CODE OF PRACTICE

JULY 2015

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Contents

CODE OF PRACTICE

NATIONAL TECHNICAL ADVISORY GROUP ON IMMUNISATION

Introduction

1. The National Technical Advisory Group on Immunisation (NTAGI) was established by an order of the Ministry of Health and Family Welfare (MoHFW) in 2001. As India's apex advisory body on immunization, the NTAGI provides guidance and advice to the MoHFW on **provision of vaccination and immunization services for the effective control of vaccine preventable diseases in the country**.
2. Since its establishment, the NTAGI has been reconstituted twice, in 2010 and 2013. As per the MoHFW order dated 25 June 2013 (13011/01/2013), the NTAGI now includes a Standing Technical Sub-Committee (STSC). The STSC is tasked with undertaking technical review of scientific evidence on matters related to immunization policy and programmes. Final recommendations are drafted by the NTAGI taking into account the scientific review by the STSC and any other relevant evidence.
3. This Code of Practice contains information about the responsibilities, structure, functioning, and procedures of the NTAGI and STSC. This document has been prepared after reviewing the best practices at global and national scientific advisory committees and has been ratified by chair & co-chairs of the NTAGI with inputs from members of the STSC. All members (current and prospective) of the NTAGI and STSC as well as individuals attending meetings are required to confirm their acceptance of the provisions set out in this document by signing the declaration as indicated [Annexure 1].
4. The Code of Practice must be reviewed every five years. An earlier review of the Code of Practice may be taken up, if needed, at the discretion of Chair and Co-chairs.

Objective and scope of activities

5. The overall objective of the NTAGI is to provide advice to the Ministry of Health and Family Welfare on the strategies to control the burden and appropriately evaluate the impact of immunization on Vaccine Preventable Diseases (VPDs) in the country.
6. The NTAGI shall evaluate licensed vaccines as well as prioritize other related interventions such as associated immune globulins and chemo-prophylactic agents and new technologies for delivery, logistics, disease prevention and monitoring of VPD prevalence, vaccination programme and other adjuncts to VPD control'. Guidance for use of unlicensed vaccines may be developed if circumstances necessitate their use.
7. NTAGI recommendations may include guidance on all matters related to immunization policy and programmes:
    - route, dose and frequency of administration of the vaccine
    - population groups (e.g. high risk groups, urban slums and tribal populations)
    - circumstances (e.g. pandemics, natural disaster etc.) in which a vaccine or related agent is recommended
    - strategies for introduction of the vaccine (e.g. pilot/phased introduction, Special Immunization Activities (SIAs), vaccines for post-exposure prophylaxis etc.)
    - contraindications and adverse events associated with the vaccine or related agent
    - recommendations on generation of relevant evidence, prior to and after vaccine introduction, monitoring of delivery and impact after vaccine introduction.
8. In developing these recommendations, the NTAGI may consider (all available, including domestic evidence, wherever available") evidence on burden and epidemiology of disease, vaccine safety, efficacy and effectiveness, economic analyses and implementation issues. In the

absence of available evidence, the NTAGI may also recommend to the government the requirement for specific studies or cumulation of data. The NTAGI may revise or withdraw their recommendation(s) regarding a particular vaccine in the light of new information on any of the criteria mentioned above.

9. The NTAGI may also recommend relevant studies to be conducted (pilot/operational) for vaccines e.g. Post marketing surveillance study for a vaccine may be recommended to the national regulatory authority, technological assessments of new vaccine delivery technologies and studies for impact assessment of new vaccine introductions may be recommended, if and when required.

10. The NTAGI also may provide recommendations that address the general use of vaccines and immune globulin preparations, including travel vaccinations or occupational health vaccinations. These general recommendations may address the principles that govern administration technique; dose and dosing interval; recognized contraindications and precautions; profile of adverse events; the correct storage, handling, and recording of vaccine and immune globulin preparations; and immunization in special situations (e.g. pandemics or natural disasters) or special populations (e.g. urban slums, tribal populations, adolescents, school or college students vaccinations at work etc.) that may warrant new recommendations or modification of the routine recommendations.

11. The NTAGI shall also establish and appropriately revise, a list of vaccines for administration to children and adolescents, adults, pregnant women and immunocompromised individuals eligible to receive vaccines through the Universal Immunization Programme (UIP), along with schedules regarding the appropriate dose and dosing interval, and contraindications to administration of the vaccines.

12. The NTAGI must review its recommendation on every major VPD at least once every five years.

Recommendations formulated by the NTAGI shall be used by the Government to inform, develop and make policy relevant to immunization. **The NTAGI is not a policy making body in its own right and has no regulatory function.** Membership and composition of the NTAGI

Membership

13. The NTAGI is chaired by the Secretary of Health and Family Welfare (H & FW), Ministry of Health and Family Welfare, while the Secretary of Department of Biotechnology, Ministry of Science and Technology and the Secretary of Department of Health Research, Ministry of Health and Family Welfare serve as the Co-chairs, all functioning in an ex-officio capacity.
14. Core membership is composed of Government of India representatives functioning in an ex-officio capacity and independent experts. Core independent experts are expected to serve in their own personal capacity and to not represent the interest of any particular group or organization. In addition, liaison members comprised of representatives of MoHFW, professional organizations and international partners functioning in an ex-officio capacity, as notified in the NTAGI reconstitution order, represent their respective organizations.
15. The Chair, Co-chairs and independent Core Members engage in advising and deciding on final recommendations.
16. Liaison members and ex-officio members (other than the Chair and Co-Chair) may contribute to the discussion, but are not engaged in decisions or final recommendations.
17. Ex- officio members and liaison representatives are expected to represent the position and views of their organizations/departments. Members can only serve in one capacity.

18. As per reconstitution order dated 25 June 2013, Members of the NTAGI will not be paid an honorarium but the costs of their travel and incidentals will be covered for participating in meetings and discussions.

Appointment of NTAGI members

19. NTAGI members are selected based on their expertise and qualifications necessary to contribute to the accomplishments of the NTAGI's objectives. The membership of NTAGI will normally include one to two experts from the following disciplines: epidemiology, biotechnology, infectious diseases, community medicine, pharmacology, vaccinology, health economics, paediatrics, virology, bacteriology, immunology, neurology, mathematical modelling, general practice, public health, nursing, clinical research, community engagement and communication or other relevant disciplines, health systems and delivery and management of immunisation programmes.

20. Distinguished experts in relevant fields will be nominated and appointed as Core Independent Members of the NTAGI and its Sub-committee(s) by the NTAGI chair, the Secretary of Health and Family Welfare, in consultation with the Co-chairs, the Secretary of Biotechnology and the Secretary of Health Research. Experts will be evaluated on the following key attributes for nomination to the NTAGI:

- An outstanding record of achievement and professional and personal credibility in their field of work;
- Advanced training and scientific knowledge of vaccines, immunization and immunization programs;
- Expertise and strategic experience of working in high level advisory roles;
- A deep understanding, expertise and experience in the field of immunization related areas covered by NTAGI;
- An understanding of national immunization issues in the Indian context;

- Excellent interpersonal and communication skills to support effective discussion with a range of stakeholders;
- Ability to evaluate complex issues and weigh conflicting opinions;
- Ability to influence at a senior level;
- A broad range of expertise and interest in vaccines and immunization

21. New members of NTAGI will undergo one day of orientation which will be arranged by the Secretariat, prior to attending a meeting of the NTAGI or its STSC. The new members will review the structure and function of the Indian public health immunization system, the functioning of global and regional technical advisory groups on immunization. They will be introduced to the functioning of the Secretariat for the NTAGI. They will be provided with a briefing that covers the roles and responsibilities of the NTAGI and its membership, the function, operation and practices of NTAGI and its working groups, the support that the secretariat provides, the type of evidence reviewed by NTAGI, the methods for review and how the NTAGI interacts with its stakeholders and all the various aspects covered in this Code of Practice.

Rotation

22. All core independent members of NTAGI will serve a three-year term, and will be eligible for renewal once, after which they will be rotated off the NTAGI. At a minimum, each member will serve a three-year term with up to one third of members rotating off each year in order to ensure continuity. Renewals of appointments are at the discretion of the Chairs and Co-chairs.
23. A core independent member who has served their maximum term, a total of six years including extension can be reappointed after an absence from the group of one term (three years).
24. Liaison members can continue to serve as long as they continue to hold the posts represented on the NTAGI.

Termination

25. Membership of an individual may be terminated by the Chair in consultation with the Co-chair in the following scenarios:

A) Failure to attend three consecutive unchanged scheduled meetings without prior notification or subsequent explanation

B) Change in affiliation, resulting in a conflict of interests

C) Breach of the confidentiality agreement

Standing Technical Sub-Committee

26. The Standing Technical Sub-Committee (STSC) is tasked with reviewing data and deliberating on specific technical issues, which may require more detailed consideration than would be possible by the NTAGI and that may need substantial input from additional experts who are not NTAGI members. Members of the STSC are members of and will also be involved in the decision making process at the NTAGI.

27. The STSC is co-chaired by the Secretary, Department of Health Research (DHR) and Secretary, Department of Biotechnology (DBT).

28. Members of the STSC (excluding ex-officio members) will comprise of ten to fifteen independent experts appointed by the Secretary (H & FW) in consultation with the Secretary, DBT and Secretary DHR. Members may include experts relevant fields such as epidemiology, biotechnology, infectious diseases, community medicine, pharmacology, vaccinology, health economics, paediatrics, virology, and others which are covered in para 19. Ex-officio members of the STSC will include Director (Epidemiology and Communicable Diseases), ICMR, two state immunization officials by rotation across states for one term each and one Director of an institution that conducts vaccine preventable disease surveillance (e.g. Director National Centre for Disease Control or Director, National Vector Borne Disease Control Programme).

29. Representatives of vaccine manufacturers may not serve as members of STSC, but at the discretion of the co-chairs may be invited to make presentations and answer questions for informing the discussion at hand, especially regarding forecasting trends for preparedness, scientific advances in industry etc. Following presentations all non-STSC members may be asked to leave in order to allow deliberations to be limited to members of the STSC.

30. Confidential or proprietary information received by the STSC may be discussed at STSC meetings since all STSC members and meeting participants will have fulfilled confidentiality and conflict of interest requirements. Meeting participants and members are individually responsible for maintaining confidentiality where such information has been presented or discussed. All STSC findings and recommendations will be presented to the NTAGI where these can be further deliberated. Confidential and proprietary information may be discussed with NTAGI members in closed sessions.

31. Unless otherwise mentioned, the responsibilities of the STSC members and the functioning of the STSC will follow the same guidelines as the NTAGI, outlined in this document.

32. In order to facilitate its functioning, the STSC will establish working groups of two types, standing and ad-hoc, both of which will be supported by the NTAGI secretariat. The standing working groups will have at least two STSC members with one acting as chairperson, other expert members of the standing working group will be nominated by the STSC and approved by the co-Chairs. Ad-hoc groups will be established when needed by direction of the co-Chairs and will include two STSC members and external subject experts who will be co-opted by consensus of the co-Chairs and all STSC members. The working groups will meet as often as required, in order to fulfil objectives defined below.

33. The standing working groups will work on i) Vaccine preventable disease surveillance and ii) Research and capacity building for the functioning of the NTAGI. The standing working groups

will prepare an annual work plan and report to the NTAGI STSC on progress at least annually. The Secretariat will be responsible for organization of meetings, liaising with stakeholders, obtaining relevant data and publications and supporting the working group for synthesis and presentation to the STSC and NTAGI.

34. The ad-hoc working groups will be constituted as time-limited groups to address specific issues. The group will define its terms of reference at its first meeting and circulate them, prior to initiation of activities. When considering a topic (e.g. a new vaccine for introduction in the UIP), the working group will hold meetings, call on relevant experts for discussions, review available data and literature and synthesize the information for presentation to the STSC. They will be supported in these efforts by the Secretariat who will be responsible for organization of meetings, liaising with stakeholders, obtaining relevant data and publications and supporting the working group for synthesis and presentation to the STSC and NTAGI.

Secretariat

35. The NTAGI Secretariat will be financially supported by Government of India.
36. The Secretariat will provide necessary support for organization of meetings of NTAGI and STSC and other associated activities. However, the secretariat does not play a role in setting of agenda, decision making process and functioning of NTAGI.
37. In consultation with the relevant STSC working group, the NTAGI Secretariat will prepare materials in advance of each meeting, which will be circulated to members at least two weeks prior to each meeting. The Secretariat will consult with the working groups and Chairs to invite relevant external topic experts to present at NTAGI and STSC in person or through web links.
38. The NTAGI Secretariat support staff will attend meetings in order to facilitate and to record minutes. These staff will remain throughout the discussion and approval of recommendations, but will not participate in the discussion, recommendations, or voting.

Standard operating procedures for meetings

Calendar and Frequency of meetings

39. The meeting dates for the NTAGI and STSC are to be determined and circulated one year in advance to members by the Secretariat in consultation with the NTAGI Chair and Co-chairs. Box 1 below describes the Standard Operating Procedures for meetings.
40. The NTAGI will meet at least once a year or more frequently, if required. The STSC will meet at least every three months or more frequently, if required.
41. Under exceptional circumstances, a meeting may be called which was not scheduled on the calendar and without the usual two weeks for preparation.
42. Unless there are exceptional circumstances, scheduled meetings may not be cancelled or rescheduled and in such situations, the meeting should be rescheduled at the next available date.

Agenda preparation

43. The agenda for the STSC will consist of i) standing items that will be reviewed at least annually with at least one item reviewed at each STSC meeting and ii) new topics identified for discussion by stakeholders.
44. Standing items for annual STSC review include i) report on routine immunization/surveys, ii) report on any special initiatives on/innovations related to immunization, iii) report of vaccine preventable disease surveillance programmes, iv) report from the National AEFI Committee, v) recommendations from global and regional advisory committees on immunization (e.g. SAGE minutes, WHO position papers) and vi) reports on any impact assessment or special studies related to immunization. Standing items may be included or deleted from the list by consensus of the STSC and co-Chairs.

45. New topics for consideration by the NTAGI and STSC may be identified by the Chair, Co-chairs, members of the STSC and health professionals from the community. The agenda for each meeting will be prioritized taking into account the public health need/urgency**,** as requested by the MoHFW through the Deputy Commissioner, Immunization, MoHFW.

46. The proposed list of items for review at future meetings of the STSC or NTAGI will be maintained by the Secretariat and will be reviewed once a year at a STSC meeting, when the schedule of meeting dates for the following year is drawn up. Based on recommendation of the Chair and Co-chairs, the Secretariat in consultation with MoHFW will prepare and circulate an agenda at least two weeks before each meeting of the NTAGI or the STSC to allow for members to prepare for the discussion.

47. Secretariat staff will further consult with the working groups, Chair and Co-chairs to arrange for relevant outside experts to present to the NTAGI and STSC.

48. The NTAGI will review every major vaccine preventable disease at least once every five years to evaluate if revised recommendations are necessary.

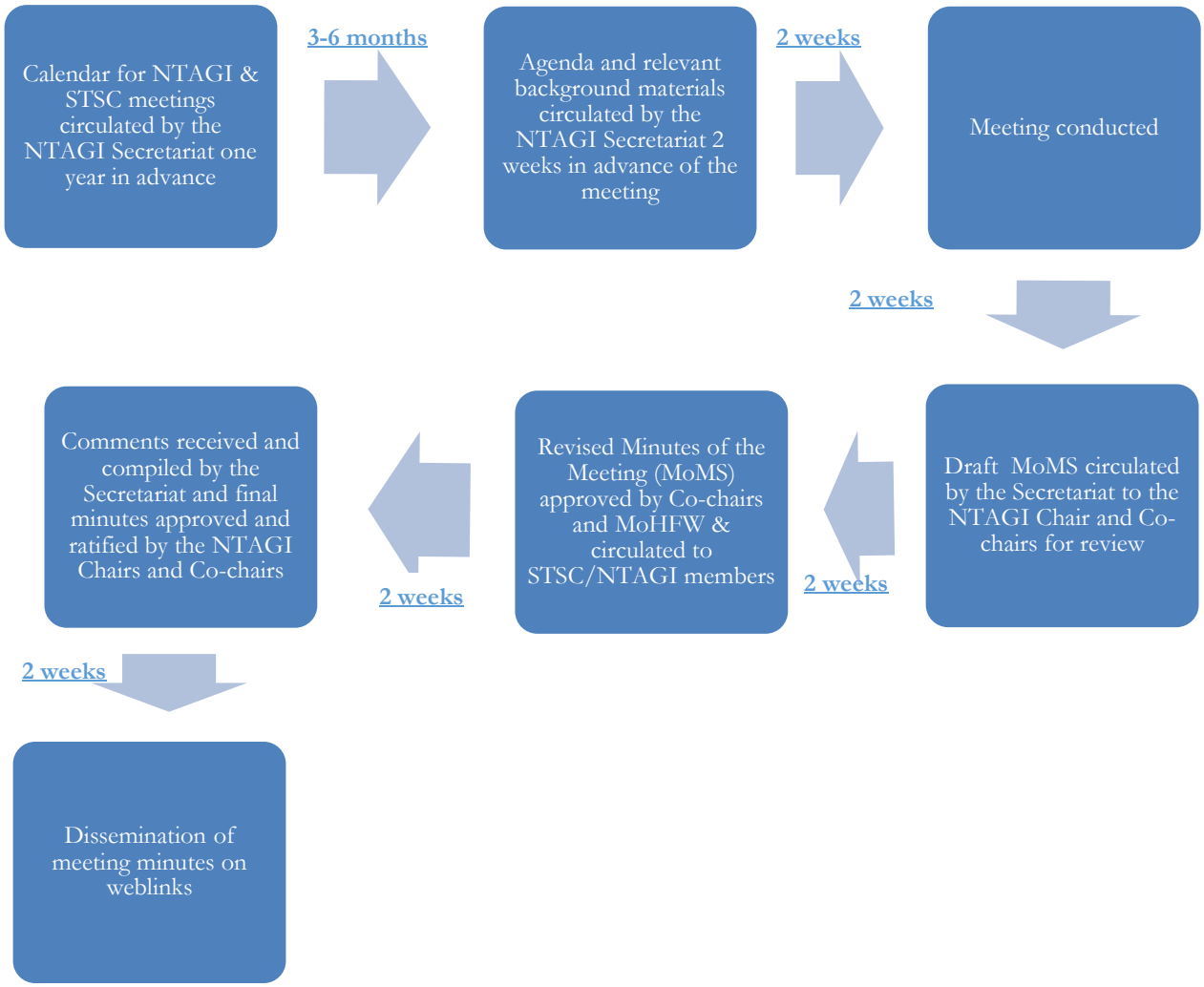
49. The agenda will usually include at least one standing agenda item, review of evidence on topics set by the NTAGI in advance, response to topical issues that arise following the previous meeting and horizon scanning of items for future discussion based on public health needs of the country.

50. The Secretariat is responsible for the timely recording and dissemination of meeting minutes and recommendation. The ratification of the minutes of the meeting will be done through circulation of minutes amongst the members. A schematic for preparation, recording and dissemination of meeting materials is described below in Box 1 under the standard operating procedures for the meeting.

51. NTAGI minutes should be circulated within two weeks after the meeting for comment by the members and simultaneously by the co-Chairs and MoHFW. The minutes and comments will be reviewed and finalized within a further two weeks by the co-Chairs and MoHFW and published under the NTAGI link at the websites of the following departments:

    - Ministry of Health & Family Welfare website
    - Indian Council of Medical Research
    - Department of Biotechnology

52. STSC minutes must be circulated to the NTAGI to allow for free and open debate on issues discussed. Once the NTAGI minutes are made public, the relevant STSC minutes should also be made public.



Box 1: Schematic for standard operating procedures for meetings

Participation in the meetings

53. All meetings are considered closed-door, with the exception of special invitees. These non-members will be vetted by the Chair and Co-chairs and the MoHFW before they attend a meeting. Special invitees will be allowed to participate in technical capacities and discussions, but

must exit before decision-making or voting occurs. Manufacturers may occasionally be invited to contribute to the discussion and inform the NTAGI or STSC about the products but will not be allowed in the closed-door sessions when recommendations are being formulated. If and when manufacturers are invited to observe meetings, the setting and handling must prevent undue influence by these manufacturers, while maintaining proprietary data confidentiality.

54. Crafting and adoption of recommendations will always be strictly closed-door. This allows members to have free and open debate before coming to any conclusions, which will be fully and clearly explained in minutes or statements.
55. The NTAGI Secretariat support staff attend meetings in order to facilitate and to record minutes. These staff remain throughout the discussion and approval of recommendations, but do not participate in the discussion, recommendations, or voting.
56. When a member does not attend a meeting or attends a portion of a meeting, the member is provided background material on the issues discussed, and is expected to be prepared to participate in the next meeting.

Responsibilities of NTAGI Chair, Co-chairs and Core Independent Members

Responsibilities of Chair and Co-chairs

57. The Chair should provide effective leadership, in particular:

A) Ensuring that the NTAGI and the STSC carries out its function effectively and does not exceed its powers or functions.

B) Ensuring that the minutes of the meetings and any reports accurately record the views of the NTAGI or STSC.

C) Ensuring that views of the NTAGI are accurately represented when providing information to the general public and press.

D) Providing performance management of the NTAGI members.

E) Ensuring that the NTAGI manages any conflicts of interest appropriately.

F) Ensuring availability for guidance to the Secretariat in case of urgent request for advice on technical matters related to immunization services.

Responsibilities of NTAGI and STSC members

All members of the NTAGI and its Sub-committee must demonstrate a high standard of conduct in exercising their duties.

Attendance at meetings

58. Except in the event of an emergency, meeting dates for NTAGI and STSC are published a year in advance. It is the responsibility of the Committee members to attend all meetings. At the discretion of the NTAGI Chair and Co-chairs, a member may be linked to a meeting by telephone or videoconference, in which case their presence shall count towards the quorum.

59. Failure by a member to attend three meetings in a row without prior notice or subsequent explanations to the NTAGI Chair and Co-chairs may constitute grounds for termination of appointment of the member, to be decided at the discretion of the NTAGI Chair and Co-chairs. Members may also resign from the NTAGI and its STSC if they wish.

Declaration of interests

60. The purpose of the declaration of interest form is to protect the NTAGI and its constituents from possible conflicts of interest ensuring that, in principle, decisions made by the NTAGI are free from any external influences, either personal or fiduciary, whilst recognizing that it is precisely their position and expertise external to the NTAGI that enables certain individuals to make valuable contributions to its work. All members of the NTAGI,the STSC and the NTAGI Secretariat, as well as special invitees that attend the meeting, must follow the rules set out in this document regarding the declaration of interest [Annexure 2].

61. A member must abide by the following rules when deciding whether to declare an interest**:**

A) Personal pecuniary interests: If a member has in the last four years received or plans to receive a financial payment or other benefit from a business or a representative body relating to vaccines or any other product of service that is specific to an agenda item under consideration by the NTAGI or its STSC, the member may be allowed to participate in the discussion, but not in any subsequent vote or decision making process. If the interest is not specific to an agenda item (i.e. payment relates wholly to other products), the member will be able to participate in both, the discussion and the vote. The main examples for personal pecuniary interests are explained below:

i) Consultancies - any consultancy, directorship, position in or work for the industry, which attracts regular or occasional payments in cash or kind.

ii) Fee-paid work -any work commissioned by the industry for which the member is paid in cash or kind.

iii) Shareholdings - any shareholding in or other beneficial interest in shares of the industry. This does not include shareholdings through unit trusts or similar arrangements where the member has no influence on financial management.

B) Personal family interest: If a family member of a current NTAGI or STSC member, has in the last four years received or plans to receive a financial payment or other benefit from a business or a representative body relating to vaccines or any other product of service that is specific to an agenda item under consideration by the NTAGI or its STSC, the member may be allowed to participate in the discussion, but not in any subsequent vote or decision making process. If the interest is not specific to an agenda item (i.e. payment relates wholly to other products), the member will be able to participate in both, the discussion and the vote.

C) Non-Personal pecuniary interests: A non-personal interest involves payment, which benefits a department for which a member is responsible, but is not received by the member personally. If the interest is specific to an agenda item, a member may be allowed to participate in the discussion and subsequent vote, at the discretion of the NTAGI Chair and Co-chairs. If the interest is not specific to an agenda item, and instead related wholly to other products, the member may be allowed to participate in the discussion and subsequent vote. However, members are under no obligation to seek out knowledge of work done for or on behalf of the industry within departments for which they are responsible if they would not normally expect to be informed. Main examples are:

i) Fellowships - the holding of a fellowship endowed by the industry.

ii) Support by the industry - any payment, other support or sponsorship by the industry which does not convey any pecuniary or material benefit to the member personally but which does benefit their position or department; for example:

- A grant from a company for the running of a unit or department for which the member is responsible
- A grant or fellowship or other payment to sponsor a post or a member of staff in the unit for which the member is responsible. This does not include financial assistance for students;
- The commissioning of research or other work by, or advice from, staff who work in a unit for which the member is responsible.

62. Members must declare all their interests at the time of their appointment and must promptly notify the NTAGI Chair, Co-chairs and the Secretariat of any changes. Before or at the start of every meeting, members will be asked to declare any changes to their interests and the minutes of each meeting will include interests that are declared and how they have been handled. In addition, it is the responsibility of each member to indicate if they have an interest in any item of business on the agenda of a meeting of NTAGI or its STSC at the appropriate time. Where this happens, in accordance with the provisions below, the Chair will determine whether a member should take part in any discussion or decision on an issue.

63. Members are not under an obligation to search out links between one company and another, for example where a company with which a member is connected has an interest in another company of which the member is not aware and could not reasonably be expected to be aware of.

64. Where members are uncertain as to whether an interest should be declared, they should seek guidance from the NTAGI Chair and Co-chairs and the Secretariat. If members have interests

not specified in these notes but which they believe could be regarded as influencing their advice they should declare them. Interests are considered relevant if they occurred within the last four years. The Secretariat is responsible for maintaining and updating records of member's relevant interests.

Confidentiality agreement

65. The NTAGI and STSC deal with confidential information and meetings are not open to public, as noted above. To maintain due process of decision making, members must abide by the confidentiality undertaking [Annexure 3] detailed below:

A) Commercial, academic and other research institutions and individual scientists may submit or present for discussion to the NTAGI STSC members, on research, products and processes (hereafter referred to as "Information") which the institutions and individuals consider proprietary. To help ensure the appropriate use of such information by STSC members whilst protecting the institutions' or individual's proprietary rights, the Secretariat will undertake to release such Information only to persons who have signed this agreement.

B) Information submitted by such institutions or individuals through NTAGI Secretariat to committees to inform their discussions shall be regarded by the Undersigned as confidential, unless clearly stated otherwise, by the institution, individual concerned and/or the NTAGI Secretariat.

C) The Undersigned undertakes to treat such confidential Information as proprietary information and agrees not to make copies of it, nor to disclose or use the same in whole or in part.

D) If requested to do so, the Undersigned agrees to return to the NTAGI Secretariat any and all Information identified as confidential.

E) The Undersigned shall not be bound by confidentiality if he/she is able to demonstrate that

the Information:

a. Was known to him/her prior to any disclosure to him/her by the NTAGI Chair, Co-chair or Secretariat;

b. Was in the public domain at the time of disclosure by the NTAGI and its Secretariat;

c. Becomes part of the public domain through no fault of the Undersigned;

d. Becomes available to the Undersigned from a third party not in breach of any legal obligations of confidentiality.

F) Proceedings of the NTAGI Committee meetings shall be confidential and no member who is not authorized by the NTAGI Chair or Co-chairs via the Secretariat is to speak on its behalf shall communicate externally about the discussion, decision and opinions expressed by the Committee or STSC, or by individual members during the course of this meeting, on a public or private forum. In signing below the undersigned undertakes to hold confidential what is shared and discussed within the NTAGI meeting.

G) The minutes of the meeting will be released by the NTAGI Secretariat in the public domain within six weeks of each meeting, but will not contain any confidential information as defined by the clauses previously stated.

H) This Confidentiality Undertaking is valid during the entire time the Undersigned participates in the work of the NTAGI, in whatever capacity, and for a period of five (5) years thereafter.

Communications with media

66. Members of NTAGI or STSC should not speak to the media as representatives of the NTAGI or STSC, unless the NTAGI Chair and Co-chairs designate a member to speak for the Committee. Members should inform the NTAGI Chair, Co-chair and the NTAGI Secretariat of all relevant contacts with the media. An NTAGI member may discuss with the media an issue

that has also been discussed at NTAGI, but should take care to explain that he/she is discussing it in an individual professional capacity and not as a member of NTAGI or on behalf of NTAGI or its STSC. No member should reply to official correspondence on behalf of the NTAGI without consulting the Secretariat. The only exception to this rule is that all members are free to respond to questions about established points of fact (e.g., meeting dates, citations for NTAGI recommendations, etc.)

67. NTAGI and STSC members may be solicited to participate in consultations or surveys on vaccine issues that are addressed by the NTAGI. Members can respond in their individual capacities on their areas of expertise, but should refer any questions related to specific topics discussed by NTAGI to the co-Chairs. For research studies, members should not exercise undue influence to elicit participation in national/regional/global studies on account of their NTAGI membership.

68. Members are prohibited from making any speech or producing a publication in which the purpose is to report on the member's work on the NTAGI, without the written permission of the co-Chairs. Voting members should be concerned with and report to the Secretariat, and solicitation of information about the NTAGI or STSC's activities by persons not officially affiliated with the NTAGI or STSC.

Accountability

69. Members are free to maintain associations with trade unions, co-operative societies, trade associations etc. to the extent that such associations do not conflict directly with the interest of the NATGI or STSC. If members have any doubt about any of these matters, advice should be sought from the Chair/Co-chair/Secretariat.

70. Any legal proceedings initiated by a third party are likely to be brought against the NTAGI as a whole, although in exceptional cases proceedings (civil or, in certain cases, criminal) may be brought against the Chair or individual members.

71. If a member is at any time unclear whether or not an action in contemplation would be classified as duties as members of NTAGI or its STSC he or she should clarify this with the Secretariat or co-Chairs.

72. NTAGI advice may be used by Government health departments or public health bodies in India. Any legal challenge to any action taken on the advice or recommendations of the Committee will be the responsibility of that department and not the NTAGI.

Process for evidence review and developing recommendations

73. The NTAGI will deal with evaluation of issues relevant to a new immunisation programme or major changes to, or discontinuation of, an existing immunisation programme

74. The evaluation of potential changes to the immunisation programme will usually proceed through the following steps:

    A) Defining the policy question

    B) Evidence gathering by the Secretariat and working group

    C) Working group consultation with experts and review and synthesis of evidence

    D) Evidence review by the STSC

    E) Recommendations of the STSC presented to the NTAGI

    F) NTAGI review and final recommendations

These steps are described in detail below:

A) First, the Secretariat in consultation with the Chairs and co-chairs, MoHFW and STSC working group members (where relevant) will frame the policy question(s). The issue(s) may

be based on a request for advice made by the MoHFW or identified by horizon scanning. If no working group exists, the co-Chairs, in consultation with the MoHFW will constitute an ad-hoc working group and present them with their charge.

B) Second, the ad-hoc working group for the issue and the Secretariat identify and collate relevant evidence. Evidence gathering may proceed in a number of ways, including by a systematic literature review which involves searching a wide range of medical and scientific databases, a call for evidence from stakeholders, and/or a commission issued for an impact and cost effectiveness study. This body of information will often include submissions on the safety and effectiveness of, and other information on, specific vaccines from vaccine manufacturers that may be commercially confidential. The working group may consult with independent subject matter experts, key immunization partners and research institutes as well as private vaccine manufacturers to generate a comprehensive body of evidence that will allow the relevant question to be answered, highlight any important gaps in the evidence, and identify and evaluate alternative policies (including the no-action or no-change options).

C) Third, the STSC will meet to analyse the evidence that is synthesized and presented by the working group and any external subject matter experts whose contribution the working group considers essential. The STSC members will review the evidence, discuss the recommendations of the working group, and agree upon a report/recommendation to be given to the NTAGI.

D) Fourth and finally, the NTAGI may review and approve the STSC recommendations. In making such recommendations, the NTAGI will take into account all available information about a vaccine, as well as the larger context of the health care delivery systems in India, the current epidemiology of the disease, implementation issues, ethical and legal constraints, and other factors.

75. A robust, systematic framework based on internationally agreed protocols will be used for evidence review and developing recommendations. Regular review of available methodology will fall under the purview of the standing working group on research and capacity building of the NTAGI.

76. Advice or recommendations will normally be formulated during the course of the meetings usually by consensus. If consensus is not reached and at the discretion of the Chair and Co-chairs, voting may occur. A majority is needed for approval of any recommendation and dissents will be noted in the meeting minutes. At least half of the voting members must be present for quorum and for voting to occur, although the Co-chairs may allow for exceptions in emergency circumstances.

77. At the discretion of the Chair and Co-chairs, a member may be linked to a STSC or NTAGI meeting by telephone or videoconference, in which case their presence shall count toward the quorum.

Reporting, recording and dissemination of recommendations

78. The NTAGI and its STSC are committed to making as much of its work open to public scrutiny as possible. However, there is a generic understanding that scientific advisory committees will treat unpublished research in confidence until it has been peer-reviewed and published in the scientific or medical literature, unless the investigators give specific permission for pre-publication release, as explained in the confidentiality section para 61 of this document. This helps ensure that the Committee has access to as much of the relevant, but unpublished, data as possible.

79. NTAGI and STSC advice and recommendations are published in the minutes of meetings. Where advice or recommendations relate to a new vaccination programme, or revisions to an existing vaccination programme, these are also published in an official statement on the NTAGI

web-links, crafted by the Secretariat in consultation with the NTAGI Chair and Co-chairs and the relevant working group.

80. In addition to meeting minutes and recommendations, the NTAGI aims to publish the following documents: Code of Practice, Frameworks for evidence review and systematic development of recommendations, meeting calendar and agenda, statements, annually updated recommended schedule for vaccines included in the UIP and register of members' interests. The NTAGI will publish a position paper for each vaccine included in the UIP as soon as feasible, but preferably within one year of the recommendation for inclusion being made.

ANNEXURES: CODE OF PRACTICE

The annexures below comprise forms for use for all members of the National Technical Advisory Group on Immunization and the Standing Technical Sub-committee as well as special invitees attending NTAGI and STSC meetings.

Annexure 1: Declaration of agreement to Code of Practice, including Confidentiality agreement

DECLARATION

I have read and understood the NTAGI Code of Practice. I agree that I will abide by the NTAGI code of practice for:

a) The period of time I am a NTAGI member/ a NTAGI Sub-committee member/ an invited observer.
b) In respect of confidentiality, thereafter for such periods of time as information communicated in confidence is not disclosed by authority.

SIGNED

SURNAME (BLOCK LETTERS)

FORENAME (BLOCK LETTERS)

DATE

Annexure 2: Declaration of Interests

As a new member of the NTAGI/STSC, please ensure you have read and understood the Code of Practice. We would appreciate your answers to the following questions:

1. Who is your primary employer? _____

2. Do you have any grants that are funded by vaccine manufacturers? Yes/No. If yes, what is the nature of the grant (e.g., research, education) and what is your role (e.g., PI, supervisor)?

_____

3. Do you, your spouse or dependent children own stock in any vaccine manufacturer or parent company of a manufacturer? If yes, what manufacturer(s)/company (ies)?

_____

4. Do you have a patent on any vaccine or candidate vaccine? Yes/No. If you are not the patent holder, are you otherwise entitled to royalties or other compensation from such a patent?

_____

5. Do you serve in any advisory role with a vaccine manufacturer (e.g., serving as a member of or consultant to a manufacturer's advisory committee)? Yes/No. If yes, what is the nature of this role?

_____

6. During the past year, have you received any honoraria or travel funds from vaccine manufacturers (or from educational grants from vaccine manufacturers) for presentations at scientific meetings? If yes, what was the nature of the meeting (e.g., professional society meeting, manufacturer forum)?

_____

7. Do you serve in any fund-raising role with any organization that could involve solicitation of funds from vaccine manufacturers? If yes, please describe your role.

_____

8. Have you done any consultation with law firms for vaccine-related litigation? Yes/No

_____

9. Have you any interests, as detailed in paragraphs 56-60 of the NTAGI Code of Practice document which may be considered as constituting a real, potential or apparent conflict of interest?

Yes: □ **No:** □ **If yes, please give details in the box below.**

Type of interest (refer para 54 of Code of Practice for details)	Name of commercial entity	Belongs to you, partner or unit?	Current interest? (or year ceased)

10. Is there anything else that could affect your objectivity or independence in the meeting or work, or the perception by others of your objectivity and independence?

_____

_____

I hereby declare that the disclosed information is correct and that no other situation of real, potential or apparent conflict of interest is known to me. I undertake to inform you of any change in these circumstances, including if an issue arises during the course of my engagement with the NTAGI or its STSC.

_____	_____
Signature	Date
_____	_____
Name	Institution

Annexure 3: Confidentiality Agreement

1. Commercial, academic and other research institutions and individual scientists may submit or present for discussion to the NTAGI Standing Technical Sub-committee (STSC) members, on research, products and processes (hereafter referred to as "Information") which the institutions and individuals consider proprietary. To help ensure the appropriate use by STSC members of such Information whilst protecting the institutions' or individual's proprietary rights, NTAGI Secretariat will undertake to release such Information only to persons who have signed this agreement.
2. Information submitted by such institutions or individuals through NTAGI Secretariat to committees to inform their discussions shall be regarded by the Undersigned as confidential, unless clearly stated otherwise, by the institution, individual concerned and/or the NTAGI Secretariat.
3. The Undersigned undertakes to treat such confidential Information as proprietary information

and agrees not to make copies of it, nor to disclose or use the same in whole or in part.

4. If requested to do so, the Undersigned agrees to return to the NTAGI Secretariat any and all Information identified as confidential.
5. The Undersigned shall not be bound by confidentiality if he/she is able to demonstrate that the Information:
    a) Was known to him/her prior to any disclosure to him/her by the NTAGI Secretariat;
    b) Was in the public domain at the time of disclosure by the NTAGI Secretariat;
    c) Becomes part of the public domain through no fault of the Undersigned;
    d) Becomes available to the Undersigned from a third party not in breach of any legal obligations of confidentiality.

6. Proceedings of the NTAGI and its STC meetings shall be confidential and no member who is not authorized by the NTAGI Secretariat to speak on its behalf shall communicate externally about the discussion, decision and opinions expressed by the Committee or STSC, or by individual members during the course of this meeting, on a public or private forum. In signing below the undersigned undertakes to hold confidential what is shared and discussed within the NTAGI meeting.
7. The minutes of the meeting will be released by the NTAGI Secretariat in the public domain within six weeks of each meeting, but will not contain any confidential information as defined by the clauses previously stated.
8. This Confidentiality Undertaking is valid during the entire time the Undersigned participates in the work of the NTAGI, in whatever capacity, and for a period of five (5) years thereafter.

Signature..... Name.....

REFERENCES

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5. Ministry of Health and Family Welfare, Government of India. 2013. "Reconstitution of the National Technical Advisory Group on Immunization and constitution of the Technical Sub-Committee of the NTAGI." *Government Order (No. T 13011/01/2013/CC&V)*. New Delhi, 25 June, 2013

6. Schoub, Barry D., Ntombenhle J. Ngcobo, et Shabir Madhi. 2010. «The National Advisory Group on Immunization (NAGI) of the Republic of South Africa.» *Vaccine*.