

TRANSPARENCY PROGRAMME OF NGC MEDICAL S.R.L.

METHODOLOGICAL NOTE FOR THE CORRECT INTERPRETATION OF THE PUBLISHED DATA ON TRANSFERS OF VALUE BETWEEN NGC MEDICAL, HEALTHCARE PROFESSIONALS, HEALTHCARE ORGANISATIONS AND OTHER THIRD PARTIES IN THE SCIENTIFIC COMMUNITY.

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INTRODUCTION

For NGC Medical, transparency is one of the most important values. We do not only want to maintain uncompromisingly the highest reliability and quality of our products and services, but also to be recognised as a benchmark and as an institutionally reliable company with integrity in providing its services.

For this reason, NGC Medical, fully agreeing with the principles on the transparency of transfers of value ("ToV") outlined by the Trade Associations, as of 2021 has decided to publish data on transfers of value provided by NGC Medical to **Healthcare Professionals ("HCP")**, **Healthcare Organizations ("HCO")** and **Third Parties** in the scientific community operating in Italy. The publications, on an annual basis, will be published by 30 June of the following calendar year.

1. RECIPIENTS OF TRANSFERS OF VALUE

With reference to the transparency of ToV between the medical device industry and Health Care Professionals, Health Care Organisations and Third Parties, in compliance with the provisions of the industry Code of Ethics, the recipients of ToV are defined as follows:

- Health Care Professionals

Also identified as HCP (Health Care Professionals), are those who carry out their professional activity in the health care sector (by way of example, doctors, nurses, laboratory staff, technicians, administrative staff in health care facilities, etc.) in the public and/or private sector, who in the course of their professional activity have the power, directly or indirectly, to purchase, hire, recommend, manage, use, supply, procure or determine the purchase, rental or prescription of medical technologies or related services.

-Health Care Organisations

Also referred to as HCO (Health Care Organizations), refers to any legal entity or body (regardless of legal form or organisation), association or health, medical or scientific organisation through which one or more Health Care Professionals provide services or which are able to exercise a direct or indirect influence on any prescription, recommendation, purchase, order, supply, use, sale or rental of medical technology and related services. Examples: hospitals, central purchasing departments, clinics, laboratories, pharmacies, research institutes, associations, foundations, universities, scientific societies or other educational or professional institutions. Also included in this definition are Patient Associations, i.e. organisations representing and supporting the needs of patients and their caregivers within a specific disease or health aspect.

- Third Parties

These are independent parties that propose, organise, manage, both scientifically and logistically, events of any kind and type, aimed at meeting an educational need of a scientific nature or advocating policies that promote scientific knowledge, medical progress and effective healthcare.

2. CATEGORIES OF TRANSFERS OF VALUE

The ToV, as referred to in the reports published on this website, relate to the following types of interactions:

- A. Training activities promoted and managed by Health Organisations and/or Third Parties funded by NGC Medical;
- B. Training, educational and promotional activities that may be organised by NGC Medical;
- C. Appointments, consultancies and professional services to Health Professionals and/or Health Organisations.
- D. Financial and other types of donations.
- E. Scholarships and Master's degrees.

A. TRAINING ACTIVITIES PROMOTED AND MANAGED BY HEALTHCARE ORGANISATIONS AND/OR THIRD PARTIES FUNDED BY NGC MEDICAL

NGC Medical supports events, conferences, congresses and courses, of a scientific training and/or policy-making nature that promote scientific knowledge, medical progress and effective healthcare, promoted and managed by Health Organisations and/or independent Third Parties.

This category also includes ToV in support of higher or advanced level training and updates on technical, regulatory, organisational-managerial (health management) and/or social-political issues related to the reference sector, initiatives to protect the health and psycho-physical wellbeing of the individual, and to disseminate the culture of prevention.

It is also possible to provide this kind of support through the purchase of sponsorship rights, such as, purely by way of example, the reproduction of one's own logo on the event programme, conference material and/or the conference website, the rental of exhibition space, the display of banners or the organisation of company satellite symposia.

As part of the sponsorship packages and included in the same, it is possible to purchase a certain number of congress participation fees for a certain number of healthcare professionals (registration fees and/or travel and hospitality expenses) depending on the type of sponsorship implemented, for the sole purpose of contributing to the updating of Health Care Professionals by favouring the enhancement and knowledge of

technologies and their innovation. It is understood that, in this case, the individual Health Care Professionals, who will be able to benefit from participation in the event due to the payment of said registration fees, will be chosen in absolute autonomy and independence by the promoting body (HCO or Third Party) or by the body to which the Professional belongs.

NGC Medical will be totally uninvolved in the process of identifying the Health Care Professionals.

NGC Medical will directly enter into a specific sponsorship contract with the organizer (HCO or Third Party), in which the individual sponsorship rights acquired and the individual amounts paid for each of them will be specifically identified in detail. In the sponsorship contract, NGC Medical may define the category of Health Care Professionals to whom the contribution will be destined and/or the geographical area and/or the health care facility to which they belong, without prejudice to the full and absolute guarantee that the contribution cannot be attributed to a single Health Care Professional, and without prejudice to the prohibition of direct sponsorship.

For courses or procedure training, i.e. specific events whose programme is devoted to the provision of practical training on the safe and effective performance of one or more clinical procedures, where most of the training takes place in a clinical environment, it is possible to support the Health Care Professionals. Except for the courses or procedure training, described above, the possibility to provide economic support directly to individual Health Care Professionals in order to cover the costs of participation in training and educational activities promoted and managed by Health Care Organisations and/or Third Parties is expressly forbidden. The above-mentioned support can be paid directly to the entity to which the Healthcare Professional belongs or to the Healthcare Organisation and/or Third Party organizing the event.

B. TRAINING, EDUCATIONAL AND PROMOTIONAL ACTIVITIES ORGANISED BY NGC MEDICAL

NGC Medical arranges the following types of initiatives:

- scientific-clinical updates related to the use of products, therapies and procedures, as well as to the optimisation of patient management paths;
- updates and higher or advanced level training on technical, regulatory, organisational-management (health management) and/or political-social issues related to the reference sector;
- the protection of health and the psycho-physical well-being of the individual, as well as the promotion of prevention culture.

Meetings with Health Care Professionals for the above initiatives may be held either in person or virtually, in contexts that favour the exchange of scientific or training information and that are appropriate according to local laws or regulations and to the sector's ethical codes. NGC Medical follows the ANAC guidelines, for invitations of Health Care Professionals, as attendees, to training events that may be organized by NGC Medical, which would require the appointment of individual attendees by the Health Organization to which they belong.

Invitations to the above events, organised by NGC Medical, whether in person or remotely, are forwarded to the General Management and/or other relevant office of the Health Care Organisation, with an indication of the number of professionals that NGC Medical declares itself willing to invite and the target audience of professionals to whom the event is addressed. The Health Care Organisation will select and communicate to NGC Medical the name of the participant. Excluded from the above procedure are digital training and updating events offered in e-learning and webinar mode open to all Health Care Professionals through spontaneous registration.

NGC Medical may incur travel and accommodation costs only and exclusively for HCPs invited to the events, according to the process described above and in compliance with all applicable regulations and industry codes of ethics.

In case of cancellation before the event, the related costs shall not be published, as they do not represent a transfer of value to the beneficiary.

C. ASSIGNMENTS, CONSULTATIONS AND PROFESSIONAL SERVICES, TO HEALTH CARE PROFESSIONALS AND/OR ORGANISATIONS

NGC Medical has always promoted medical and clinical collaboration inspired by scientific accuracy and ethics, with the aim of guaranteeing the safety, innovation and quality of treatments and therapies, with total and rigorous adherence to the laws and procedures required by the Authorities.

Collaboration between industry and healthcare professionals in the field of medical devices is a necessity for research and development of new technologies, as well as for educational purposes for a safe use of medical devices.

NGC Medical has adopted a company policy according to which any consultancy contract for professional services against payment must be entered into with the Health Care Organisation and not with the individual Health Care Professional. Therefore, NGC Medical will publish the transfer of value, compensation for the consultancy and possible travel and accommodation expenses of the entrusted Health Care Professional, to the Health Care Organisation to which the transfer of value is addressed.

For contracts that extend over several years, payments are usually made in several stages, based on the services actually rendered and invoiced. Each of these separate payments will be included in the calculation for the publication of transfers of value in the calendar year in which the payment or reimbursement was approved in our systems.

D. FINANCIAL AND OTHER TYPES OF DONATIONS

NGC Medical may donate money or other goods for educational, scientific, social, humanitarian, philanthropic or other relevant charitable purposes.

Donations may only be made at the specific request of the beneficiary entity, free from any commercial interest, and only in favour of organisations and entities that are entitled to receive them in accordance with the applicable laws, regulations and ethical industry codes, and in accordance with an appropriate rotation system. Any kind of donation to private individuals is prohibited.

E. SCHOLARSHIPS

In compliance with the provisions in force on the subject, scholarships may be awarded according to written agreements between NGC Medical and the requesting beneficiary Health Care Organisation, in which it must be specified that the choice will be made by the latter under its own transparent and objective procedures for evaluating the candidates and according to recognised scientific and training criteria. NGC Medical will remain totally uninvolved in the process of selection and evaluation of candidates. Scholarships may only be awarded to the requesting beneficiary Health Care Organisation, in compliance with an adequate rotation system.

3. METHODS OF PUBLICATION

A - EDUCATIONAL INITIATIVES PROMOTED AND MANAGED BY HEALTH CARE ORGANISATIONS AND/OR THIRD PARTIES FINANCED BY NGC MEDICAL - PUBLICATION METHODS

NGC Medical will publish, on an individual basis for each organizing entity (HCO and/or Third Party), the amount of ToV made during the previous year with reference to:

- contributions for the financing of events (e.g. sponsorship of conventions, congresses and scientific meetings, etc.);
- registration fees;
- travel and hospitality expenses (excluding meals and beverages).

Moreover, NGC Medical will publish, on an individual basis, the amount of ToV made during the previous year, for the participation of Health Care Professionals in the courses or procedure training, described above, who have given their consent to the individual publication of the data, the amount of ToV made during the previous year in reference to:

- registration fees;
- travel and hospitality (excluding meals and beverages).

In the event that consent from the recipient of the ToV is not provided, NGC Medical will publish the data relating to the ToV in aggregate form, indicating:

- the number of recipients on an absolute basis and as a percentage of the total number of recipients;
- the aggregate data pertaining to Health Care Professionals who have not given consent to the processing of data;
- the percentage data of value transfers in aggregate form on the total number of transfers.

B - TRAINING, EDUCATIONAL AND PROMOTIONAL ACTIVITIES ORGANISED BY NGC MEDICAL - METHOD OF PUBLICATION

NGC Medical publishes, on an individual basis for each Health Care Professional who has given consent to the individual publication of the data, the total amount of ToV carried out during the previous year with reference to:

- expenses for participation in training, educational and promotional activities organised by NGC Medical (excluding meals and drinks, unless they are included in the registration fee, maintaining absolute anonymity).

In the event that the consent of the recipient of the value transfer is not provided, NGC Medical will publish the data relating to the ToV in aggregate form, indicating:

- the number of recipients on an absolute basis and as a percentage of the total number of recipients;
- the aggregate figure attributable to Health Care Professionals who have not given consent to data processing;
- the percentage figure of transfers of value in aggregate form over the total number of transfers.

No data will be published concerning the Health Care Professionals who took part in the events organised by NGC Medical mentioned above, for which no participation expenses were incurred.

Data will not be published on Health Care Professionals who took part in the events organised by NGC Medical mentioned above, for which no participation costs were incurred.

C - APPOINTMENTS, CONSULTANCIES AND PROFESSIONAL SERVICES, TO HEALTH CARE PROFESSIONALS AND/OR HEALTH CARE ORGANISATIONS - METHOD OF PUBLICATION

NGC Medical publishes, on an individual basis for each Health Care Organisation, the total amount of ToV made during the previous calendar year, by way of:

- fees for consulting activities and professional services, including speaking activities as defined in any contract between NGC Medical and the Health Care Organisation; and
- related travel and hospitality expenses for carrying out the services (excluding meals and beverages, unless they are included in the registration fee, maintaining absolute anonymity).

D – FINANCIAL AND OTHER TYPES OF DONATIONS - METHOD OF PUBLICATION

NGC Medical will publish, on an individual basis for each beneficiary (HCO), the total amount of ToV made during the previous year with reference to:

- financial and other assets type of donations made to the Health Care Organisation and any additional public interest organisations (by way of example, but not limited to schools and/or territorial bodies, on the basis of a solid reasoned shared rationale).

E - SCHOLARSHIPS - METHOD OF PUBLICATION

NGC Medical will publish, in aggregate form, the total number of beneficiaries and the total amount of ToV made during the previous year with reference to:

- scholarships and/or master's degrees.

The publication is structured on a nominal basis with reference to each beneficiary of a transfer of value, whether it is a healthcare professional, a healthcare organisation or a third party and, clearly, after obtaining consent for healthcare professionals.

4. METHODOLOGY

As fulfilling the Transparency requirements for the Medical Devices industry is a voluntary obligation, the publication of the data depends on the consent of the concerned Health Care Professionals: therefore, such consent, according to the Italian Privacy Laws, should be collected before the publication of the individual data of the Health Care Professionals possibly involved. Such consent would include the recording, processing and disclosure of personal information for the stated purpose.

In the event of data processing, the same will be published for a period of 3 years and kept for a period of at least 5 years, in order to ensure the widest transparency. NGC Medical will keep appropriate documentation

showing that the Health Care Professional's consent to the publication of data concerning him/her has been requested. Access to the site and to the data is free.

In this regard, NGC Medical makes every effort to obtain the consent of the Health Care Professional to the individual publication of data, in compliance with the legislation in force on data protection. In case consent from the beneficiary of the transfer of value is not provided, NGC Medical will publish the ToV data in aggregate form.

Moreover, we would like to point out that all contracts NGC Medical enters into with HCPs, HCOs and Third Parties, for the activities under points A, B, C, D and E, as defined above, have a specific clause allowing NGC Medical to comply with the requirements of industry codes and legal regulations on transparency of value transfers.

In all cases where it is necessary to publish data on an aggregate basis for each of the categories identified in the previous points, it must be possible to identify:

- the number of recipients on an absolute basis and as a percentage of the total number of recipients;
- the aggregate figure attributable to the Health Care Professionals who have not given their consent to the processing of the data;
- the percentage figure of transfers of value in aggregate form over total transfers.

The amounts published are generally amounts net of VAT except in the case of payment of expenses related to travel and stays, for which VAT is included in most cases. Withholding tax (where applicable) is included.

ToVs will be published in the local currency of the country in which they are published, thus in Euro even if executed in another currency. ToV originally paid in a different currency will be converted to the local currency; details of the exchange rate can be provided on a case by case basis upon request.

In order to identify the amount of value transfers to be published for each calendar year, NGC Medical uses the accrual criterion: all amounts authorised for payment and relating to services rendered in the previous year are therefore published in the report.

The publication of ToV with multiple installments of payment, spanning several fiscal years, is managed by charging for each year the ToV authorised and pertaining to the year, recorded within the management system, at the time of consolidation of the data to be published.

Transfers of value related to promotional material, meals, beverages and product samples are excluded from the obligation to publish.

The information in published reports reflects our good faith and efforts to comply with the requirements of the industry codes on the transparency of transfers of value. If, despite our efforts to ensure accurate reporting, we do not include complete and correct information, we will make appropriate checks and amend the data if they are incorrect.

If you have any queries or wish to receive further information on the NGC Medical Transparency Programme, please use the dedicated PEC email address ngc@legalmail.it.

REFERENCES

[- Code of Ethics Confindustria Medical Devices, latest version](#)

[- MEDTECH Code of Ethics, latest version](#)

- National Authority for Anti-Corruption (ANAC) resolution 831 of 3 August 2016

- Legislative Decree 231 of 8 June 2001

- Law 190 of 6 November 2012

- Presidential Decree no. 62 of 16 April 2013

- Legislative Decree No. 196 of 30 June 2003 as subsequently amended and supplemented with the amendments introduced by Legislative Decree No. 101 of 10 August 2018 and EU Regulation 2016/679 of 27 April 2016.