



The Global Language of Business

# GS1 Healthcare Governance Charter

Charter governing the operations of GS1 Healthcare

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## Document Summary

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4.0	March 2023	Geraldine Lissalde-Bonnet / Tania Snioch / Claire Clarke / Bruce Volbeda / 2022/2023 GS1 Healthcare Leadership Team	Overall comprehensive document review to reflect changes identified since 2018

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## 1 Charter

- A. This GS1 Healthcare Governance Charter and its appendices (the "Charter") set out the terms and conditions applicable to GS1 AISBL, an international non-profit association formed under Belgian law (legal entity registration number 0419.640.608, District of Brussels), with its registered office at Avenue Louise 326, bte 10, B-1050 Brussels, Belgium ("**GS1**"), **GS1 Healthcare** (see sec. 1.B), and each of GS1 Healthcare's **Members** (sec. 5) regarding their respective roles, rights and responsibilities in administering and participating in GS1 Healthcare.
- B. **GS1 Healthcare** is an initiative (i.e., it is an unincorporated entity) established by GS1, and is administered by a team designated by GS1 and GS1 Healthcare Members (see sec. 5) for the purpose of advancing the Vision and Mission (secs. 2 and 3). GS1 Healthcare is accountable to GS1 as provided in section 4.

## 2 Vision

GS1 Healthcare envisions a future in which the healthcare sector achieves interoperable implementation of global standards in business and clinical processes enabling interoperability, optimal quality and efficiency of healthcare delivery to benefit patients ("Vision").

## 3 Mission

GS1 Healthcare is a neutral and open community bringing together all related healthcare stakeholders to lead the successful development and implementation of global GS1 standards enhancing patient safety, operational and supply chain efficiencies("Mission").

## 4 Accountability

GS1 Healthcare reports to the GS1 Management Board and is supervised by the GS1 Board Committee for Healthcare (a committee of the GS1 Management Board).

## 5 Membership

Membership of GS1 Healthcare is subject to full and unconditional acceptance by the Member of this Charter, as amended from time to time.

There are two classes of Members, defined as follows:

- **Voting Member:** a party from the User Community (defined in sec. 5.1.1), meeting the voting membership criteria set out in section 5.1.1 below, and which shall be required to pay membership fees.
- **Non-Voting Member:** a party from the User Community, meeting the non-voting membership criteria set out in section 5.2.1 below, who shall not be required to pay membership dues.

Membership applications can be accessed from the GS1 website and submitted by email addressed to the Vice-President Healthcare (as defined below). The Vice-President Healthcare checks applications to determine whether the applicable criteria have been met and, if so, informs the applicant and the Leadership Team. Membership becomes effective immediately upon payment of membership fees, pro-rated if applicable.

Note that GS1 Member Organisations are not eligible to become Members, per se, of GS1 Healthcare, but they can participate in GS1 Healthcare in a number of important ways, as provided in section 5.3.

## 5.1 Voting Membership

### 5.1.1 Criteria for Voting Membership

- A. **Eligibility.** A party is eligible to apply to become a Voting Member if the party meets all three of the following requirements:
1. is operating in the healthcare supply chain, which includes, but is not limited to, parties that are manufacturers, suppliers, wholesalers, distributors, logistic providers, healthcare providers (e.g., hospitals, retail pharmacies, care homes, etc.), Procurement-Related Agencies (as defined below), and solution providers (collectively, the "**User Community**");
  2. is a member, customer, or licensee of a GS1 MO;
  3. can demonstrate, through for example, implementation and advocacy, their interest in the use of global standards to improve patient safety.
- B. "**Procurement-Related Agencies**" means those organisations that (i) are solely funded by government; (ii) represent national, regional, state, or provincial interests; and (iii) actively procure healthcare products or clearly represent government organisations that do procure healthcare products. Such agencies eligible to be considered Voting Members must not be responsible for setting regulations relating to supply, identification, traceability, recall of such products. However, these organisations may set requirements (i.e., terms of trade) for the provision or use of GS1 standards as part of the procurement activity.
- C. **Annual Fees.** Voting Members of GS1 Healthcare contribute to GS1 Healthcare activities and basic operational costs with an annual fee to GS1 Healthcare unless the Voting Member is in a category that is exempt from such fees (e.g., hospitals; see "GS1 Healthcare Membership Fees" posted on the GS1 Healthcare website: <https://www.gs1.org/healthcare>). Voting Members that are not exempt from fees are only eligible to vote in any decision of GS1 Healthcare after they have paid their annual membership fees. Membership renewal fees apply for the calendar year and are due on or before 31 May of each year.

### 5.1.2 Voting Members' rights

Voting Members shall:

- Have voting rights;
- Have access to the GS1 Healthcare Public Policy and Healthcare Provider Materials in accordance with section 10.3;
- With the exception of Procurement-Related Agencies, have the right to participate in the GS1 Healthcare Public Policy work group;
- Have the right to participate in other GS1 Healthcare work groups;
- Be candidates for the GS1 Healthcare Leadership Team;
- Be candidates for Tri-Chair positions of GS1 Healthcare; and
- Have the right to participate for a reduced fee at conferences.

## 5.2 Non-Voting Members

### 5.2.1 Criteria for Non-Voting Membership

Non-Voting Membership is limited to trade associations, regulatory bodies and other governmental healthcare authorities (but not Procurement-Related Agencies; see Section 5.1.1), educational institutions and other standards bodies.

Entities that are not eligible for Non-Voting Membership may be eligible for Voting Membership if they meet the criteria provided in Section 5.1.1.

### 5.2.2 Non-Voting Member Rights

Non-Voting Members may participate in GS1 Healthcare work teams, in a non-voting capacity only, depending on the Non-Voting Members' alignment and interest in the scope and deliverables of the group. Non-Voting Members may use certain GS1 Healthcare Materials as further detailed in section 10.3 below.

Non-Voting Members **shall not:**

- Have any voting rights, except as provided otherwise herein;
- Have access to the GS1 Healthcare Public Policy and Healthcare Provider Materials in accordance with section 10.3 below;
- Participate in the GS1 Healthcare Public Policy work group;
- Be candidates for the Leadership Team, unless subject to special appointment per section 6.1.1(iii); or
- Be candidates for Tri-Chair positions of GS1 Healthcare, unless subject to special appointment per section 6.1.1(iii).

### 5.3 GS1 MOs Rights

"GS1 Member Organisation" ("**GS1 MO**") means a party admitted by GS1 as a GS1 member organisation. GS1 MOs are not eligible to become Members of GS1 Healthcare, per se, but they can participate in GS1 Healthcare in a number of important ways, as provided herein. Because GS1 MOs cannot serve as GS1 Healthcare Members, they are not required to complete a GS1 Healthcare Membership Application.

GS1 MOs **are permitted:**

- To access GS1 Healthcare Materials, including the GS1 Healthcare Public Policy and Healthcare Provider Materials in accordance with section 10.3 below;
- To participate and vote in the GS1 Healthcare Public Policy work group as well as other GS1 Healthcare work groups;
- To be candidates for the GS1 Healthcare Leadership Team and participate in Leadership Team voting.

GS1 MOs **are not:**

- Eligible to nominate for the Tri-Chair positions of GS1 Healthcare;
- Considered Voting Members or Non-voting Members as defined in section 5.1.1.

### 5.4 Resignation or Expulsion

(a) Loss of GS1 Healthcare membership may result either from resignation or expulsion.

(b) A Member may **resign** their membership by delivering written notice to GS1 (attention of GS1 Healthcare) in any calendar year on or before 30 September, and that membership shall then terminate with automatic effect on 1 January of the following calendar year (effective date of termination). During the period from the date on which notice was delivered and the effective date of termination, all terms and conditions of this Charter shall remain valid and in full force and effect with respect to such Member.

(c) A Member may be **expelled** from GS1 Healthcare by a vote of the Leadership Team if the Member or its representative:

- (i) fails to comply with the terms of this Charter;
- (ii) commits any act which may be prejudicial to the work of GS1 Healthcare and/or GS1 standards in Healthcare;
- (iii) or ceases to fulfil any of the applicable conditions for membership set out in this Charter.

(d) The Tri-Chairs initiate such expulsion action by submitting a request for expulsion to the Leadership Team containing the facts and considerations which led to the request. The Member in



question shall be given the opportunity to defend itself before the Leadership Team takes a final decision.

(e) Expulsion becomes effective immediately upon the vote of the Leadership Team approving such expulsion (see sec. 5.4(c)). Written notice of expulsion shall be provided to the expelled Member by registered mail, however, any failure to deliver such written notice shall have no impact on the effectiveness of such expulsion.

(f) The Member shall pay the full membership fee for any calendar year during which it is a Member for any portion of that year, regardless of whether the Member resigns or is expelled during that year. No outgoing Member shall have any claim whatsoever on any assets or funds of GS1 Healthcare or funds managed by GS1 for GS1 Healthcare as a result of resignation, expulsion or on any other basis.

## 5.5 Decision-Making Process

### 5.5.1 General

- (a) Quorum and voting. In order for a vote to be conducted or to be considered valid with respect to a proposed action, and unless stated otherwise herein, a quorum of fifty percent (50%) of the parties authorised to vote on such action must (1) be present at a duly held meeting where such vote takes place **or** (2) participate in such vote permitted to take place outside a meeting (e.g., voting by e-ballot, sec. 5.5.1(g)).
- (b) Consensus. Unless provided otherwise herein, decision-making is made through consensus which, for the purposes of this Charter, is defined as approval without sustained opposition ("consensus"). In the case of sustained opposition, such proposed action shall not be taken unless terms herein provide for reaching a decision notwithstanding such opposition (see, e.g., sec. 5.5.1(c)).
- (c) Overcoming opposition. In the case of sustained opposition, the proposed action may nevertheless be approved provided that: (1) the reasons for such opposition are documented, (2) a quorum of 50% of the group authorised to vote on the proposed action is present or participates in such vote pursuant to section 5.5.1(a), and (3) the action is approved by a 66% majority vote.
- (d) One vote. More than one individual can represent a Voting Member within GS1 Healthcare; however, each Voting Member is only allowed one (1) vote in any ballot or election activity.
- (e) Records. All proceedings will be noted and recorded for future reference by the designated group secretary or other person holding a similar role for such group. Such records will be maintained in a "community room" or other shared resource accessible to relevant GS1 Healthcare parties.
- (f) GS1 Global Office role. GS1 supports and manages the decision-making process but has no voting privileges.
- (g) E-ballot. For the avoidance of doubt, the term "e-ballot" shall mean any electronic or online means of voting including, without limitation, by email or via an online community room.

### 5.5.2 Decisions of the Leadership Team

- (a) The Leadership Team may only vote on a proposed action if the proposal is (1) submitted by GS1 or a Leadership Team member and (2) submitted during a duly called meeting of the Leadership Team.
- (b) Voting during Leadership Team meetings shall take place in person, by telephone, or via online video-teleconference. Voting by e-ballot shall take place as provided in sub-section (c) below.
- (c) In the case of e-ballot voting, votes must be received within fifteen (15) working days following communication of the proposal submitted for a vote, otherwise abstention is assumed. Any Leadership Team member voting "no" must submit their rationale for voting "no" either verbally or in writing, and such rationale(s) shall be documented in writing by the coordinator of the vote.

### 5.5.3 Election of Leadership Team

#### i. Election by Voting Members

Regarding Leadership Team positions representing Voting Members, if there are more candidates than positions to be filled, Voting Members shall elect those Leadership Team positions by vote. In such case, the Voting Members shall vote by e-ballot and votes must be submitted within the voting period communicated at the commencement of the vote. If reasonably possible, such notice of voting period shall be given at least four (4) weeks before the last date that voting is permitted. Failures to vote will be recorded as abstentions.

In the case there is an equal or fewer number of candidates than positions to be filled, then those candidates are automatically appointed as Leadership Team members, providing the nominees meet the criteria defined in sec. 6.1.1.i.

#### ii. Election by GS1 MO CEOs

Regarding Leadership Team positions representing GS1 MOs, as defined in section 6.1.3, if there are more candidates nominated by GS1 MO CEOs than positions to be filled, GS1 MO CEOs shall elect those Leadership Team positions by vote. In such case, GS1 MOs shall vote by e-ballot and votes must be submitted within the voting period communicated at the commencement of the vote. If reasonably possible, such notice of voting period shall be given at least four (4) weeks before the last date that voting is permitted. Failures to vote will be recorded as abstentions.

In the case there is an equal or fewer number of candidates than positions to be filled, then those candidates are automatically appointed as LT members, providing the nominees meet the criteria defined in sec. 6.1.1.ii.

### 5.5.4 GS1 Healthcare work team decisions

Unless specified otherwise herein, decisions of GS1 Healthcare work teams relating to standards development are conducted in compliance with the **GS1 Global Standards Management Process ("GSMP")** and the **GSMP Manual**, including provisions relating to membership requirements and voting procedures (see, e.g., GSMP User Manual, July 2022, sec. 18, *Appendix: Work Group Types and Formation*; sec. 22, *Appendix: Voting Procedures*), Voting will normally be done by e-ballot and the votes must be received within fifteen (15) working days after an authorised proposal is submitted; failures to vote will be recorded as abstentions.

Implementation work teams that function under the supervision of the Leadership Team to improve implementation of GS1 standards developed under GSMP will undertake decision-making per sec. 5.5.1.

### 5.5.5 GSMP decisions and process

The processes and decision-making rules for GSMP are contained in the GSMP User Manual. Since 19 April 2010, any company wishing to participate in new GSMP Groups must sign the GS1 IP Policy and Opt-In Agreement (<http://www.gs1.org/gsmg/gsmg/ip>).

## 6 Organisational Leadership

### 6.1 Leadership Team

#### 6.1.1 Composition of the Leadership Team

The Leadership Team shall be comprised of representatives of the following classes of Members, subject to the indicated requirements:

#### i. **Voting Member representatives**

(a) Composition.

1. **Maximum Number.** The Leadership Team shall be comprised of up to twenty (20) representatives of Voting Members, including Tri-Chairs, plus any special appointments (see sec. 6.1.1(iii)) (collectively, the "**Maximum Number**" of representatives).
  2. **HCP Reserved Positions**
    - (a) As part of the Leadership Team election process, if fewer than three (3) healthcare provider representatives ("**HCP**") are directly elected, sufficient positions shall be reserved for HCP to ensure they occupy at least three (3) positions on the Leadership Team (the "**Reserved Positions**").
    - (b) Reserved Positions shall be filled by any remaining HCP candidates in order of descending votes, despite receiving fewer votes than other, non-HCP candidates.
    - (c) If there are insufficient HCP candidates to fill all of the Reserved Positions, the remaining Reserved Positions may be filled by other, non-HCP candidates in order of descending votes.
    - (d) For the sake of clarity, (i) Reserved Positions are *part of* the Maximum Number of positions allowed under section 6.1.1(i)(a)(1) — they are *not in addition to* that Maximum Number; and (ii) the Reserved Positions terms herein do not apply if there are already a minimum of three (3) HCP on the Leadership Team by direct vote, prior election or otherwise.
  - (b) **Diversity.** Voting Members should seek to elect a Leadership Team that represents a balanced diversity of geographic regions and healthcare supply chain functions.
  - (c) **General requirements.** Each Voting Member representative shall, at the time of the election and at all times during his/her tenure:
    - Be a representative of a Voting Member in good standing (i.e., the Voting Member must have paid the current year's membership fees on or before **31 May**);
    - Have subject matter expertise about the GS1 System and associated technologies;
    - Be able to represent the views of his/her organisations and segment of the healthcare supply chain in key decisions;
    - Be engaged in GS1 Healthcare work efforts;
    - Be able to promote implementation of GS1 global standards and best practices within his/her organisation and should therefore be able to provide linkage between his/her organisation and GS1 Healthcare.
  - (d) **Specific qualifications.** Voting Member representatives of healthcare providers, solution providers, manufacturers and wholesalers should have the qualifications listed in **Appendix A**.
  - (e) **Nomination; fee requirements.** A Voting Member may nominate a representative for the GS1 Healthcare Leadership Team in the year in which that Member joins, provided that the membership application is completed and all membership fees are paid before the nomination period closes. If these requirements are not met, a nominee of such Voting Member will not be included in the list of candidates that qualify for GS1 Healthcare Leadership Team election.
- ii. **GS1 MO representatives.** The Leadership Team shall be comprised of up to six (6) representatives of GS1 MOs.

In performing its role on the Leadership Team, each GS1 MO representative should endeavour to represent the interests of all geographic regions, as well as their individual organisation/colleagues/region, in healthcare-related discussions and decisions of the Leadership Team. Nevertheless, MOs should seek to nominate and elect a Leadership Team that represents a balanced diversity of geographic regions. If the election results do not support all five (5) GS1 regions, the Vice-President Healthcare may nominate additional representatives, with the approval of the President Community Engagement and CEO of GS1, until up to two (2) additional representatives are elected for the purpose of improving geographic representation on the Leadership Team.

The GS1 MO representatives on the Leadership Team should be responsible for nominating two (2) of the three (3) Reserved Positions for healthcare provider representatives each year (see sec. 6.1.1(i)(a)(3), HCP Reserved Positions).

- iii. **Special Appointees.** The Leadership Team may, at its discretion, elect one or more Non-Voting Member representative (the "Special Appointee(s)") to sit on the Leadership Team if the Leadership Team believes such representative(s) will provide strategically important direction to leadership discussions. The decision to make such an appointment shall be made by a vote of the Leadership Team (excluding the nominee). The Special Appointee shall have the same rights as other Leadership Team members, including the ability to vote as part of the Leadership Team and to be elected to a Tri-Chair position. Special Appointees shall not be counted as part of the maximum twenty (20) Leadership Team positions. For the avoidance of doubt, if twenty (20) Leadership Team positions have already been elected pursuant to sec. 6.1.1(i), the Leadership Team is still permitted to appoint a Special Appointee pursuant to this sec. 6.1.1(iii).
- iv. **One representative only.** No Member or MO shall have more than one representative in the Leadership Team.

### 6.1.2 Roles and Responsibilities

#### i. Individual Roles and Responsibilities

- (a) Leadership Team members will be engaged in GS1 Healthcare work teams and will take responsibility for either leading a work team during their term or serving as a liaison to a work team.
- (b) The average time commitment per Leadership Team Member is estimated to be between 3-4 hours per week, depending upon the areas of work the particular Leadership Team member is nominated for or chooses to work on.
- (b) In the event that a Leadership Team member is unable to attend a Leadership Team meeting due to illness, he/she may appoint another representative of his/her organisation to participate and vote on its behalf by a written proxy (including via email).
- (c) However, because regular participation is key to the effectiveness of the Leadership Team, if a Leadership Team member (i) is absent for more than four (4) successive Leadership Team calls or meetings, **or** (ii) does not attend two (2) successive global conferences (whether in-person or virtually), the Leadership Team has the authority (but not the obligation) to remove the member from the Leadership Team.
- (d) If a position in the Leadership Team becomes available, for example due to retirement or removal, the Vice President, subject to consensus approval of the Tri-Chairs, has the authority, but not the obligation, to fill the empty position with the next candidate (i.e., the candidate that received the next highest number of votes) of the same category (i.e., Voting Member, or GS1 MO) from that year's election. In the case that such candidate chooses not to participate, the next highest voted candidate can be engaged, and so on. In the absence of an available candidate from that year's election, the Vice President, subject to consensus approval of the Tri-Chairs, may undertake an extraordinary appointment, approved by Leadership Team vote.

#### ii. Collective Roles and Responsibilities

The Leadership Team shall:

- Elect Tri-Chairs through nomination and consensus, and where necessary vote
- Develop and maintain the overall GS1 Healthcare strategy and timeline for successful development and implementation of global standards
- Review and approve: finances (two times a year), conference/meeting planning, public relations, and policy
- Work with the Public Policy work team to develop the strategy to carry the GS1 standards message to the government bodies regulating the healthcare industry
- Work with GS1 staff to represent GS1 Healthcare membership to external groups and organisations with interests in standards and patient safety

- Create work teams to respond to or drive specific initiatives
- Develop processes to ensure that work teams are adequately resourced and geographic and supply chain stakeholder balance is obtained
- Appoint work team leaders, review progress of the work teams on a regular basis and ensure that there is alignment between the work teams
- Ensure participation and represent GS1 Healthcare in the GSMP and the GS1 governance groups
- Approve healthcare work requests for developments (not maintenance) to progress work into GSMP
- Ensure regular communication to the GS1 Healthcare membership community to update and engage them through various mechanisms to increase awareness of on-going global activities and to solicit participation in the discussions, work groups and all other GS1 Healthcare activities
- Provide leadership in resolving conflicts

The Leadership Team shall hold regular scheduled teleconferences to monitor progress, discuss issues and will meet in person in conjunction with GS1 Healthcare conferences. In addition to face-to-face meetings at GS1 Healthcare conferences, one video conference will be scheduled per year. Further face-to-face meetings may be organised if necessary.

### 6.1.3 Leadership Team Selection Process

#### i. Voting Members

Nomination for the Leadership Team occurs in April every year. Candidates will self-nominate using the process defined by GS1 Healthcare. At the time of nomination, the Vice President Healthcare ensures that the criteria as detailed in section 6.1.1 are met and that not more than one candidate per Voting Member has self-nominated.

The candidates with the highest votes are selected for the Leadership Team, as outlined in section 5.5.3 and 6.1.1.

If there are insufficient nominees to fill available empty or reserved positions, the Vice President, at her/his discretion, may engage and appoint additional interested representatives who were not part of the initial nominations, and such appointments shall be subject to consensus approval of the Tri-Chairs and vote approval by the Leadership Team.

The Leadership Team membership applies to the elected individual representative of the Voting Member, not to the Voting Member as an organisation. If an individual Leadership Team member leaves his/her current Voting Member, the current Voting Member cannot nominate an alternate candidate for the Leadership Team position. Instead, if the individual Leadership Team member joins another Voting Member, he/she may remain a member of the Leadership Team if the Voting Member he/she has joined agrees to support his/her engagement in the framework of the governance and does not already have a sitting Leadership Team representative.

The Vice President Healthcare has the authority to alter the GS1 Healthcare Leadership composition, and such appointments shall be subject to consensus approval of the Tri-Chairs and vote approval by the Leadership Team.

#### GS1 Member Organisations

Nomination for the Leadership Team occurs in April each year. GS1 Member Organisation (MO) CEOs may nominate one representative from their organisation to the Leadership Team, provided the MO has:

1. an active local healthcare user group which meets regularly
2. at least 90% of 1 FTE (may be multiple roles) working only in healthcare
3. a nominee working minimum of 60% only in healthcare and who is directly responsible for the healthcare tactical operations in the MO
4. a nominee who participated in the most recent GS1 Global Healthcare Conference

5. a nominee whose MO has participated in 60% of the GS1 Healthcare Interest Group calls in the last 12 months

The candidates with the highest preference scores are selected for the Leadership Team. If there are more candidates than positions to be filled, the candidates shall be elected by a vote of the GS1 MO CEOs (as provided in section 5.5.3 above).

- ii. General practices

A representative may be elected for multiple consecutive or non-consecutive GS1 Healthcare Leadership terms.

The Vice President Healthcare, subject to consensus approval of the Tri-Chairs, has the authority to alter the GS1 Healthcare Leadership composition, as communicated by the Vice President to the current GS1 Healthcare Leadership Team.

#### 6.1.4 Term Limits

Leadership Team members serve a one-year term starting on 1 July and running to June 30 of the next year. Outgoing Leadership Team members are eligible for re-election.

A Leadership Team member shall cease to hold a seat on the Leadership Team:

- upon expiry of the above term;
- upon resignation by the Leadership Team member;
- upon dismissal on the same grounds and following the same procedure as set forth for the dismissal of a Member in section 5.4 above.
- upon leaving employment or occupation with the Member, except in cases of joining a Voting Member as set forth in section 6.1.3.

The Vice President Healthcare, subject to consensus approval of the Tri-Chairs, has the authority to alter the GS1 Healthcare Leadership election timing or term duration due to special circumstances, as communicated by the Vice President to the current GS1 Healthcare Leadership Team.

## 6.2 Tri-Chairs

### 6.2.1 General

The Leadership Team shall elect three (3) chairpersons (the "Tri-Chairs") in accordance with the decision-making process set out in section 5.5.2 above.

Nominees to serve as Tri-Chairs shall be selected from the Leadership Team according to the following guidelines:

- To ensure the effectiveness of GS1 Healthcare, Tri-Chair representation should provide perspectives from these **three (3) healthcare supply chain partner categories**: (a) manufacturers, (b) wholesalers and solution providers, and (c) healthcare providers (e.g., hospitals, pharmacies, care homes, etc.).
- At a minimum, the Leadership Team should seek to nominate and elect at least one (1) Tri-Chair member that represents a hospital/healthcare provider.
- GS1 Healthcare Leadership Team representatives in other categories may also nominate category peers to be Tri-Chairs.
- If only one nomination for each of the above three (3) categories is received, those nominees will automatically be elected to serve as Tri-Chairs. The Vice President shall provide written notice of such election to the GS1 Healthcare Leadership Team at a Leadership Team meeting.
- If more than one nomination for a given category is received, then an election will be run for that category with a three (3)-week voting period, following the process provided in section 5.5.3.

- Tri-Chair elections will be held when each individual Tri-Chair representative's term ends.
- In the case of a Tri-Chair election, the process will be the same as for the Leadership Team elections and the person with the highest votes elected.
- Self-nomination or nomination of peers for the Tri-Chair roles is allowed.
- GS1 MO representatives are not authorised to nominate in Tri-Chair elections.
- A former Tri-Chair not re-elected to a Tri-Chair position will remain in the Healthcare Leadership Team for the current term (until 30 June of the current financial year) and then be able to nominate for GS1 Healthcare Leadership Team election for the next term as section 6.1.3 above.

The Vice President Healthcare, subject to consensus approval of the Tri-Chairs, has the authority to alter the GS1 Healthcare Tri-Chair election timing or term duration due to special circumstances, as communicated by the Vice President to the current GS1 Healthcare Leadership Team.

## 6.2.2 Roles and Responsibilities

Tri-Chairs shall:

- Preside at GS1 Healthcare conferences and meetings
- Approve Leadership Team meeting agendas
- Facilitate the consensus process
- Disseminate and monitor communications with membership where appropriate
- Report to and liaise with the GS1 Board Committee for Healthcare
- Where expressly provided herein, shall have consensus approval authority with respect to certain Vice President decisions.

## 6.2.3 Term Limits

Tri-Chairs serve a term of two (2) years with the possibility to be re-elected. Where possible, Tri-Chair terms are staggered to ensure continuity. A representative may be elected for multiple consecutive or non-consecutive Tri-Chair terms.

## 6.3 Vice-President Healthcare

### 6.3.1 Roles and Responsibilities

- Facilitates GS1 Healthcare decisions
- Executes the Leadership Team's strategy
- Coordinates Marketing & PR responsibilities for healthcare with GS1 staff
- Provides general communication
- Liaises with the GS1 Board Committee for Healthcare
- Ensures that the GS1 Healthcare Leadership Team has sufficient support from GS1 staff and provides the Leadership Team with an overview of resources available for projects
- Drives GS1 alignment with GS1 Healthcare goals and objectives
- Is accountable to the GS1 President Community Engagement and the Leadership Team
- Coordinates relations with other organisations/associations
- Where expressly provided herein, some decisions of the Vice President Healthcare shall be subject to consensus approval of the Tri-Chairs.

### 6.3.2 Term Limits

The Vice-President Healthcare is appointed by GS1 and remains in that position until termination or resignation, whichever occurs earlier.

## 7 Work Teams

- (a) GS1 Healthcare develops global standards in work teams following the GSMP process (see sec. 5.5.4). These work teams focus on specific business issues and follow the GSMP rules as provided in the GSMP Manual. The working language within work teams is English.
- (b) All development work requests (i.e., work requests for development of standards) for healthcare are reviewed by the Leadership Team, and development work requests that relate to healthcare are progressed in line with GSMP after approval of the Leadership Team.
- (c) All maintenance work requests (i.e., work requests for ongoing maintenance and enhancement of standards) that may impact healthcare are brought to the attention of the Leadership Team for their information.
- (d) There is an expectation that the Leadership Team will actively review, comment and vote on work requests that impact healthcare in GSMP. Where work requests have a significant impact, working groups will be formed to review the materials for these requests.
- (e) The Leadership Team has the authority to decide, in alignment with GS1, to create new work teams to improve implementation of GS1 standards developed under GSMP. Such implementation work teams function under the supervision of the Leadership Team outside the GSMP process.

### 7.1 Work team leaders

Ideally, work teams are to be co-chaired by more than one chair-person; each chair-person shall be advised to the Leadership Team prior to leading a work team. Implementation work teams may be chaired by a GS1 Healthcare Member and/or GS1 staff member.

#### 7.1.1 Roles and Responsibilities

Work team leaders:

- Ensure the progress of the team according to the scope and deliverables defined at the inception of the group;
- Ensure adequate and representative participation from all relevant parts of the healthcare supply chain during discussions;
- Provide administration for all team activities, and will be supported in that task by GS1 staff;
- Report on the progress of their work teams to the Leadership Team on a regular basis.

#### 7.1.2 Term Limits

Work teams whose work is governed by the GSMP Manual (e.g., standards development and maintenance work teams) are formed and disbanded, and their leadership chairs are appointed and removed, according to the terms of the GSMP Manual in addition to any other applicable terms herein (see sec. 7.1). Implementation work teams, as described in sec. 7(e), are formed and disbanded, and their leadership chairs are appointed and removed, at the discretion of the Leadership Team.

## 8 Fees

GS1 is an international non-profit association and global standards organisation. GS1 Healthcare is a GS1-facilitated global healthcare user group. GS1 Healthcare activities are funded from the fees of Voting Members of GS1 Healthcare. The funds collected are intended to cover the cost of the



projects, activities and work plans of GS1 Healthcare. Activities and fees are determined by the Leadership Team in consultation with GS1 and are adjusted based on forecasted funding levels together with inflation.

Membership fees are due on 31 May each calendar year. Members who have not paid after 31 March will not be allowed to participate as Voting Members (e.g., will not be allowed to nominate or vote for Leadership Team members) until they have paid the fee. Fees are non-refundable.

A financial review with the Leadership Team shall be conducted two (2) times annually.

A proposed adjustment to the membership fees indexed to the Belgian inflation rate is submitted to the approval of the GS1 Healthcare Leadership Team every year.

## 9 Conferences and conference procedures

There will be one global GS1 Healthcare conference per year. The conferences will take place in different geographical locations, as coordinated by GS1 and GS1 Healthcare Leadership Team. GS1 Member Organisations have the opportunity to offer to co-host a conference in their region. In alignment with GS1, and the co-hosting MO, the GS1 Healthcare Leadership Team decides the dates and venues.

### 9.1 Conference fees

There are fees applicable for conferences.

Voting Members, GS1 MOs, industry associations and representatives from Low- and Middle-Income (LMIC) countries, as defined by the World Bank, pay a reduced fee.

The following participants shall attend conferences free of charge: speakers, hospital/pharmacy staff, regulatory bodies and development partners (i.e., humanitarian organisations).

The Vice President GS1 Healthcare decides if GS1 Healthcare will reimburse the travel costs for a healthcare provider speaker; otherwise there will be no remuneration for speakers.

### 9.2 Antitrust Caution

The GS1 Competition Law Caution must be brought to the attention of all participants at the beginning of every conference/meeting and teleconference. (See, e.g., <https://www.gs1.org/standards/development/how-we-develop-standards/gs1-competition-law-caution>.)

### 9.3 Code of Conduct

GS1 Healthcare Members must adhere to the Code of Conduct (attached hereto as **Appendix B**).

## 10 Communication

### 10.1 Document Development Process

#### 10.1.1 Specific Responses regarding Public Policy

The Public Policy work team shall be ultimately responsible for drafting and approval of specific responses to requests for consultation from regulatory authorities, with subject matter support from GS1 or the relevant GS1 MO. If time permits, the Leadership Team will then review the proposed response and inform the full GS1 Healthcare membership. Substantive and editorial changes are suggested and approved by consensus (according to the decision-making process set out in section 5.5). Review can be via a physical meeting, e-mail, teleconference or webinar. GS1 Healthcare will submit the response to the regulatory authorities either via the local GS1 MO or through the GS1 President - Community Engagement or the Vice President GS1 Healthcare.

### 10.1.2 Position Papers & Position Statements

Any Member of GS1 Healthcare or a GS1 Member Organisation can draft a proposed GS1 Healthcare position paper or position statement. Once drafted, the document shall be submitted for approval to the Leadership Team. Substantive and editorial changes are suggested and approved by consensus of the Leadership Team (see sec. 5.55.5). Review and adoption can be via a physical meeting, e-mail, teleconference or webinar. If, and only if, the Leadership Team approves the position paper or position statement, it can then be posted on, and distributed via, the GS1 Healthcare website and presented as a GS1 Healthcare position paper or position statement.

### 10.1.3 Press Releases

GS1 Healthcare may issue press releases from time to time on relevant topics, such as agreements among healthcare stakeholders, regulatory bodies and key customers, organisations adopting GS1 Standards, a change in GS1 Healthcare Leadership, or other major achievements. Topics must be presented to the Leadership Team before forwarding to GS1 GO marketing team to draft. The final press release will be shared with the Leadership Team for voting before publication.

## 10.2 Communication process

GS1 Healthcare's communication with associations and regulatory bodies regarding global issues is conducted by the Vice-President Healthcare and responsible GS1 Global Office staff supporting GS1 Healthcare. Where necessary, such communications are also coordinated together with the Tri-Chairs, Public Policy co-chairs or members of the Leadership Team from the geographic region impacted. The communications will be aligned with the Vision, Mission and strategy document adopted by GS1 Healthcare ("Strategy"). When the association and/or regulatory topic is for a specific geographic area, the GS1 MO involved with this geographic area will take the lead in communications in collaboration with the Vice-President Healthcare and consistent with the GS1 Healthcare Mission, Vision and Strategy.

GS1 Healthcare provides a neutral platform for its Members to engage in discussions with healthcare stakeholders and regulatory bodies.

Communications, including social media communications, relating to GS1 Healthcare global marketing activities may be reviewed by the Leadership Team, and shall align with the GS1 branding guidelines. GS1 shall maintain the GS1 Healthcare website ([www.gs1.org/healthcare](http://www.gs1.org/healthcare)), brochures, newsletters, and related collateral.

## 10.3 Intellectual property

- a. Ownership; Materials. GS1 owns the intellectual property rights in and to any and all information, analyses, documents, presentations, data and any other output or works, in whatever form, developed, drafted or produced by itself, its Affiliates (see sec. 10.3.d) and their respective employees, agents, officers or directors, for GS1 Healthcare (the "**GS1 Healthcare Materials**"). The GS1 Healthcare Materials include, more specifically, (without limitation) presentations, analyses, surveys, comparisons, information stored in the "Public Policy Database" and in the "Healthcare Provider Database" as well as other output on public policy matters of interest to the healthcare sector that are developed by GS1 (the "**Public Policy and Healthcare Provider Materials**").
- b. Licence. GS1 grants to any and all **Members** for the duration of their membership in GS1 Healthcare a non-exclusive, non-transferable (except to an Affiliate), revocable, royalty-free, fully paid-up, perpetual, worldwide licence, without the right to sublicense (except to an Affiliate), to use any and all GS1 Healthcare Materials, excluding the Public Policy and Healthcare Provider Materials, for internal purposes only (the "**GS1 Healthcare Materials Licence**"). Any other use shall require GS1's prior written consent.
- c. Public Policy License. GS1 grants to any and all **Voting Members** for the duration of their membership in GS1 Healthcare and all GS1 MOs a non-exclusive, non-transferable (except to an Affiliate), revocable, royalty-free, fully paid-up, perpetual, worldwide licence, without the right to sublicense (except to an Affiliate), to use the Public Policy and Healthcare Provider Materials for internal purposes only (the "**Public Policy License**"). Any other use shall require GS1's prior written consent.

- d. Affiliate. For the purposes of this Charter, an "**Affiliate**" of a party means any other entity that, directly or indirectly, is in control of, is controlled by, or is under common control with such party. "Control" means the direct or indirect authority or power to direct or cause the direction of the management and policies of an entity, whether through ownership of voting securities, by contract, or otherwise.
- e. Internal purposes. For the purpose of this section 10, "**internal purposes**" shall mean use within the Member's own organisation and/or use that is not directly (e.g., selling the Public Policy and Healthcare Provider Materials) or indirectly (e.g. copying the materials in the Member's own promotional materials) intended for or directed towards commercial advantage or monetary compensation.
- f. For the sake of clarity, this section 10 does not grant any licence rights to any person that is not an employee of a GS1 Healthcare Member.
- g. When using the GS1 Healthcare Materials or the Public Policy and Healthcare Provider Materials, Members and/or Voting Members shall ensure that GS1 shall be credited as the author of these materials.
- h. **Examples (for illustration purposes only):**
  - There is no need to ask for GS1's permission to share the existence of a draft (or that draft itself) of a new regulation issued by a regulatory authority as such information is not developed within GS1 Healthcare and, in any case, it is likely to be in the public domain.
  - There is no need to ask for GS1's permission to share an approved GS1 Healthcare position paper within one's own company (or group of companies) or with other companies or third parties to socialise the position set out in the paper. If the company quotes the paper in a document, then it should indicate the source as being GS1. If the company shares only extracts of the paper with another party, it should make sure the other party is aware that GS1 is the author of the position paper.
  - There is no need to ask permission to share a document available on the "Public Policy Database" containing a public policy analysis within one's own company or with other companies, unless the purpose is to gain compensation from sharing the document. In that case, GS1's written permission is needed in advance.
  - It is not allowed to copy GS1 Healthcare Materials or portions thereof into a company's marketing materials without GS1's written permission in advance. If such written permission is obtained, such uses must identify GS1 as the author of the quoted materials.

## 10.4 Amendment.

This Charter may be amended or modified only by the Leadership Team in accordance with the decision-making process set out in section 5.5.2 above. Upon such amendment or modification, all GS1 Healthcare Members will be provided with the latest version.

## 10.5 Governing law; jurisdiction

- (a) Governing law. This Charter and any dispute, claim or obligation (whether contractual or non-contractual) arising out of or in connection with it, its subject matter or formation shall be governed by the law of Belgium, excluding any applicable choice of law and conflict of laws rules.
- (b) Jurisdiction. The parties hereto irrevocably consent to and agree that the Belgian courts in the greater Brussels metropolitan area shall have exclusive jurisdiction to settle any dispute or claim (whether contractual or non-contractual) arising out of or in connection with this Charter, its subject matter or formation.

## 11 Appendix A: Skill Requirements for the Leadership Team

### 1. Skill requirements for healthcare provider representatives on the Leadership Team

#### A. Essential

- (1) Experience: Of the clinical environment in a healthcare provider setting and knowledge of GS1 standards and associated technologies in that context
- (2) Strategic thinker: As is essential for leading a team and ensuring that projects are completed successfully
- (3) Strong leadership skills: The ability to effectively lead and share/shape opinion
- (4) Strong communication skills: As is necessary for effectively communicating with other stakeholders involved in the Leadership Team
- (5) Community collaboration: Ability to represent the community view on market needs, market trends and potential solutions

#### B. Desirable

- (1) Technical expertise: May be needed in areas such as barcode scanning at point of care, data management, or procurement, etc
- (2) Strong business acumen: For identification of opportunities that will improve patient safety and operational efficiencies linked to implementation of GS1 standards
- (3) Strong attention to detail: The ability to see the link between standards implementation and patient safety / operational efficiency benefits

### 2. Skill Requirements for solution provider representatives on the Leadership Team

#### A. Essential

- (1) Experience of implementation of GS1 standards: In solutions in the healthcare environment and knowledge of GS1 standards and associated technologies in that context
- (2) Strategic thinker: As is essential for leading a team and ensuring that projects are completed successfully
- (3) Strong leadership skills: The ability to effectively lead and share/shape opinion
- (4) Strong communication skills: As is necessary for effectively communicating with other stakeholders involved in the Leadership Team
- (5) Community collaboration: Ability to represent the community view on market needs, market trends and potential solutions

#### B. Desirable

- (1) Technical expertise: In areas such as barcode scanning at point of care, data management, or solutions that aid interoperability with other systems, etc
- (2) Strong business acumen: For identification of opportunities that will improve patient safety and operational efficiencies linked to implementation of GS1 standards
- (3) Strong attention to detail: The ability to see the link between standards implementation and patient safety / operational efficiency benefits

### **3. Skill requirements for manufacturer and wholesaler representatives on the Leadership Team**

#### **A. Essential**

- (1) Experience: Of their business environment and knowledge of GS1 standards and associated technologies in that context
- (2) Strategic thinker: As is essential for leading a team and ensuring that projects are completed successfully
- (3) Strong leadership skills: The ability to effectively lead and share/shape opinion
- (4) Strong communication skills: As is necessary for effectively communicating with other stakeholders involved in the Leadership Team
- (5) Community collaboration: Ability to represent the community view on market needs, market trends and potential solutions

#### **B. Desirable**

- (1) Technical expertise: May be needed in areas such as barcode scanning at point of care, data management, or procurement, etc
- (2) Strong business acumen: For identification of opportunities that will improve patient safety and operational efficiencies linked to implementation of GS1 standards
- (3) Strong attention to detail: The ability to see the link between standards implementation and patient safety / operational efficiency benefits

## 12 Appendix B: Code of Conduct

### 1. Principles

One of GS1 Healthcare's greatest and proudest strengths is the rich diversity of people and businesses that work with the organisation and attend meetings. We recognise that, not everyone is used to working in such a diverse group, and therefore draw your attention to basic principles and standards of behaviour that apply to all meetings.

Comments on the following subjects may cause offense and are not acceptable, however intended:

- Race, national identity, national language or nation of origin. All races and nations are equal at GS1 Healthcare;
- Age, gender, sex, or sexuality. Men and women of all ages and backgrounds are treated as equals;
- Disparaging remarks about companies, types of companies or industries. We welcome all types and sizes of enterprises from all industries.

GS1 Healthcare is a place where buyers and sellers meet, however:

- Presentations and remarks may not promote or attempt to sell a particular company, proprietary product or product type, implicitly or explicitly.
- These are strict networking opportunities and should not be used to conduct company business or sales opportunities. Therefore, please arrange a private follow-up visit outside of times organised for breaks and social gatherings if you choose to engage in company business matters.
- GS1 Healthcare depends on a constructive spirit of innovation. You are welcome to be as positive or sceptical as you like about prospects, but you should respect the views and credibility of others, especially those with credentials and training in their field. Do not denigrate individuals or their ideas just because you disagree with them about whether or not something is possible.
- GS1 Healthcare and its Members are committed to abide by the "Code of Conduct and Conflict Management Rules" set out in Appendix M of the GSMP Manual, which shall be deemed part of this Code of Conduct and apply to any meeting of GS1 Healthcare.

### 2. Meeting Conduct

The work of GS1 Healthcare is primarily undertaken via face-to-face, telephone-based, or video-conference meetings. These meetings have specific agendas approved or modified at meeting commencement.

To ensure these meetings are productive it is important that every attendee has the opportunity to put forward his or her perspective and input. In addition, it is important that once approved, the meeting agenda is followed.

The GS1 Healthcare Tri-Chairs will monitor meeting activity to ensure that all stakeholders have equal chance to participate as part of discussions. They will also ensure the meeting agenda is respected.

In cases where the meeting has become unproductive, for example due to domination of discussions by a single participant or deviation from agreed agenda topics, the Tri-Chairs will stop the conversation and request adjustments to participant behaviour to reinstate a productive work environment for all.

Repeated breaches of this Code of Conduct may result in participant expulsion in line with section 5.4.

## 13 Appendix C: How to Use This Document – Document Conventions

**MUST:** This word, or the terms "WILL," "REQUIRED" or "SHALL", means that the definition is an absolute requirement.

**MUST NOT:** This phrase and the phrases "WILL NOT" or "SHALL NOT" mean that the definition is an absolute prohibition.

**SHOULD:** This word, or the adjective "RECOMMENDED", means that there may exist valid reasons in particular circumstances to ignore a particular item, but the full implications must be understood and carefully weighed before choosing a different course.

**SHOULD NOT:** This phrase, or the phrase "NOT RECOMMENDED", means that there may exist valid reasons in particular circumstances when the particular behaviour is acceptable or even useful, but the full implications should be understood and the case carefully weighed before implementing any behaviour described with this label.

**MAY:** This word, or the adjective "OPTIONAL", means that an item is truly optional.