors and were not based on the principles of publicity and transparency.



Simultaneously, there are expert patients, whose opinion is crucial when dealing with all steps of State Procurement and Supply Chain Management. International experience on GIPA has demonstrated the benefits of patient involvement into all procurement processes, particularly in price reduction. That is why the link between the three main stakeholders: pharmas, government and patients, with patient as an essential part of the treatment chain, needs to be strengthened in the consultative mechanism.

Therefore, an urgent necessity arose in Ukraine in creation of a platform for open dialogue between patient organizations and pharmaceutical companies and the government to improve access to high quality and affordable treatment for all in need.

GOALS AND OBJECTIVES

Charitable Foundation “Ukrainian Community Advisory Board” (short name **UCAB**) is a specialized union of patients, created on the initiative of the All-Ukrainian Network of PLHIV. UCAB unites patients in order they protect their rights and advocate their interests with the pharmaceutical companies and the government. Their lives directly depend on quality, access and effectiveness of drugs they get. This is why UCAB is called to become an influential force on the drugs supply market in Ukraine.

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UCAB Goal:

Ensuring access to modern, effective and safe treatment in sufficient quantity in Ukraine.

UCAB Mission:

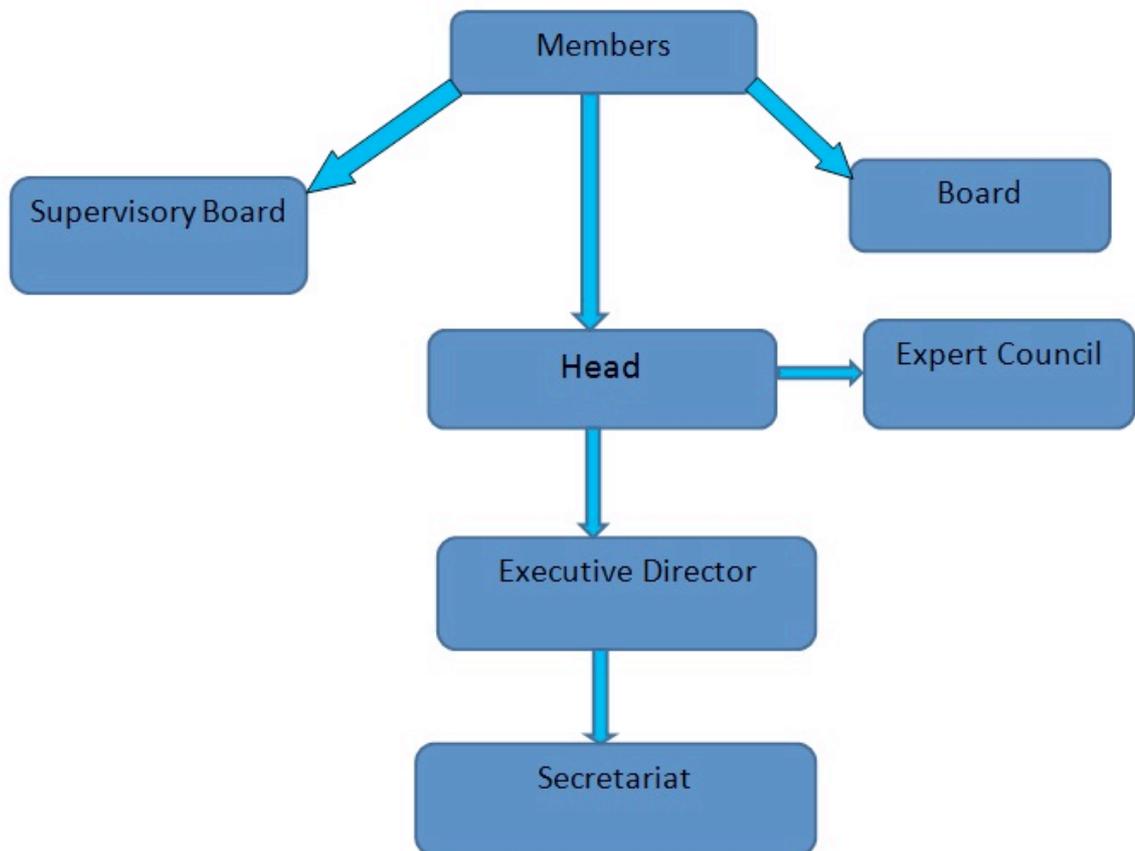
We improve access to effective treatment in Ukraine

UCAB objectives:

- To mobilize patient communities in various disease areas in Ukraine.
- To maintain tripartite dialogue between patient communities, pharmaceutical companies and the government.
- To increase patients' treatment literacy in order to establish powerful patient movement, whose members are able to lead equal dialogue with pharmaceutical companies and the government.
- To facilitate the inclusion of Ukraine into the list of countries for new clinical trials and application of best medical practices.
- To control drugs effectiveness and work on side effects prevention.
- To promote effective price policy in the area of medical products, diagnostics and prevention methods.

Structure

UCAB founders represent different patient communities.



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Decision-making process in UCAB

Decisions on all issues concerning UCAB activity, except of those, which according to this Policy belong to the competence of the Chair, the Board or the Executive Director, are made through consultations, organized by the Chair during meetings, by electronic mail, fax or post.

No later than in 3 days until the deadline, the Chair sends the description of the issue, as well as additional documents and materials affiliated to it, for consideration of all UCAB members by electronic mail, fax or post.

In order the decision is made, not less than a half of the members should give their votes by electronic mail, fax, and post or during the meeting. In case the agreement of the half of UCAB members was not reached, the issue should be forwarded to UCAB meeting, where it will be made by the simple majority of members' votes present at the meeting.

UCAB meeting is considered to be legitimate in case not less than a half of UCAB members take part in it.

Every UCAB member has one vote. In case votes are divided equally, the vote of UCAB Chair is crucial.

In case the UCAB member cannot take part in the meeting, he/she can delegate his/her vote to another UCAB member by sending the letter to the UCAB Chair by electronic mail, fax or post.

The Chair of UCAB determines deadlines for each decision-making process based on the situation to his/her consideration.

The Chair of UCAB

The Chair and the Deputy Chair of UCAB are elected out of UCAB members by simple majority of UCAB members' votes on two-years' term. The UCAB Deputy Chair performs the duties of the Chair in case of his/her absence.

Duties and responsibilities of the Chair:

The Chair has the following functions and duties, which he/she can delegate to the Deputy Chair and the members of UCAB:

- To maintain regular communication with national, international and regional initiatives on access to treatment.
- To establish contacts with pharmaceutical companies (international, regional and national representative offices).
- To present UCAB interests in front of pharmaceutical companies.
- To ensure selection, development and training for UCAB members.
- To organize UCAB meetings, approve the reports and minutes as well as other documents resulted from the meetings before distribution.
- To be responsible for UCAB funds use.
- To ensure the work of administrative body for effective functioning of the Foundation.
- To represent UCAB at external meetings.

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- To ensure transparent decision-making process within UCAB.

The Chair reports about his/her work at UCAB the General Assembly meetings or any other events, organized by other patient organizations.

Termination of UCAB Chair's position

In case the Chair doesn't fulfil his/her duties in appropriate manner (inactivity, lack of commitment, serious mistakes, untoward behaviour towards members, etc.), UCAB Deputy Chair, the member or the member of Expert Council have to take the matter to the meeting or electronic discussion. Not less than 2/3 of UCAB members present at the meeting should vote for termination of UCAB Chair's position in order the decision is made. Except of regular meetings, the decision about termination of UCAB Chair's position can be made at special UCAB meeting, which can be initiated by the UCAB Deputy Chair, 1/3 of UCAB members or the Expert Council. In case the member cannot take part in special meeting, his/her vote can be delegated according to the above-mentioned procedure.

Before the Chair's position is terminated, the Chair has the right to be heard and present his or her side of the matter.

Members

UCAB members are chosen so as to represent patient community or any other interested parties.

Not less than 2/3 of UCAB members should be people living with diseases. Representatives of pharmaceutical industry, practicing medical doctors cannot have membership in UCAB.

People become UCAB members as individuals and not as representatives of their own home organisation. UCAB membership is limited to 20 persons in total.

UCAB is a self-organized group of patients, who determine UCAB membership as well as design and approve constituent documents during the first General Assembly meeting.

UCAB members are admitted for the term of 2 years.

Every new UCAB member is admitted by the decision of UCAB Board and is based on the decision-making procedure and on the candidates' membership form.

UCAB members constitute supreme governing body – the General Assembly (hereinafter GA).

Duties and responsibilities of the members:

- To determine UCAB key activities.
- To approve charitable programs.
- To establish contacts with pharmaceutical companies (international, regional and national representative offices), take part in meetings preparation with companies, speakers and members if appointed by the Chair of the GA.

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- To provide input to meeting agendas and ensure personal meeting preparation, participate actively in UCAB meetings.
- To respect confidentiality of UCAB work, based on this Policy.
- To stick to the procedures and fulfil UCAB decisions.
- To be available for tasks such clinical trials protocol reviews and thematic portfolios.
- To be visible and interact with the local community.
- To be informed about local patient, clinical trial and treatment issues.
- To identify and propose new members suitable for UCAB.
- To annually sign the UCAB confidentiality agreement, declaration of interests and disclosure of financial contributions received from the industry for performing personal activities (before every meeting with pharmaceutical company) and the UCAB membership form.
- Initiate UCAB Policy and Statute updates.
- To represent patients' interests in other bodies, working groups, state institutions etc. on behalf of UCAB.
- To select executive (the Board) and supervisory (Steering Committee) bodies and elect the Chair of UCAB.

The GA has a right to make all decisions concerning Foundation functioning including those lying in the competence of the executive body.

Update of UCAB membership

Once in two years UCAB Secretariat sends a letter to all UCAB members with request to fill in and to send back the membership form for the next year. Not sending the membership form after the second reminder letter causes automatically membership termination. UCAB Chair informs all the members and the Expert Council about such cases of membership termination.

Termination of UCAB membership

Membership can be ended for any of the following reasons:

- UCAB members who move out of Ukraine for more than a year can stay on the UCAB list as list-only members. Their membership is automatically reactivated without formal procedure when returning to Ukraine if their absence has been shorter than two years.
- Breaching confidentiality.
- Disrespect of group procedures and other members.
- Unexplained inactivity and lack of commitment.
- Not submitting/renewing the UCAB membership form with the declaration of interest form.
- Not showing up at two meetings without serious reasons
- A request by a member to terminate his or her membership.

Disrespect of group procedures or other members and guests

If a member disrespects group procedures or other members, the Chair must bring this to their attention immediately and ask the member to respect rules, procedures and show good conduct. If the member continues to breach group procedures, or if the Chair deems that the problem is too serious, then s/he will bring the matter to the electronic

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discussion. The final decision for a termination of UCAB membership rests with the above-described decision-making procedure. All parties must be heard in terms identified by the Chair before the final decision is reached.

Inactivity and lack of commitment

Members are expected to inform the Chair if for any reason they have to stay inactive for any long period of time (e.g. health reasons, workload, travelling, etc). During this period, they may stay on as list-only members.

When a member fails to attend UCAB meetings for half a year (2 meetings) without having let the Chair know why, the Chair sends a letter asking the member whether s/he wishes to continue being a member of UCAB. If one month after this letter has been sent the member has not responded, his or her membership is terminated. If the member responds, explaining his or her legitimate reasons, then s/he stays on as a member. If, however, s/he remains inactive (either through failure to attend meetings or participate actively on the mailing list) during the next 6 months, then her or his membership is automatically terminated, and a letter is sent by the Chair informing the ex-member of the decision.

The decision about termination of UCAB membership is made according to the above-mentioned decision-making procedure.

Re-activation of membership

A member whose membership has been terminated for any reason and who wishes to become UCAB member again, has to go through the following procedure: to take part in two UCAB meetings as a guest, signing a special confidentiality agreement. After the discussion between the Chair, members and the Expert Council, his/her membership can be re-activated by the Chair.

Expert Council

Expert Council is a consultative body providing expert support to UCAB members. The members of this body don't make any decisions, but take an active part in organizing UCAB meetings, maintaining contacts with pharmaceutical companies, review of clinical trials protocols and members' capacity building. The Expert Council members are involved into meetings based on the theme of the meeting, his/her expert profile and experience of work with products and trials of the pharmaceutical company.

Expert Council members are elected according to the following procedure: once a year the Chair makes an experts list (where UCAB members are not included) and brings it to UCAB review and approval. In case UCAB members don't approve the proposed candidates, the Chair should propose other options. The experts, supported by the GA should receive a letter of invitation on behalf of UCAB Chair. After Expert Council list is agreed, the new members sign confidentiality agreement.

The Board

The executive body of the Foundation is represented by the Board. The Chair and the 5 members of the Board are elected at the GA meeting for the term of 2 years, and can be appointed for new term or terminated any time by the GA decision.

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Duties and responsibilities of the Board:

- To ensure effective functioning of UCAB.
- To control implementation of the tasks of the Foundation.
- To take decisions on annual budget, financial support for programs and projects, grants payments of the Foundation, and to control their implementation.
- To establish and maintain contacts with pharmaceutical companies.
- To ensure selection, development and training for UCAB members.
- To be responsible for UCAB funds use.
- To represent UCAB at external meetings.
- To ensure transparent decision-making process within UCAB.
- To decide on UCAB members admission and termination.

The Board reports to GA at their request. The Board has meetings not less than once per quarter. The Board is legitimate with the presence of the majority of its members. The decisions are taken by the majority of members' votes present at the meeting.

Secretariat

To ensure regular UCAB functioning, an administrative-executive body managed by the Executive Director is established. The Executive Director creates this body to organize the work of Foundation, which qualitative and quantitative structure is defined by him/herself. In case of Deputy Head absence, the Executive Director performs his/her function.

Duties and responsibilities of the Secretariat:

- To maintain regular communication with national, international and regional initiatives on access to treatment.
- To establish contacts with pharmaceutical companies (international, regional and national representative offices), make preparations for the meetings with companies, speakers and the members of UCAB.
- To ensure preparatory work for UCAB meetings and trainings.
- To moderate UCAB e-mail list.
- To ensure UCAB effective functioning in between the meetings, according to the goals, appointed by the GA.
- To represent UCAB at external meetings.
- To document UCAB best practices and success stories.
- To maintain contacts with national, international and European partners.
- To ensure monitoring of UCAB decisions implementation.
- To conduct fundraising for UCAB effective and continuous functioning.

Steering Committee

The Steering Committee conducts administrative and control functions, appointed by the GA.

The Steering Committee meetings are held not less than once a year.

The Steering Committee is responsible for: controlling financial activity of the Foundation; preparing reports on the activities of the Foundation and informing the GA about them; making conclusions on annual reports and balances. The Steering

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Committee has a right for: GA ad hoc assembling; solving other issues in its competence according to the legislation of Ukraine and other documents of the Foundation; requesting necessary materials, book-keeping documents and personal explanations from the staff members of the Foundation.

UCAB Meetings

Schedule

UCAB meets on a regular basis not less than 3 times per year. Additional and ad hoc meetings are possible. Except of dialogue of patient organizations, pharmaceutical companies and the donors, sufficient time is to be dedicated to internal work, lectures and trainings in order to raise community awareness about treatment access issues.

A call for each meeting will be sent by Secretariat by email 3 weeks before each meeting. Members are expected to register within 2 working days following the call. Registrations of participants for UCAB meetings are made by the Secretariat.

Meeting moderators

The moderator is selected at the pre-meeting with pharmaceutical company by the simple majority of UCAB members' votes.

The moderator's main responsibility is to prepare the agenda for the meeting, involving responsible members, recording the list of questions and other materials and handouts for the participants and the representatives of pharmaceutical companies, ensuring that the issues raised in the agenda are followed in a timely way. The moderator is in charge of conducting the meeting with fair time for all members to speak. The moderator summarises the meeting to the company at the end. Participants should respect the position of moderator and speak when given the floor.

Guests

People who are likely candidates are invited to attend UCAB meetings as guests. All guests are obliged to sign a special confidentiality agreement and have a right to take part in the training part.

Admission of new members

Guests that have proved that can actively contribute to UCAB are encouraged by the Chair or the Expert Council to become UCAB members after two attendances at the earliest. A guest can become a new member after the discussion between the Chair, all members and the Expert Council. The Board makes decisions on the admission and termination of membership.

List-only Members

For practical reasons, there is a possibility of being a list-only member, following a decision of the Chair after the attendance of the first UCAB meeting. List-only members are obliged to sign confidentiality agreements and the declaration on conflict of interests:

- All the discussions and materials within the list are strictly confidential.
- **Only personal e-mails should be included into the mailing list.**

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Confidentiality

It is important for treatment activists to have access to confidential information from the pharmaceutical industry. Therefore, UCAB requires companies, state institutions and NGOs, individuals to disclose information of scientific and commercial value, connected with clinical trials (current or future). All such confidential information is hereafter referred to as "confidential information".

At the same time, UCAB members represent different patient communities from all over Ukraine, for whom the information provided by pharmaceutical companies, state institutions representatives and experts during the meetings, may be lively important. Therefore this Policy is to clearly regulate the balance between the confidential information, which is important for the general public in order to fulfil the mission of UCAB.

A confidentiality agreement is signed by all UCAB members when they join the group.

UCAB guest participants must sign the UCAB confidentiality agreement in order to protect the group and the rights of companies/other stakeholders and to remove the latter's objection to reveal confidential items. The confidentiality agreement also covers discussions held on the group's mailing list.

According to the agreement, all information disclosed by companies is considered non-confidential unless expressly stated otherwise. Positions and decisions taken by UCAB are public. Internal discussions and contents are strictly confidential to members.

In case the information is considered confidential, reposting or forwarding it to other lists, not included into UCAB e-mail list, is not allowed. Reposting of information that is in the public domain is allowed, but has to be copy/pasted in a new e-mail, in order to protect the privacy of the original sender.

Pharmaceutical companies, state institutions and NGOs, individuals agree to disclose the confidential information to the UCAB participants who agree to receive the same on the following conditions:

- Confidential information will be used solely for the purpose set out above and for no other purpose whatsoever. No conclusions, results or other material created as a result of the direct participation in the company presentations (hereinafter referred to as "the results") will be used without prior written consent from the UCAB.
- All confidential information and results will be held in the strictest confidence at all times and will not be disclosed, as a whole, or in part therefore, to any third party, nor will any third party be allowed to have access to the same or any part thereof without prior written consent granted by the company.
- The above mentioned limitations refer to material that is specifically mentioned as confidential and is of commercial or academic value and shall not apply to any other part of information or results.

It is agreed that the limitations mentioned above shall not apply to any part of information or results that:

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- Were not specifically marked as confidential
- Were already known to any UCAB member prior to its disclosure by the company
- Are public knowledge or subsequently become known to the public other than by breach of this agreement
- Are received without restriction from any third part that is entitled to disclose the information.

Breaching confidentiality

In case of a breach of confidentiality without the agreement of the Chair the following procedure will be followed:

- A hearing will be held within the next or special meeting of the Board, at which the member in question will have to explain why s/he breached confidentiality. The Chair should report on the amount of damages, caused by this breach of confidentiality.
- After the hearing the issue on person's termination is put on UCAB GA voting.
- The UCAB decision will be communicated to all interested parties.

If the member in question has already broken confidentiality before, membership is automatically terminated without applying the procedure described above. The final decision rests with the chair. This procedure is valid for all individuals who signed the confidentiality agreement.

However, there may be extremely serious exceptional cases when confidentiality may have to be compromised if patients are at risk. In such cases, it is absolutely imperative to seek discuss the matter with the Chair before any action is taken.

Conflict Resolution

This procedure is the same as the decision-making procedure. All conflicts should be solved by discussions between the Chair, the Deputy Chair, the members and UCAB representative. Ideally, decisions on such matters are reached consensually. In case there's no possibility to reach consensus, the decision is made by the majority of votes of the members present at the meeting.

Conflict of interests

This chapter identifies the principles of resolving of the conflict of interests. The goal of this chapter is to ensure fair decisions of UCAB, reputation protection, transparency and confidence of the patients in Foundation functioning.

UCAB functions on the principles of legitimacy, transparency and publicity.

The UCAB member has conflict of interests when she/he starts having financial relations with the pharmaceutical companies/y, which can cause his/her personal interest in lobbying the interests of the relevant companies/y. The UCAB member should inform the Chair and the members about the existing conflict of interest before the discussion of the relevant point in the agenda was launched. The UCAB member, having the conflict of interests has no right to take part in voting around the company.

In case the abuse by the UCAB member (not disclosing the conflict of interests information at the beginning of discussion, participation in the voting) is discovered,

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his/her termination is put on the voting of UCAB GA due to breaching the conflict of interests principles.