

DATED **2021**

**NATIONAL INSTITUTE FOR HEALTH (1)
AND CARE EXCELLENCE**

**and
THE ROYAL PHARMACEUTICAL
SOCIETY OF GREAT BRITAIN,
BMJ PUBLISHING GROUP LTD (2)
and
RCPCH PUBLICATIONS LIMITED**

AGREEMENT FOR
The British National Formulary (BNF)
Publications for the NHS

NICE Contract Number



Terms and Conditions of Agreement

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THIS AGREEMENT is made on

01 April 2021

BETWEEN:

- (1) **NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE** of Level 1A City Tower, Piccadilly Plaza Manchester M1 4BT ("**NICE**"); and
- (2) **THE ROYAL PHARMACEUTICAL SOCIETY OF GREAT BRITAIN** (Company no: RC 000799 England) ("**RPSGB**") of 66-68 East Smithfield, London, E1W 1AW and **BMJ PUBLISHING GROUP LIMITED** (Company no: 03102371 England) of BMA House, Tavistock Square, London WC1H 9JP and **RCPCH PUBLICATIONS LIMITED** (company no: 03670119 England) of 5 – 11 Theobalds Road, London WC1X 8SH which together have formed a consortium (each being a '**Consortium Party**' and together being "**the Contractor**").

IT IS AGREED AS FOLLOWS

1 DEFINED TERMS AND INTERPRETATION

In this Agreement the words and expressions below will be interpreted to have the meanings adjacent to them:-

- 1.1 "**2010 Order**" means the Postgraduate Medical Education and Training Order of Council 2010.
- 1.2 "**Affected Party**" means, in the context of Clause 34 the Party whose obligations under the Agreement have been affected by the Force Majeure Event.
- 1.3 "**Agreement**" means this agreement between NICE and the Contractor including the Annexes.
- 1.4 "**Agreement Period**" means (subject to earlier termination in accordance with its terms or by operation of law) the duration of the Agreement, starting on the 01 April 2021 and ending 31 March 2033 or the earlier date of the termination of this Agreement in accordance with its provisions.
- 1.5 "**Agreement Price**" means the Services Fee and the BNF Volumes Price.
- 1.6 "**Agreement Standard**" means such standard as complies in all material respects with all relevant provisions of the Agreement including dates for delivery.
- 1.7 "**Annual Business Plan**" means the plan to be agreed by the Parties on an annual basis incorporating any KPIs applicable for that year as provided for in Clauses 4.3 and 6.9 and following the format set out in Annex 6.
- 1.8 "**Authorised Officer**" means a person designated as such by NICE from time to time as notified in writing to the Contractor to act as the representative of NICE for all

purposes connected with the Agreement, including any authorised representative of such person.

- 1.9 **"BNF"** is the abbreviation for the *British National Formulary*.
- 1.10 **"BNF App"** means one or more software programs (including extensions, media, and libraries that are enclosing within a single software bundle) developed by the Contractor for distribution of the BNF Content under the trademark or branding of the RPSGB or the Consortium Parties and for specific use with products running on iOS and Android, as applicable, including bug fixes, updates, upgrades, modifications, enhancements, supplements to, revisions, new releases and new versions of such software programs.
- 1.11 **"BNF (Children)"** is the abbreviation for the *BNF for Children*.
- 1.12 **"BNF Content"** means the text, artwork, designs, data and other material and content in the BNF and BNF (Children) in all formats including the BNF Volumes, BNF App, NICE Feed.
- 1.13 **"BNF Intellectual Property"** means the Intellectual Property in and to the BNF Content, BNF App, BNF Volumes, NICE BNF and/ or the NICE Feed.
- 1.14 **"BNF (Nurses)"** means *The Nurse Prescribers' Formulary for Community Practitioners* content contained within the BNF Content.
- 1.15 **"BNF Publication(s)"** refers to both the BNF and BNF (Children) publications in any format.
- 1.16 **"BNF Volume(s)"** means a printed volume of any published or updated edition of BNF or BNF (Children) which constitutes a Deliverable as specified in Annex 4.
- 1.17 **"BNF Volumes Price"** means the fee for the printing and delivery of the BNF Volumes specified in the Specification as may be varied in accordance with the provisions of this Agreement.
- 1.18 **"Change"** means any change to this Agreement including to any of the Services or to the Supply or Annual Business Plan and includes any Changes necessitated by a General Change in Law or a Specific Change in Law.
- 1.19 **"Commencement Date"** means 01 April 2021.
- 1.20 **"Computer Network"** means the servers, PC networks, stand-alone computers and other hardware and software utilised by an organisation both within its premises and hosted for such organisation by others.
- 1.21 **"Computerised Decision Support"** shall mean any online or offline electronic system that provides drug and medicine information or knowledge, intelligently filtered or presented at appropriate times to enhance health and health care. This encompasses a variety of tools to enhance decision-making in the clinical workflow.
- 1.22 **"Confidential Information"** means any and all information, data and material of any nature which one Party may receive or obtain from the other Party, or the other Party's agents, in connection with the operation of the Agreement or otherwise relating in any way to the business, operations and activities of the other Party and

the other Party's employees, consultants, agents and/or any other person with whom the other Party has dealings.

- 1.23 **"Connected Parties"** means any person connected with any Consortium Party by virtue of ownership (whether in whole or part), control, joint venture, partnership or other profit-sharing, or common directors.
- 1.24 **"Contractor Personnel"** means the employees and contractors (whether full or part time) engaged by the Contractor to perform the Services and/or the Supply;
- 1.25 **"Controller"** has the meaning given in applicable Data Protection Laws from time to time;
- 1.26 **"Convictions"** means other than in relation to minor road traffic offences, any previous or pending prosecutions, convictions, cautions and binding-over orders (including any spent convictions as contemplated by Section 1(1) of the Rehabilitation of Offenders Act 1974 or any replacement or amendment to that Act).
- 1.27 **"Costs"** includes costs, charges, outgoings and expenses of every description.
- 1.28 **"Data Protection Laws"** means all laws and regulations pertaining to processing and protection of Personal Data as applicable to either Party in relation to this Agreement or the Services and the Supply including: (a) the UK GDPR; (b) the Data Protection Act 2018; (c) as applicable, General Data Protection (GDPR) Regulation, Regulation (EU) 2016/679 ("GDPR"); (d) any laws which implement any such laws; and (e) any laws that replace, extend, re-enact, consolidate or amend any of the foregoing, where **"UK GDPR"** means GDPR as it forms part of UK domestic law by virtue of the European Union (Withdrawal) Act 2018, with adjustments as provided in the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019;
- 1.29 **"Data Subject"** has the meaning given in applicable Data Protection Laws from time to time.
- 1.30 **"Deliverable"** means any data, report, drawing, specification, design, invention, plan, program, document, agreement, and/or other material (whether audible, in writing or otherwise) and whether in hard copy or electronic form, (a) produced by or to be produced by or acquired by or to be acquired by the Contractor in the course of the performance of the Services and Supply and (b) delivered or made available to NICE pursuant to the provisions of this Agreement; and including, for the avoidance of doubt, BNF Content, the NICE Feed, the BNF App and the BNF Volume(s).
- 1.31 **"Delivery Dates"** means the respective dates for delivery of the Deliverables set out in the Annual Business Plan (Annex 6) and so appended to Annexes 1, 2, 3, 4 and 7 and **"Delivery Date"** means any such date.
- 1.32 **"Dispute Resolution Procedure"** means the procedure set out in Clause 22.
- 1.33 **"Editorial Independence"** means, subject to the overriding requirement that a publication conforms to its specification: the identification of the text and other content to be included in a publication; its abridgement, grammatical changes, sentence and paragraph ordering; and the decision as to inclusion or exclusion of any material.
- 1.34 **"Electronic Goods"** means the NICE Feed and the BNF App.

- 1.35 **"Force Majeure Event"** means one or more of the following (limited, where the Affected Party is the Contractor, to the extent that it is not attributable to the Contractor or the Contractor's staff and is not attributable to any financial matters or issues as to non-payment or part-payment to the Contractor or any Consortium Party, or the Contractor's or any Consortium Party's cash position or solvency or that of any parent); war, civil war (whether declared or undeclared), riot or armed conflict; radioactive, chemical or biological contamination; epidemic or pandemic; pressure waves caused by aircraft or other aerial devices travelling at sonic or supersonic speed; acts of terrorism; explosion; fire; flood; extraordinarily severe weather conditions which are both unforeseen and for which precautions are not customarily taken by prudent business organisations so as to avoid or mitigate the impact thereof; industrial action which affects the provision of the Services and Supply, but which is not confined to the workforce of the Contractor (or any of the Consortium Parties) with the exception of strikes or is site specific; pestilence; the actions of governmental authorities to the extent that such actions are implemented either pursuant to emergency powers or otherwise outside the usual course of governmental business; or act of God to the extent that and that such an event is beyond the reasonable control of the Party in question and could not have been avoided or mitigated by the exercise of all reasonable care by that Party and further provided that such event materially affects the ability of the Party seeking to rely upon it to perform its obligations under the Agreement.
- 1.36 **"General Change in Law"** mean any change in law or regulation which has a commercial, financial or administrative impact on business but which is not a Specific Change in Law.
- 1.37 **"GPs"** means medical practitioners registered in the General Practitioner Register as defined by the Medical Act 1983 in accordance with the 2010 Order.
- 1.38 **"Insolvent"** means:
- 1.38.1 the passing by a Consortium Party of a resolution for its winding-up or the making by a court of competent jurisdiction of an order for the winding-up of a Consortium Party, or the dissolution of a Consortium Party, or if an administration order is made (or an administrator or administrative receiver is appointed) in relation to a Consortium Party or the appointment of a receiver over, or the taking possession or sale by an encumbrancer of any of their assets, or a Consortium Party makes an arrangement with its creditors generally or makes an application to a court of competent jurisdiction for protection from its creditors generally or documents are filed with the Court for the appointment of an administrator or notice of intention to appoint an administrator is given by a Consortium Party or their respective directors or by a qualifying floating charge holder (as defined in paragraph 14 of Schedule B1 to the Insolvency Act 1986) or circumstances arise which entitle the Court or anyone else to appoint a receiver, manager, administrator or administrative receiver or which would entitle the Court to make a winding-up or bankruptcy order or a Consortium Party takes or suffers any action analogous to any of the above in consequence of debt; and
 - 1.38.2 any event in any jurisdiction other than England and Wales which is analogous to any of the above.

- 1.39 **"Intellectual Property"** or "IPR" means any and all patents, trademarks, service marks, domain names, registered designs, utility models, applications for and the right to make applications for any of such rights, inventions, Know-How (as defined below), rights to restrain disclosure of any confidential information, unregistered trademarks and service marks, trade and business names, including rights in any get-up or trade dress, copyrights, (including rights in computer software and in websites) unregistered design rights and other rights in designs and rights in databases, database right; rights under licences, consents, orders, statutes or otherwise in respect of any rights of the nature specified in this definition "Intellectual Property"; and rights of the same or similar effect or nature as or to those above in each case in any jurisdiction.
- 1.40 **"in writing"** or **"written"** shall be interpreted to include any document which is recorded in manuscript or typescript, and email, but excluding for the avoidance of doubt instant messaging, mobile telephone text messages, tweets, and voicemail and other voice messages automatically converted to text.
- 1.41 **"Joint Formulary Committee"** means the independent committee with a remit to review and advise on the content of the BNF.
- 1.42 **"KPIs"** means the Key Performance Indicators agreed by the Parties;
- 1.43 **"Know How"** means all information not publicly known which is used or required to be used in or in connection with the Services and Supply existing in any form (including, but not limited to, that comprised in or derived from engineering, chemical and other data, specifications, formulae, experience, drawings, manuals, component lists, instructions, designs and circuit diagrams, brochures, catalogues and other descriptions) and relating to the design, development, manufacture or production of any products; the operation of any process; the performance of any Services and Supply; the selection, procurement, construction, installation, maintenance or use of raw materials, plant, machinery or other equipment or processes; the rectification, repair or service or maintenance of products, plant, machinery or other equipment; the supply, storage, assembly or packing of raw materials, components or partly manufactured or finished products; quality control, testing or certification of any person.
- 1.44 **"Loss"** includes losses, liabilities, claims, Costs, charges and outgoings of every description (including legal expenses), compensation payable under contracts, loss of normal operating profits, loss of opportunity, loss of goodwill, loss of reputation, loss of revenue from related contracts and pure economic loss.
- 1.45 **"Milestones"** means the milestones as defined in the annual business and thereby appended to Annex 7 and the quarterly reviews as detailed in Annex 7.
- 1.46 **"Monitoring Report"** means the progress report from the Contractor following the format specified in Annex 7 showing the Milestones and KPIs and detailing when previous Milestones and KPIs have been achieved and the Contractor's progress towards the achievement of the remaining Milestones and KPIs;
- 1.47 **"month"** means a calendar month.
- 1.48 **"NHS" means:**
- 1.48.1 the Secretary of State for Health;
 - 1.48.2 the Department of Health and all agencies thereof;

1.49 **“NHS Users” means:**

1.49.1

- the Secretary of State for Health
- NHS England and Improvement
- the Department of Health and Social Care and all agencies including, but not limited to:
 - Non-Departmental Public bodies thereof (for example)
 - Public Health England
 - NICE
 - Care Quality Commission
 - Medicines and Healthcare Products Regulatory Agency
 - Human Tissue Authority
 - Human Fertilisation and Embryology Authority
 - Health Research Authority
- NHS Trusts and Foundation Trusts including
 - Acute Trusts
 - Ambulance Trusts
 - Community Trusts
 - Mental Health Trusts
 - Isle of Wight NHS Trust
- Primary Care including GPs
- Care homes in receipt of government funding
- Hospices
- Clinical Commissioning Groups established pursuant to the Health and Social Care Act 2012
- Commissioning Support Units established pursuant to the Health and Social Care Act 2012
- Defence Medical Services within the Ministry of Defence in the UK
- Prison Healthcare Services within NHS England and Improvement
- Any non-commercial successor body exercising the same or similar functions in whole or part to any of the above, including for the avoidance of doubt any organisation arranged under Section 75 of the National Health Service Act 2006
- Any equivalent organisation within Scotland, Wales or Northern Ireland

1.49.2

- In addition:
 - Any prescriber (including V100, V150, V200 and V300 prescribers) or health and social care professional that is an employee or worker of the organisations listed in 1.49.1 above
 - Registered pharmacists providing services through community pharmacies commissioned to provide NHS services
 - Registered dentists providing NHS dental care

1.49.3

Exclusion: The following entities are excluded:

- Public sector organisations (unless explicitly covered above)

- Royal Colleges and other professional bodies
 - Higher and Further education establishments
 - Health-related research and information charities
 - Commercial organisations, including but not limited to
 - information providers
 - pharmaceutical companies
 - health insurance providers
 - organisations contracted/financially remunerated to provide services for the NHS
- 1.50 **“NICE BNF”** means the reproduction of the NICE Feed on the NICE website.
- 1.51 **“NICE Computer Network”** means the Computer Network used by NICE for its internal purposes and for communicating with third parties.
- 1.52 **“NICE Feed”** means the electronic feeds of the BNF Content, described in Annex 2.
- 1.53 **“NICE Guideline”** means the publications owned by NICE which are provided to the Contractor for the provision of the services and supply.
- 1.54 **“NHS Organisation”** means those organisations listed in Clause 1.49.1.
- 1.55 **“Paediatric Formulary Committee”** means the independent committee with a remit to review and advise on the content of the BNF (Children).
- 1.56 **“Party”** means NICE or the Contractor and “Parties” refers to both collectively. A Party shall include all permitted assigns of the Party in question. A persons who is not a Party and not a Consortium Party is a third party.
- 1.57 **“person”** includes any individual, partnership, firm, trust, body corporate, government, governmental body, statutory body, authority, agency, unincorporated body of persons or association and a reference to a person includes a reference to that person's successors and permitted assigns.
- 1.58 **“Personal Data”** has the meaning given in the applicable Data Protection Laws from time to time.
- 1.59 **“Personal Data Breach”** has the meaning given in applicable Data Protection Laws from time to time.
- 1.60 **“Portable Devices”** means mobile electronic devices to which text and other content may be downloaded or viewed including but not limited to: Smartphones and text readers, laptops, notebooks, mobile phones, portable hard-drives, memory sticks and other portable storage devices.
- 1.61 **“Processor”** has the meaning given in the applicable Data Protection Laws from time to time.
- 1.62 **“Processing”** has the meaning given in applicable Data Protection Laws from time to time.
- 1.63 **“Replacement Supplier”** means any contractor engaged instead of the Contractor to deliver services equivalent to the Services or goods equivalent to the Supply.

- 1.64 **"Review Period"** means the period commencing on a date six months before, and ending on a date three months before each fourth (4th) anniversary of the Commencement Date.
- 1.65 **"Senior Lead"** means a senior representative of the Contractor nominated by the Contractor as the duly authorised representative of the Contractor for all purposes connected with the Agreement.
- 1.66 **"Services"** means the research, development and other services necessary to: (a) create the BNF Content in accordance with the requirements of Annex 1; (b) to maintain and verify the BNF Content in accordance with Annex 1; (c) carry out the origination, creation, formatting and delivery of the NICE Feed; and (d) carry out the origination, creation, formatting, editing and other work to be in a position to publish the BNF Volumes and BNF App;
- 1.67 **"Services Fee"** means the fee payable for the performance of the Services in accordance with Annex 8.
- 1.68 **"Source Material"** means any text, data, commentary or other literary or artistic works prepared (other than by or on behalf of the Contractor) in relation to any drug listed in the BNF Publications and which has been prepared principally for purposes other than publication therein.
- 1.69 **"Specific Change in Law"** means any change in law or regulation which has a commercial, financial or administrative impact on business and which is directed at, and is declared to be applicable to, the Contractor or any Consortium Party or the BNF Content or the Source Materials.
- 1.70 **"Specification"** means the description of the Services, and Supply, as specified in Annexes 1, 2, 3 and 4, together with (where applicable) the requirements as to the Deliverables to be provided pursuant to such Services and Supply.
- 1.71 **"Supervisory Authority"** means the relevant supervisory authority in relation to personal data protection in the territory(ies) where the Parties to this Agreement are established.
- 1.72 **"Supply"** means the supply and delivery (in the specified formats) of the BNF Publications and any other Deliverables as described in Annexes.
- 1.73 **"Syndication Services"** means the web service available at <https://api.nice.org.uk/> and the associated systems and facilities made available by NICE for delivering NICE content electronically.
- 1.74 **"Territory"** means England, Scotland, Northern Ireland and Wales.
- 1.75 **"TUPE Regulations"** means the Transfer of Undertakings Protection of Employment Regulations 2006 (as amended, re-enacted or extended from time to time) and any successor legislation having equivalent effect following the exit of the United Kingdom from the European Union.
- 1.76 **"Unit Price"** means the cost incurred by the RPSGB for each BNF Volume printed as part of the Supply as set out in Annex 4.
- 1.77 **"Year"** means the period of 12 months starting on the Commencement Date and each succeeding 12-month period thereafter.

- 1.78 In this Agreement all references to any statute or statutory provision shall be deemed to include references to any statute or statutory provision which amends, extends, consolidates or replaces the same and shall include any orders, regulations, codes of practice, instruments or other subordinate legislation made there under and any conditions attaching thereto. Moreover, where relevant, references to English statutes and statutory provisions shall be construed as references also to equivalent statutes, statutory provisions and rules of law in other jurisdictions.
- 1.79 Any headings to Clauses, together with the front cover and the contents pages are for convenience only and shall not affect the meaning of the terms and conditions of this Agreement. Unless the contrary is stated references to Clauses shall mean the clauses of this Agreement.
- 1.80 Unless otherwise expressly defined in this Agreement, the words used in this Agreement shall bear their natural meaning.
- 1.81 Where a term of this Agreement provides for a list of items following the word "including" or "includes" then such list is not to be interpreted as being an exhaustive list. Any such list shall not be treated as excluding any item which might have been included in such list having regard to the context of the contractual term in question. The ejusdem generis principle is not to be applied when interpreting the terms and conditions of this Agreement. General words are not to be given a restrictive meaning where they are followed by examples intended to be included within the general words.
- 1.82 In this Agreement, words importing any particular gender include all other genders.
- 1.83 In this Agreement, words importing the singular only shall include the plural and vice versa.
- 1.84 Subject to the contrary being stated expressly or implied from the context in this Agreement, all communication between the Parties (or with or by a Consortium Party) shall be in writing.
- 1.85 All monetary amounts are expressed in pounds sterling but in the event that pounds sterling is replaced as legal tender in the United Kingdom by a different currency then all monetary amounts shall be converted into such other currency at the rate prevailing on the date such other currency first became legal tender in the United Kingdom.
- 1.86 Except where an express provision of this Agreement states the contrary, each and every obligation of a Party (or a Consortium Party) under the terms and conditions of this Agreement is to be performed at that Party's cost.
- 1.87 Any reference to a Party (or a Consortium Party) "procuring" another person to act or omit to act in a certain manner shall mean that the Party so procuring shall be liable for any default on the part of the person acting or omitting to act in that manner.
- 1.88 All references to the Agreement include (subject to all relevant approvals) a reference to the Agreement as amended, supplemented, substituted, novated or assigned from time to time.
- 1.89 If at any time the Contractor (or a Consortium Party) becomes aware of any act or omission or any proposed act or omission by NICE or by any member, official or employee of NICE which prevents or hinders or may prevent or hinder the Contractor (or a Consortium Party) from performing the Services or the Supply in accordance with the Agreement then the Contractor shall immediately inform the Authorised Officer of

that fact. For the avoidance of doubt, the Contractor's compliance with this Clause shall not in any way relieve the Contractor (or a Consortium Party) of any of its obligations under this Agreement.

2 AGREEMENT AND PRICE

2.1 In consideration of NICE agreeing to pay the Agreement Price to the Contractor in accordance with the terms of this Agreement the Contractor undertakes, with effect from the Commencement Date, to:-

2.1.1 perform the Services in accordance with the provisions of Clause 3 and Annex 1;

2.1.2 make the Supply in accordance with the provisions of this Agreement.

2.2 In the absence of agreement by the Parties to the contrary, the obligation to deliver the Services, and the Supply is not severable and the Contractor must deliver all.

2.3 The Agreement Price is:

2.3.1 inclusive of all taxes, duties, expenses and disbursements save for VAT (if applicable);

2.3.2 fixed in respect of the Services Fee, save for the provisions of clauses 2.5, 2.6, 21 and 37 and the mutually agreed Annual Business Plans. For the avoidance of doubt, the BNF Volumes Fee will be variable and dependent on the Unit Price as set out in the Specification and notified to NICE from time to time;

2.3.3 includes the costs of all equipment, materials and training supplied by the Contractor, all travelling expenses involved;

2.3.4 includes all royalties, licence fees, equitable remuneration or similar expenses or fees in respect of the making, use or exercise by (a) the Contractor of any Intellectual Property for the purpose of its delivery of the Services and the Supply and its other performance of the Agreement and (b) NICE and any NHS Organisation of the NICE Feed and any Intellectual Property licensed or assigned to any of them hereunder.

2.4 This Agreement shall begin on the Commencement Date and subject to earlier termination in accordance with the terms of this Agreement, end on the twelfth (12th) anniversary of the Commencement Date thereafter.

2.5 During each Review Period, the Parties shall meet to review their relationship including the BNF Volumes Price, the Services Fee recognising the annual increase in cost pressures and any proposed variations as specified in Clause 7.1.

2.6 The Contractor will review the efficiency of the Supply and the Contractor will make annual proposals to establish a set of reasonable improvement criteria and plan with the intention of reducing the overall cost of the Supply through gaining reasonable efficiencies that may be mutually agreed by the Contractor and NICE following reasonable consultation and implemented only following such mutual agreement and variation of this Agreement under the provisions of Clause 21 and where such implementation will not materially prejudice either Party's rights under this Agreement.

- 2.7 NICE agrees to represent and manage all communications and relationships with the devolved administrations of the countries making up the Territory and submit print orders on their behalf.

3 OBLIGATIONS OF THE CONTRACTOR

3.1 BNF Volumes

The Contractor shall deliver the BNF Volumes, in accordance with the terms and Annexes of this Agreement and substantially in accordance with the Specification, by the Delivery Dates, to NICE or to places for delivery at its reasonable direction.

3.2 The NICE Feed

The Contractor shall deliver the NICE Feed in accordance with the terms and Annexes of this Agreement and substantially in accordance with the Specification, from the Commencement Date to NICE and/or to NHS Organisations at its direction.

3.3 BNF Apps

The Contractor shall continue to maintain and provide the BNF App for Android and iOS without charge for the NHS and eligible NHS Users for use for non-commercial purposes within the UK.

3.4 The Services

3.4.1 The Contractor shall carry out the Services:

- (i) in accordance with the terms of this Agreement (including the Annexes);
- (ii) by the Milestones and the respective Delivery Dates;
- (iii) in accordance with all applicable UK and European laws and regulations; and
- (iv) in accordance with the principles set out in the declarations of interests policy of NICE (as amended from time to time)

3.4.2 The Contractor shall use all best endeavours to retain NICE accreditation and produce the BNF in accordance with the methods and processes agreed in the accreditation submission. The processes and methods shall be outlined on a publicly available website. Nothing in this Clause 3.4.2 shall oblige the Contractor to disclose its confidential information or Know-How.

3.4.3 No changes to the Services or the Supply shall be permitted without the written consent of both NICE and the Contractor.

3.4.4 The Contractor will ensure that the Services and Supply will be performed by a group of appropriately experienced, qualified and trained personnel (with reference to relevant stakeholders) with all due skill, care and diligence.

3.4.5 The Contractor shall provide at its own expense all staff, equipment, tools, appliances, materials or items required for the provision of the Services and Supply to the Agreement Standard.

- 3.4.6 The Contractor will promptly notify NICE of any actual or potential problems (including, but not limited to, industrial action and whether or not likely to be a Force Majeure Event) that might affect their ability to provide the Services and Supply.
- 3.4.7 The Contractor will be responsible for providing and maintaining performance of the Services and Supply to the Agreement Standard at all times and will ensure continuity of performance (at no extra cost to NICE) in accordance with the Specification.

3.5 Instructions

- 3.5.1 The Contractor shall comply with the terms of this Agreement and give due consideration to the instructions of the Authorised Officer required to implement its terms. Where the Contractor disagrees with an instruction from the Authorised Officer it shall promptly provide its reasons for doing so.
- 3.5.2 The Contractor shall, where reasonably possible, ensure that all communications with NICE concerning the Services or the Supply shall only be between the Senior Lead and the Authorised Officer.

3.6 Financial Control

- 3.6.1 The Contractor shall keep accurate books, records and accounts in respect of the Services and Supply (in accordance with sound and prudent financial management) and, if requested with reasonable notice in writing by NICE, for the avoidance of doubt these requests will be ad-hoc and not requested more than once per annum, the contractor shall (at NICE's expense) have them certified by a professional firm of auditors, including for the avoidance of doubt:
- (i) The individual job title, and the whole time equivalent employed or contracted by the Contractor or any Consortium Parties;
 - (ii) their hours/days allocated to the Services or the Supply;
 - (iii) The pay costs for hours/days allocated to the Services or the Supply;
 - (iv) all and any amounts invoiced or paid to or by the Contractor or the Consortium Parties relating to the Services and the Supply;
 - (v) the allocation of any overheads by the Consortium Parties and the reasons and justification therefore;
 - (vi) Payments to Connected Parties;
 - (vii) Payments to third parties for use of their Intellectual Property in the BNF Content;
 - (viii) Monies received and licensing details relating to any NHS Organisation.
- 3.6.2 The Contractor shall, if requested in writing by NICE, (at NICE's expense) have the books, records and accounts referred to in 3.6.1 above certified by a professional firm of auditors. Such audit shall take place no more than

once a year and may only relate to the books, records and accounts of the 12 months immediately prior to the audit date or for the previous accounting year, whichever is relevant.

3.6.3 The Contractor shall once per Year permit NICE, at NICE's expense, to inspect and take electronic copies of any books, records and accounts that NICE may require in relation to this Agreement including those referred to in Clause 3.6.1 above.

3.6.4 For the purpose of:

- (a) the examination and certification of NICE's accounts; or
- (b) any examination pursuant to section 6(1) of the National Audit Act 1983 of the economy, efficiency and effectiveness with which NICE has used its resources;

the Comptroller and Auditor General and NICE or its auditors may examine documents which relate to this Agreement, but no more than once in any financial year, which are owned, held or otherwise within the control of the Contractor and may require the Contractor to produce such oral or written explanation as he considers necessary. For the avoidance of doubt it is hereby declared that the carrying out of an examination under Section 6(3)(b) or (d) of the National Audit Act 1983 or any re-enactment thereof in relation to the Contractor is not a function exercisable under this Agreement.

3.7 Communication between NICE and Contractor

- 3.7.1 Each Party shall ensure, where reasonably possible, that all communications between the Contractor and NICE concerning the Services and Supply shall only be between the nominated representatives of both Parties, that is, the Authorised Officer, and the Senior Lead.
- 3.7.2 Each Party shall ensure that all communications from the other Party are acknowledged within 5 working days of receipt of the communication.
- 3.7.3 The Contractor shall attend meetings at the request of NICE when NICE, acting reasonably, considers it appropriate.

3.8 Governance

- 3.8.1 Each Year the Contractor shall invite a representative of NICE to attend in an observer capacity up to four meetings (total) of the governance boards established by the Consortium known as the BNF Board and the Paediatric Publications Board. Such representative shall only be entitled to attend those sections of the meetings that relate to management of this Agreement and the content of the meetings shall be Confidential Information and shall not be disclosable by NICE under Clause 14.2 of this Agreement. The representative of NICE nominated to attend such meetings shall not be entitled to receive other Confidential Information pertaining to the same meetings.

3.9 Data Protection, Laws and Regulations

- 3.9.1 Each Party shall comply and shall (at its own expense unless expressly agreed otherwise) ensure that in the performance of its duties under this Agreement, its employees, agents and representatives will comply with all applicable laws and regulations, including Data Protection Laws, health and safety, employment and environmental legislation as in force and applicable, provided that neither Party shall be liable for any breach of this Clause 3.9.1 to the extent that such breach is directly caused or contributed to by any breach of this Agreement by the other Party (or its employees, agents and representatives).
- 3.9.2 Each Party agrees that, it is an independent Controller and determines by itself the purpose and means of Processing of any Personal Data in relation to the Services and Supply and to this Agreement, and that neither Party processes any Personal Data on behalf of the other Party in relation to this Agreement.
- 3.9.3 Without prejudice to the Party's obligation under Clause 3.9.1, the following will apply in relation to Processing of any Personal Data in relation to this Agreement:
- (i) The Parties will only share the Personal Data to the extent it is necessary for the purpose of performance or exercise of this Agreement,
 - (ii) Each Party must ensure it complies with Data Protection Laws in relation to its Processing of the Personal Data;
 - (iii) Each Party shall ensure that it processes the Personal Data fairly and lawfully and ensure that it has legitimate grounds under the Data Protection Laws for the Processing of the Personal Data;
 - (iv) In relation to any Personal Data that is shared by the Parties pursuant to this Agreement, each Party agrees to provide such assistance as is reasonably required to enable the other Party to comply with requests from the relevant Data Subjects to exercise their rights under the Data Protection Laws within the time limits imposed by it;
 - (v) Each Party undertake to have in place throughout the Agreement Period appropriate technical and organisational security measures to:
 - (A) prevent unauthorised or unlawful Processing of the Personal Data; and
 - (B) prevent the accidental loss or destruction of, or damage to, the Personal Data
 - (C) ensure a level of security appropriate to:
 - 1) the harm that might result from such unauthorised or unlawful processing or accidental loss, destruction or damage; and
 - 2) the nature of the Personal Data to be protected.
 - (vi) The Parties shall each comply with its obligation to report a Personal Data Breach in relation to the subject matter of this Agreement to the

appropriate Supervisory Authority and (where applicable) Data Subjects under Article 33 and Article 34 of the UK GDPR.

- (vii) The Parties agree to provide reasonable assistance as is necessary to each other to facilitate the handling of any Personal Data Breach in relation to the subject matter of this Agreement in an expeditious and compliant manner.

- 3.9.4 Each Party shall use their reasonable endeavours to ensure that its employees or agents and/or sub-contractors shall, at all times, act in a way which is compatible with the Convention rights within the meaning of Section 1 of the Human Rights Act 1998.
- 3.9.5 The Contractor and each Consortium Party shall use all reasonable endeavours to assist NICE to comply with such obligations as are imposed on NICE by the Code of Openness in the NHS and the Freedom of Information Act 2000 ("FOIA") including providing NICE with reasonable assistance in complying with any Request For Information served on NICE under the FOIA. NICE shall use all reasonable endeavours to assist the Contractor and each Consortium Party as the case may be to comply with such obligations as are imposed on them by the FOIA including providing the Contractor and/or the relevant Consortium Party with reasonable assistance in complying with any Request for Information served on them under the FOIA. In this Clause 3.9.5 "Request For Information" shall have the meaning given in the FOIA.
- 3.9.6 The Contractor shall neither be relieved of its obligations to perform the Services and make the Supply in accordance with the terms of this Agreement nor be entitled to an increase in the charges as the result of:
 - (i) a General Change in Law where the effect of that General Change in Law on the Services is known or reasonably able to be anticipated at the Commencement Date; or
 - (ii) a Specific Change in Law where the effect of that Specific Change in Law on the Services is known or reasonably able to be anticipated at the Commencement Date.
- 3.9.7 If a Specific Change in Law occurs or will occur during the Agreement Period the Contractor shall notify NICE of the likely effects on it of that change, including:
 - (i) whether any Change would be recommended to the Services or the Supply or this Agreement; and
 - (ii) whether such change is a Force Majeure Event whereby there is likely to be non-compliance with the Contractor's obligations, including any obligation to achieve any Milestones or to meet any service level requirements at any time.
- 3.9.8 As soon as practicable after any notification in accordance with Clause 3.9.7 the Parties shall discuss and agree the matters referred to in that Clause and any ways in which the Contractor can mitigate the effect of the Specific Change of Law, including:

- (i) providing evidence that the Contractor has minimised any increase in costs or maximised any reduction in costs, including in respect of the costs of its subcontractors;
- (ii) demonstrating that a foreseeable Specific Change in Law had been taken into account by the Contractor before it occurred;
- (iii) giving evidence as to how the Specific Change in Law has affected the cost of providing the Services; and
- (iv) demonstrating that any expenditure that has been avoided has been taken into account in amending the Agreement Price.

3.9.9 The Parties shall then consider, at that time, the total cost of the Contractor of providing the Services and the Supply and whether such aggregate cost has exceptionally increased from the figures, staffing and costings on which the Contractor based the Agreement Price as at the Commencement Date and whether there are areas where any of its other figures, staffing and costings have decreased in the meantime. Any relief from the Contractor's obligations which may exceptionally be agreed by the Parties pursuant to this Clause 3.9.7 shall be implemented in accordance with Clause 377.

4 RESOURCES

- 4.1 Subject to Clauses 2.5 and 2.6, 21 and 37 and the mutually agreed Annual Business Plan the Services Fee is fixed, save where any agreed variation is effected in accordance with Clause 37, and includes payment in full for the provision of the Services and all facilities and resources required by the Contractor to perform the Services in accordance with the Agreement.
- 4.2 The Contractor warrants that it has carefully and diligently assessed, in accordance with industry-standard methodologies the resources needed for the Services and the Supply to the Agreement Standard. The Contractor confirms its satisfaction of its abilities and experience in all respects to perform the Services pursuant to the Agreement to the quality standards as set out in this agreement.
- 4.3 The Contractor shall provide the first submission of an Annual Business Plan as detailed in Annex 6, no later than 31 October in each year for review by NICE. Final agreement of the Annual Business Plan shall be no later than 31 March the following year. Once the Annual Business Plan is approved by NICE it shall be deemed to be incorporated to the relevant annexes and so become part of this agreement.

5 DELIVERABLES

- 5.1 Wherever the Services and Supply or the Specification require the Contractor to provide a Deliverable:
 - 5.1.1 such Deliverable will be delivered in the form and medium prescribed and in accordance with the Specification and any relevant Variation of Agreement. If no such form and medium is prescribed in the Specification, the Contractor will provide Deliverables in the form and medium reasonably agreed between the Parties and within a reasonable timeframe. Any electronic documents or data sent to NICE by the Contractor pursuant to this Agreement shall be in open document format (PDF) format (or such other format as NICE may specify from time to time);

- 5.1.2 NICE may accept such Deliverable or reject it in its reasonable discretion on the grounds that such Deliverable does not (in whole or in part) meet the brief set out in the Specification or the Agreement Standard. Such acceptance or rejection must be confirmed to the Contractor within the timescale specified within the relevant Annex or, where the relevant Annex is silent, within 14 days of delivery to NICE;
- 5.1.3 NICE will not reject any Deliverable (wholly or in part) without providing written reasons to the Contractor as to why such Deliverable has been rejected;
- 5.1.4 any dispute as to whether NICE has exercised such right to reject any Deliverable shall be resolved by the Dispute Resolution Procedure; and
- 5.1.5 any Deliverables which are rejected as to form or medium shall be replaced by the Contractor (at no extra charge to NICE) by Deliverables which conform to this Agreement.

Delivery of BNF Volumes

- 5.1.6 Unless otherwise stated in the Specification, where any physical goods are delivered by the Contractor to NICE, the point of delivery shall be when the physical goods are removed from the transporting vehicle, or other appropriate method of delivery, at such address as NICE may have notified the Contractor in writing shall be the place of delivery. Where the physical goods are collected by NICE, the point of delivery shall be when the physical goods are loaded on NICE's vehicle or other appropriate method of delivery.
- 5.1.7 Except where otherwise provided in the Agreement, delivery shall not have taken place until the BNF Volumes have arrived at such place as NICE shall reasonably direct.
- 5.1.8 Delivery shall be in compliance with any given delivery instructions supplied by NICE and updated from time to time.
- 5.1.9 Where any access to NICE's premises or such place as NICE shall reasonably direct is necessary for delivery or installation, the Contractor and the Contractor's sub-contractors or suppliers shall at all times comply with the reasonable requirements of NICE's delivery and security procedures.

Delivery of Electronic Goods

- 5.1.10 Unless otherwise stated in the Specification, where the NICE Feed (or other Deliverables in electronic form except the BNF App) are delivered by the Contractor, the point of delivery shall be when, if delivered on physical media, such media are delivered in accordance with 5.1 above, or if transmitted electronically when a complete, uncorrupted and intact file is received on NICE's servers.
- 5.2 The Contractor warrants that the information, content and data in each Deliverable and in the BNF Content is accurate, complete according to the specifications in Annex 1 and Annex 2 and not misleading and accords with the Specification as set out in Annex 1 as at the date upon which it was sent to the Contractor's printers for printing and that none of the same contains any data, content or statement which gives rise to any

liability on the part of NICE following publication of the same or use by them in accordance with this Agreement.

- 5.3 In the event that the Contractor becomes aware that any information, content and data contained in any Deliverable ceases to be accurate during the Agreement Period, the Contractor shall promptly notify NICE in writing of the same and deliver, by no later than the next scheduled update of the BNF Content or the relevant Deliverable, any modification or addition to remedy any such inaccuracy or omission in the same.

6 QUALITY ASSURANCE AND AUDIT

- 6.1 In addition to any more specific obligations imposed by the terms of the Agreement, it shall be the duty of the Contractor to perform the Services and Supply to the Agreement Standard.
- 6.2 The Contractor shall institute and maintain a properly documented system of quality control in its performance of its obligations hereunder and its carrying out of the Services and making of the Supply.
- 6.3 In addition to any other rights of NICE under the Agreement, the Authorised Officer shall be entitled to inspect the Contractor's quality control system referred to in Clause 6.2 above as set out in Clause 7.10.
- 6.4 During the Agreement Period, the Authorised Officer (or, subject to their entering into confidentiality obligations, an agent or consultant at his or her direction) may, inspect and examine the performance of the Services and Supply being carried out by the Contractor as set out in Clause 7.10.
- 6.5 The Contractor and each of the Consortium Parties shall allow NICE and any person, firm or organisation authorised by NICE to have access to and to audit all records maintained by them in relation to the performance of the Services and the making of the Supply. The Contractor and each of the Consortium Parties shall assist NICE or any party authorised by NICE (as the case may be) in the conduct of the audit as set out in Clause 7.10.
- 6.6 If any part of the Services is found to be Defective or different in any way from the Specification (as may be varied in accordance with Clause 21.1) or otherwise has not been provided to the Agreement Standard, other than as a result of a default or negligence on the part of NICE), on reasonable notice of the default from NICE, the Contractor shall at its own expense re-perform, the part of the Services in question (without additional remuneration therefore) within such time as NICE may reasonably specify. Any such notice shall not affect or limit NICE's rights under the provisions of Clause 244 hereunder or otherwise in respect of the same default nor shall exercise of rights under this clause be any waiver of its rights under such other provisions.
- 6.7 If the performance of the Services by the Contractor is delayed by reason of any act or contractual default on the part of NICE the Contractor shall be allowed a reasonable extension of time for completion of the Services and Supply so affected.
- 6.8 The Contractor will provide a regular report to NICE, as described in 7.7.2, of uptake of the NICE Feed
- 6.9 The Contractor shall provide an Annual Business Plan with KPIs for NICE's approval. The approved Annual Business Plan shall set the Deliverables for the period to which the plan relates.

7 MONITORING AND REVIEW

7.1 Fourth Year Review Period Contract Review Meetings

7.1.1 In respect of this Agreement, as specified in Clause 2.5 a formal minuted contract review meeting will be held every four years during each Review Period under this Agreement to agree any necessary action or change to address areas of dissatisfaction. Unless NICE indicates to the contrary, this review meeting shall be chaired by the Authorised Officer (or their nominee). The Contractor will not unreasonably obstruct or withhold its agreement to any such necessary action and will take all agreed actions or steps within the timescales reasonably agreed between both Parties or, if no timescales are specified, within a reasonable time.

7.1.2 The contract review under Clause 7.1.1 shall take place at NICE's offices or by virtual meeting as communicated by NICE.

7.2 Quarterly Contract Review Meetings

7.2.1 The Contractor shall attend formal, minuted quarterly review meetings (each such meeting being a "**Quarterly Review**"), as required by the Authorised Officer, to discuss NICE's levels of satisfaction in respect of the Services and Supply, compliance with the Agreement (including for the avoidance of doubt the Annexes) and to agree any necessary action to address areas of dissatisfaction. Unless NICE indicates to the contrary, these Quarterly Review meetings shall be chaired by the Authorised Officer (or their nominee). The Contractor will not obstruct or withhold its agreement to any such necessary action and will take all agreed actions or steps within the timescales reasonably specified by NICE or, if no timescales are specified, within a reasonable time. Such Quarterly Reviews shall take place at least quarterly (or more frequently if NICE requires).

7.2.2 The timings of each Quarterly Review meeting, in accordance with Clause 7.2.1 are scheduled as:

- July
- October:
- January
- April

7.3 A health service representative from each of England, Wales, Scotland and Northern Ireland approved by NICE shall be invited to attend at least one of the Quarterly Review meetings as detailed in 7.2, in any given year.

7.4 The Contractor will create internal administrative mechanisms to manage the delivery of the Services and the Supply and compliance with the Agreement. The Contractor will report to NICE (in the form as set out in Annex 7) on the progress of the Services and the origination, publication and delivery of the Supply and the identification and management of risks (financial, regulatory or otherwise) arising from or relating to the Services and Supply (including any sub-contracting arrangements).

- 7.5 The Quarterly Review shall be hosted by NICE either at NICE's offices or by virtual meeting as communicated by NICE. The Quarterly Review shall be attended by representatives of NICE and the Contractor as set out in Annex 7.
- 7.6 NICE shall monitor the provision of the Services and Supply in the form and manner and to the extent it determines. To assist in this, the Contractor shall prepare the Monitoring Report. The Monitoring Report will be updated and presented in good time for each quarterly Review meeting. The Contractor will forward to NICE an updated version of the Monitoring Report no less than two weeks prior to each Quarterly Review meeting.
- 7.7 The Monitoring Report shall follow the forms as set out in Annex 7 but in summary it shall include:
- 7.7.1 a detailed report on the progress of the Services and Supply;
 - 7.7.2 a report on the supply of the NICE Feed directly from the Contractor to the NHS this includes any direct usage of the BNF Content by the NHS (e.g. local formularies for specific trusts) from the Contractor to the NHS entity
 - 7.7.3 a report on the uptake and usage of BNF App
 - 7.7.4 a summary of the issues discussed at previous review meetings and any related actions taken by the Contractor;
 - 7.7.5 the Contractor's adherence to the timetable (if any) as set out in the Specification and the Milestones);
 - 7.7.6 detailed finances from the Contractor in relation to the Services and Supply for the period covered by the Monitoring Report;
 - 7.7.7 the risk register (which must be maintained by the Contractor) detailing all risks identified by the Consortium Parties and details of how these were, or are to be, handled; and
 - 7.7.8 Key Performance Indicator (KPI) report, containing the data for KPI achievement in Annex 7
 - 7.7.9 a summary of any actions and decisions taken by the Contractor in relation to the Services and Supply which were not contemplated in the preparation of the Milestones.

None of the reporting specified in this clause 7.7 shall include Personal Data.

- 7.8 Both Parties acknowledge that, subject to Clause 8.2, the submission and acceptance of such Monitoring Reports shall not prejudice nor be a waiver of any other rights or remedies of either Party under the Agreement nor shall the viewing of such progress reports or the hearing of verbal reports mean that either Party has accepted any variation to this Agreement or the Specification or waived any breach.
- 7.9 Additional ad-hoc reports may from time to time be required by NICE, the production time for these will be agreed with the Contractor as they occur. The Contractor shall

provide information in a format, medium and at times specified by NICE, relating to the performance of the Services and Supply as NICE may reasonably require.

- 7.10 Where this Agreement provides that a Party ("**Inspecting Party**") shall have the right to audit the other Party's ("**Audited Party**") compliance with this Agreement, the following provisions shall apply: -

- 7.10.1 The Inspecting Party must give the Audited Party reasonable notice of not less than 30 days of the proposed intention to audit any aspect of this Agreement;
- 7.10.2 Any right to audit specified in this Agreement may not be exercised more than once in any 12 month period.
- 7.10.3 The Audited Party shall provide to the Inspecting Party or its Authorised Officer/Senior Lead such reasonable facilities (including, access to any staff or personnel involved in the delivery of the Services or the performance of this Agreement) as the Inspecting Party may require for such inspection and examination and shall notify the Inspecting Party in advance of any policies that the Inspecting Party, its Authorised Officer/Senior Lead, and its contractors and other authorised representatives must comply with during the audit;
- 7.10.4 The Audited Party shall provide to the Inspecting Party or its Authorised Officer/Senior Lead only such information as is strictly relevant to the right of audit that arises under this Agreement and is necessary to determine the Audited Party's compliance with the obligations in this Agreement that are subject to such rights of audit;
- 7.10.5 All audit shall be subject to the obligations of confidentiality set out in this Agreement, and the Inspecting Party shall ensure that its Authorised Officer/Senior Lead, all contractors and authorised representatives engaged by the Inspecting Party for the purposes of carrying out such audits shall be subject to obligations of confidentiality equivalent to those imposed on the Inspecting Party in this Agreement;

8 PAYMENT

- 8.1 The only sums payable by NICE to the Contractor for the performance of the Services and Supply each in accordance with the timescales and other requirements of this Agreement shall be the Agreement Price (paid in accordance with Annexes 8 and 4) which for the avoidance of doubt is only payable to RPSGB. Subject to Clause 2.3.2, 2.5, 2.6, 21 and 37, such price is a fixed price and the disclosure, inspection and sharing of financial, resource and staffing information such as pursuant to the provisions of Clauses 3.6, 4.34.3, 6, 7 and Annexes 6 and 7 are principally for NICE to be alert to issues arising, for it to understand the processes and Costs involved and for it to understand better whether it is securing best value for money. All Costs, charges, fees and expenses of whatever kind arising out of or in connection with the Agreement shall be the responsibility of the Contractor.

- 8.2 In consideration of performance by the Contractor of its obligations under this agreement all sums due under this Agreement shall be paid by NICE to RPSGB in accordance with Annex 8 subject to (a) the receipt of an invoice, and (b) receipt by NICE of the Monitoring Reports, and (c) a copy of the minutes or report of each of the Quarterly Review meeting for the immediately preceding quarter, as appropriate.
- 8.3 RPSGB shall send all invoices to National Institute for Health and Care Excellence, (Shared Business Services), [REDACTED], quoting the agreement number, the period to which the invoice relates and the services provided by the Contractor together with any other details that NICE may require.
- 8.4 Subject to the due and timely performance of the Contractor's obligations under this Agreement (including, for the avoidance of doubt, Clauses 8.2 above and 8.5, 8.7 and 8.8 below) NICE will pay all invoices (by BACS or such other method that may be agreed) submitted by RPSGB in accordance with Annex 8 within 30 days of their receipt.
- 8.5 Invoices sent to NICE shall be accurate and correct in all material respects. Furthermore all invoices for BNF Volumes shall include a breakdown of all costs involved in printing, copies of invoices for each of these elements, unit cost and how the unit cost was calculated.
- 8.6 Invoices sent to NICE must be from RPSGB.
- 8.7 NICE reserves the right to withhold payment of invoices in relation to the portion of Services or Supply not delivered, in whole or in part, until the Services and Supply (and/or any Deliverables to which any invoices relate), in whole or in part is successfully concluded, completed and/or delivered to the satisfaction of NICE (acting reasonably). Any payments withheld will relate to only that portion of supply or Deliverables in question and not as a whole.
- 8.8 If NICE has a genuine and bona fide reason to dispute any invoice:
- 8.8.1 it shall notify RPSGB within ten Working Days of receipt of such invoice, such notice specifying in reasonable detail the reason for the dispute;
 - 8.8.2 save for any reasons stated in or notice so given the invoice shall be deemed to be undisputed and agreed by NICE;
 - 8.8.3 each Party shall use its reasonable endeavours in good faith to resolve a dispute concerning any invoice;
- 8.9 NICE shall pay the undisputed amount of such invoice in accordance with the credit terms provided for in this Agreement.
- 8.10 If NICE for any reason other than breach of this Agreement by the Contractor or genuine and bona fide dispute under Clause 8.8 fails to make any payment under this Agreement (other than a payment which is the subject of Clause 8.7) on the due date then, without prejudice to any other right or remedy available to the Contractor or any Consortium Party, the Contractor shall be entitled to suspend further performance of all or any of the Services and refuse any purchase orders for BNF Volumes until payment is received.

- 8.11 NICE shall be entitled to deduct from any monies due or to become due to the RPS any monies owing to NICE from RPSGB under this Agreement.
- 8.12 In the event that the Agreement is varied under Clause 21 in such a way as to affect the Agreement Price and if agreement between the Parties cannot be reached on the adjustment to the Agreement Price within 3 months both Parties shall jointly act to resolve the dispute in accordance with Clause 22.
- 8.13 If the adjusted Agreement Price is not so agreed or certified until after such variation has taken effect, NICE shall continue to pay RPSGB at the rate current prior to the variation. RPSGB shall be entitled to recover from NICE and NICE shall be entitled to recover from RPSGB as the case may be such sum if any as is equal to the difference between the amount which should have been paid in accordance with the adjusted Agreement Price and the amount which was actually paid.
- 8.14 Subject to Clauses 8.7 and 8.8 in the event of non-payment of the undisputed monies due under this Agreement, the Contractor shall be entitled to suspend access to digital content licensed under Clause 11 and suspend the Supply and performance of the Services.

9 STAFF AND RESOURCES

- 9.1 The Contractor and each Consortium Party shall be fully responsible in every way for the employment and conditions of service of all their respective staff and all consultants (whether part-time or full-time).
- 9.2 The Contractor and each Consortium Party shall exercise equal opportunity policies in its employment of staff and consultants.
- 9.3 The Contractor will use all reasonable endeavours to employ sufficient employees to ensure that all parts of the Services and Supply are performed at all times and in all respects in complete conformity with the Specification. In relation to the Services and Supply, the Contractor will employ only such persons as are careful, skilled and experienced in the duties required of them, and will ensure that every such person is properly and sufficiently trained and instructed (at the Contractor's expense).
- 9.4 The Contractor shall ensure that it and each Consortium Party complies with all current employment legislation and in particular, does not unlawfully discriminate within the meaning of the Equality Act 2010, the Employment Equality (Sex Discrimination) Regulations 2005, or any other relevant legislation relating to discrimination in the employment of employees for the purpose of providing the Services. The Contractor shall take all reasonable steps (at its own expense) to ensure that any employees employed in the provision of the Services do not knowingly unlawfully discriminate within the meaning of this Clause 9.4 and shall impose on any sub-contractor obligations substantially similar to those imposed on the Contractor by this Clause 9.4.
- 9.5 The Contractor and each Consortium Party shall procure that all potential staff or persons, party to this contract, performing any of the Services and Supply during the Agreement Period who may reasonably be expected in the course of their employment or engagement to have access to children or other vulnerable persons and/or access to persons receiving healthcare services:
- 9.5.1 are questioned concerning their Convictions; and

- 9.5.2 only in the case of potential staff who may reasonably be expected in the course of their employment to have access to children or other vulnerable persons, obtain appropriate disclosures from the Disclosure and Barring Service (or other appropriate body) before the Contractor and each Consortium Party as the case may be engages the potential staff or persons in the provision of the Services and Supply to NICE.
- 9.5.3 The Contractor shall procure that no person who discloses any Convictions upon being questioned about their Convictions in accordance with Clause 9.5.1, or who is found to have any Convictions following receipt of appropriate disclosures from the Disclosure and Barring Service (or other appropriate body) in accordance with Clause 9.5.2, or who fails to obtain standard and enhanced disclosures from the Disclosure and Barring Service (or other appropriate body) upon request by the Contractor in accordance with Clause 9.5.2 is employed by the Contractor or any Consortium Party without NICE's prior written consent.
- 9.6 The Contractor shall procure that NICE is kept advised at all times of any member of staff who is working on or in relation to the Services and Supply who, subsequent to his/her commencement of employment as a member of staff receives a Conviction or whose previous Convictions become known to NICE.
- 9.7 It is the joint responsibility of the Contractor and its employees to ensure that the employees supplied to carry out the Services and Supply have not worked excessive hours which could prejudice the standards of service. In accordance with the Working Time Regulations 2003 it is the responsibility of the Contractor to keep records of hours worked for each employee, inclusive on any such waiver agreed by the individual employee.

10 COPYRIGHT AND INTELLECTUAL PROPERTY

- 10.1 NICE acknowledges and agrees that Intellectual Property in and to the BNF Volumes, BNF Publications, BNF Content, NICE BNF and the NICE Feed and the BNF App, are and shall remain owned by the Contractor, including without limitation the following:
- 10.1.1 The marks 'BNF' and 'British National Formulary'
- 10.1.2 The logos for BNF Publications;
- 10.1.3 In respect of each edition of the BNF Publications:
- (i) Copyright in the structure and chapter headings (the "BNF Hierarchy")
 - (ii) Copyright in each entry
 - (iii) Copyright in each BNF Publication and BNF Volume as a compilation;
 - (iv) Copyright in each BNF Publication and BNF Volume as a database;
 - (v) Database right in each BNF Publication and BNF Volume as a database;
 - (vi) Copyright in each BNF Volume as a typographical arrangement of a

published edition;

(vii) Copyright in the NICE Feed;

10.1.4 For the avoidance of doubt, this is without prejudice to the ownership of IPR in any Source Material which shall be owned by the respective owner of the IPR in such Source Material.

10.2 NICE retains copyright and database right in and to its published and unpublished research findings, reports, recommendations, commentaries, clinical guidelines and other Source Material created by NICE;

10.3 NICE retains copyright and database right in and to its annual evidence updates, its software, databases, commentaries, data and research collections and its other Source Material.

11 LICENCE OF THE BNF INTELLECTUAL PROPERTY

Licence

11.1 In consideration of the mutual covenants and undertakings provided for herein and in accordance with the terms and conditions set forth herein, the Contractor hereby grants to NICE and thereby to the NHS a non-exclusive, non-transferable, non-sub licensable licence, limited in each case to use in the Territory for non-commercial purposes to:

11.1.1 use the BNF Intellectual Property for the purpose of exercising the rights granted in this Clause 11.1, for the duration of this Agreement;

11.1.2 be entitled to place the NICE BNF on the NICE website, hosted in the UK in the English language, intended only for use by NHS Users and members of the public within the UK and forbidding access to the NICE BNF to users with an IP address outside the UK;

11.1.3 store the content and data comprised within the NICE BNF and NICE Feed on the NICE Computer Network and on the Computer Networks of the NHS Organisations

11.1.4 permit NHS Users to access of the BNF Publications via the NICE BNF, and download, store and use the same on Portable Devices for non-commercial purposes

11.1.5 permit and enable NHS Users to access and use BNF Content through the BNF App for non-commercial purposes;

11.1.6 (if requested by an NHS Organisation) link to and display within NICE Guidance syndicated to such NHS Organisation for non-commercial purposes and without charge, (only) those parts of the BNF Content, NICE Feed or NICE BNF data, that are included or referred to in the relevant NICE Guidance and provided always that such syndication shall be for NHS Users only and shall preclude any commercial use of BNF Content

11.2 The licence granted under Clause 11.1 above shall not be interpreted as including Computerised Decision Support by the Contractor and NICE shall not be entitled to use the BNF Intellectual Property to create Computerised Decision Support content.

For the avoidance of doubt this does not prevent NICE from providing links from NICE to the NICE BNF, as described in 11.1.2.

NHS use reporting

- 11.3 The Contractor undertakes to inform NICE of the intention to grant any licence for digital access to the BNF Content in the NICE Feed to any NHS Organisations, as provided for under the terms of this Agreement.

11.3.1 NICE will refer to the Contractor all applications for BNF Content that it receives.

BNF Content to the BNF App and NHS Organisations

- 11.4 The Parties agree that:

11.4.1 The Contractor shall allow access without applying a charge to and use of all BNF Content through the BNF App to individuals in the Territory for non-commercial purposes;

11.4.2 At NICE's request the Contractor shall freely provide syndication services to the NHS to allow NHS Users to access receive and view the NICE Feed and download information, data, search results and other text material from it for non-commercial purposes without charge in accordance with the terms of this agreement;

11.4.3 The Contractor will consider applications from the NHS for syndication of customised (to the NHS Organisation) NICE Feed to any NHS Organisation. The Contractor may recover the cost, as agreed with the NHS Organisation, of such customisation to the NICE Feed; and

11.4.4 The syndication services in Clause 11.4.2 will be provided within 3 months of agreement of the request by the Contractor

11.4.5 For the avoidance of doubt where one NHS Organisation provides a non-commercial service to another NHS Organisation that relies upon or includes the BNF Content, both NHS Organisations shall be deemed to be exercising the rights to access BNF Content in accordance with the licence granted in Clause 11.1 of this Agreement, irrespective of which entity supplies the other, provided always that at all times both such NHS Organisations will comply with the licence granted in Clause 11.1 of this Agreement and will prevent transfer of BNF Content to an excluded Organisation.

Contractor Warranties re the BNF Content

- 11.5 The Contractor warrants that in relation to the BNF Content:

11.5.1 it accords with the Specification in all material respects;

11.5.2 It does not infringe any Intellectual Property of any third party;

11.5.3 its publication, communication to the public, and/or use in accordance with the terms of this agreement by NICE, NHS Organisations and their staff, or NHS Users in the Territory, does not infringe any Intellectual Property of any third party;

- 11.5.4 It does not contain anything offensive, obscene, libellous or otherwise unlawful; and
- 11.5.5 All reasonable care has been taken by the Contractor to ensure that all statements and factual information contained within it are true and complete according to the specifications in Annex 1.

Undertakings agreed by NICE in relation to the use of the BNF content

11.6 NICE shall:

- 11.6.1 display the content of the BNF Publications from the NICE Feed in the NICE BNF to preserve the context, clinical safety, sense and intention of the BNF Publications;
- 11.6.2 display the NICE BNF as search specific content made visible by the NICE search engine;
- 11.6.3 not, except to the extent necessary to exercise the rights expressly granted by this Agreement, reproduce, rent, sell, lease, sub-licence, loan to any third party or otherwise exploit, reverse-engineer, translate, modify or create derivative works from the whole or any part of the BNF Content, NICE Feed or NICE BNF;
- 11.6.4 provide quarterly anonymised reports detailing the traffic on the NICE BNF so the Contractor can determine whether unusual download or other usage activity is occurring. In addition, NICE will provide such reports as are reasonably requested by the Contractor in order to plan improvements to the NICE Feed; the quality assurance of the use of the NICE Feed within NICE shall be the responsibility and liability of NICE, except to the extent that any liability originates from the quality of the NICE Feed or the BNF Content as provided by the Contractor; ensure that every page of the content of the NICE BNF is recognisable as such, for example by use of the BNF logo to include a method to display an acknowledgement (for example a link to another page that has the contents of 11.6.4 (i) and (ii) and (iii)) that they are owned by the Contractor which shall also include within the NICE BNF the following acknowledgement/copyright notice or such other notices as the Contractor may require from time to time:
 - (i) In respect of the content from the BNF: “This work is published by the Royal Pharmaceutical Society of Great Britain and BMJ Publishing Group Limited. The professional bodies take full responsibility for the content, and vouch for its independence from Government and the pharmaceutical industry. The work carries the authority of the professions through the BNF Joint Formulary Committee, but does not necessarily reflect the view of any third party distributor of the work.
 - (ii) In respect of the content from the BNF (Children): This work is published by the Royal Pharmaceutical Society of Great Britain, BMJ Publishing Group Limited, the Royal College of Paediatrics and Child Health and the Neonatal and Paediatric Pharmacists Group. The professional bodies take full responsibility for the content, and vouch for its independence from Government and the pharmaceutical industry. The work carries the authority of the

professions through the BNF Paediatric Formulary Committee, but does not necessarily reflect the view of any third party distributor of the work.

- (iii) followed in as appropriate, by:

“All rights reserved. All rights, including copyright and database rights, in this digital version of the BNF/BNF for Children are owned by The Royal Pharmaceutical Society of Great Britain, the Royal College of Paediatrics and Child Health Publications Ltd. and BMJ Publishing Group Limited and are protected under UK and International Law.

No part of these web-pages may be reproduced in any material form (including copying, storing in any medium, including any other website, distributing, transmitting, re-transmitting, broadcasting, modifying or showing in public without the prior written permission of the Royal Pharmaceutical Society of Great Britain, the Royal College of Paediatrics and Child Health Publications Ltd. and BMJ Publishing Group Limited except in accordance with the provisions of the Copyright, Designs and Patents Act 1988.

Warning: The doing of any unauthorised act in relation to a copyright work may result in both a civil claim for damages and criminal prosecution.

© Royal Pharmaceutical Society of Great Britain, the Royal College of Paediatrics and Child Health Publications Ltd. and BMJ Publishing Group Limited [20[XX]]”

Undertakings agreed by NICE in relation to infringement

- 11.7 NICE shall use its reasonable efforts to monitor any infringement, unauthorised uses or misuses (“**Infringement**”) of the BNF Intellectual Property in the Territory and shall promptly notify the Contractor of any such Infringements it discovers. Determination on what action, if any, should be taken regarding such Infringements shall at all times be in the sole discretion of the Contractor.
- 11.8 NICE agrees to use its best efforts and to co-operate with the Contractor, upon the Contractor's request and at the Contractor's reasonable expense, in terminating infringing or unauthorised or wrongful uses of the BNF Intellectual Property and undertakes to furnish any documentary evidence or evidentiary materials which the Contractor may reasonable require, and which NICE can reasonably produce or obtain, for the purpose of terminating such uses.

Management rights

- 11.9 NICE may, having first discussed with and received the prior written consent of, the Contractor:
- 11.9.1 withdraw the BNF Volumes from circulation;
 - 11.9.2 issue error notices or addenda which have been approved by the Contractor;
 - 11.9.3 communicate with users and those in possession of the BNF Volumes;

11.9.4 amend or edit the NICE BNF provided that the Contractor has consented to such amendment or editing;

11.9.5 take such other steps as it deems appropriate,

where it believes that there has been a breach or non-compliance with any matter contained in Clause 11.5 above. The Contractor has the right to carry out any of the actions in Clauses 11.9.1 to 11.9.5 at any time at its sole discretion.

No grant of rights

11.10 For the avoidance of doubt this Agreement does not grant any right or licence to NICE to the websites <http://bnf.org> and the Contractor may grant rights or licenses to such site to any such third party as it chooses.

11.11 NICE agrees that it shall not obtain any right, title or interest in or to the BNF Intellectual Property other than the licences granted to it under Clause 11.1 and that NICE shall not knowingly do or permit anything to be done in its use of the BNF Intellectual Property, which is outside the scope of that licence, or which would or could jeopardise the validity of any such rights.

11.12 NICE acknowledges and agrees that nothing in this Agreement shall prevent the Contractor from providing all or any part of the BNF Content, the NICE Feed or the BNF App to third parties, regardless of whether or not that third party subsequently makes it available to any NHS Organisation or NHS User.

11.13 For the avoidance of doubt, the rights granted under Clause 11 of this Agreement, do not affect the Contractor's ownership of the BNF Intellectual Property

Contractor's licence to use NICE Guideline content

11.14 NICE hereby grants to the Contractor solely for the purposes of BNF Content a United Kingdom only, royalty-free, personal, non-transferable, and non-exclusive licence for the duration of the contract to:

11.14.1 Publish in full or in part, the content within NICE Guidelines

11.15 In all cases provided that:

11.15.1 The Contractor publishes and uses at its own cost; and

11.15.2 The Contractor complies with any relevant obligations of confidentiality, and

11.15.3 When publishing/republishing NICE Guidelines any amendments shall not change the meaning of or distort the meaning of the recommendations within the original work.

12 PUBLICITY

12.1 The Contractor shall provide reasonable assistance to NICE staff in dealing with any media interest on NICE supported Services and Supplies. The Contractor shall use reasonable endeavours to ensure that its suppliers comply with this obligation.

12.2 The Contractor's communications department shall inform the NICE's communications department of any interaction with the media pursuant to this agreement.

13 IDENTIFYING OUTPUTS AS SUPPORTED BY NICE

- 13.1 Unless the Parties agree to the contrary in writing any BNF Volumes, BNF App and any website for the NICE Feed shall acknowledge NICE's relationship with the Contractor under this Agreement and carry a disclaimer in such form as follows:

"This work was undertaken by The Royal Pharmaceutical Society of Great Britain the Royal College of Paediatrics and Child Health Publications Ltd. and BMJ Publishing Group Ltd. The views expressed in this publication are those of the authors. BNF Publications are procured for use in the NHS by the National Institute for Health and Care Excellence (NICE). NICE works in partnership with the BNF Publications to ensure appropriate development of the BNF for the NHS. This has no bearing on the Editorial Independence of the Publisher."

14 PUBLIC REPUTATION OF THE PARTIES

- 14.1 Both Parties recognise the other Party's public reputation and legal responsibilities. Each Party shall use all reasonable endeavours not to harm or compromise these.

- 14.2 The Parties acknowledge that, except for any information which is exempt from disclosure in accordance with the provisions of the FOIA and/or the Data Protection Laws, the content of this Agreement is not Confidential Information to the extent that disclosure of which has been made and is mandatory under FOIA and/or the Data Protection Laws. NICE shall be responsible for determining in its reasonable discretion whether any of the content of the Agreement is exempt from disclosure in accordance with the provisions of the FOIA and/or the Data Protection Law, provided that it acknowledges that any information obtained in respect of meetings attended by NICE under Clause 3.8 hereof shall be confidential information belonging to the Contractor. To the extent NICE is permitted to do so:

14.2.1 it will notify the Contractor as soon as practicable upon becoming aware of any request under FOIA and/or Data Protection Laws to disclose Confidential Information or content of this Agreement. Further NICE will, in good faith, consider the Contractor's representations as to why it considers the requested information to be exempt from disclosure; and

14.2.2 To allow NICE to comply with FOIA, the Contractor shall co-operate with NICE and shall respond within five (5) working days of any request by it for assistance in determining how to respond to a request for disclosure.

14.2.3 co-operate with the Contractor in avoiding or limiting the disclosure and obtaining assurances as to confidentiality from the body or persons to whom the Confidential Information is to be disclosed.

15 CONFIDENTIALITY

- 15.1 Each of (a) NICE and (b) the Contractor and the Consortium Parties, undertakes to the other use its reasonable efforts to keep all Confidential Information secret and strictly confidential and not to disclose such information to any third party without the other's prior written consent provided that:

- 15.1.1 a receiving party shall not be prevented from using any general knowledge, experience or skills which were in its possession prior to the commencement of the Agreement;
- 15.1.2 the provisions of this Clause 155 shall not apply to any Confidential Information which:-
- (i) is in or enters the public domain other than by breach of the Agreement or other act or omissions of the receiving party;
 - (ii) is obtained by a third party who is lawfully authorised to disclose such information; or
 - (iii) is authorised for release by the prior written consent of the supplying party.
 - (iv) is requested and released under the Freedom of Information Act 2000.
- 15.2 Nothing in this Clause 15 shall prevent a party from disclosing Confidential Information to the extent it is required to do so by judicial, governmental or regulatory process in connection with any action, suit, proceedings or claim or otherwise by applicable law, or in the case of NICE to accord to its publication scheme or its reporting requirements within the NHS. NICE shall promptly notify the Contractor in the event it is required to disclose any Confidential Information under this Clause 15.2 and shall minimise such disclosure as far as permitted to do so.
- 15.3 The provisions of this Clause 15 shall continue following termination of the Agreement for any reason whatsoever and without limit in time.

16 GIFTS AND PAYMENTS OF COMMISSION

- 16.1 Neither Contractor nor any Consortium Party (including their respective employees and agents) shall offer or give to any member of staff of NICE or a member of its board or their family any gift or consideration of any kind (including the payment of commission) as an inducement or reward for doing something or not doing something or for having done something or having not done something in relation to the obtaining of or execution of this Agreement or any other agreement with NICE. This prohibition specifically includes the payment of any fee or other consideration for any work, in respect of or in connection with the Services and Supply, carried out by a member of staff of NICE to the Contractor or a Consortium Party or any of their permitted sub-contractors.
- 16.2 Any breach of this Clause 166 by the Contractor or a Consortium Party or anyone employed by them (with or without their knowledge) or the commission of any offence under the Bribery Act 2010 shall entitle NICE to terminate this Agreement immediately and/or to recover from the Contractor any payment made to the Contractor in respect of which the relevant BNF Volumes or NICE Feed have not yet been delivered.

17 ASSIGNMENT

- 17.1 Save under 17.2 below, the Contractor shall not assign the whole or any part of the Agreement.
- 17.2 Either Party (the "Assigning Party") (including each Consortium Party) may transfer, assign or novate this Agreement (or, in the case of each Consortium Party, its interest

as one of the individual corporate bodies constituting the Contractor) to a corporate body or its parent with the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed.

18 SUB-CONTRACTORS

- 18.1 The Contractor shall be permitted to sub-contract the supply of any Services and Supply provided that it shall remain fully liable for the performance of its obligations hereunder by any subcontractor.
- 18.2 Prior to award the Contractor shall provide NICE with a report on all procurement exercises conducted in relation to the appointment of sub-contractors for the Supply of the BNF Volumes only. For the avoidance of doubt, these shall be excluded from the scope of clause 14.2

For the avoidance of doubt this shall not include (i) the contracting arrangements between the parties named in the agreement as the Contractor and (ii) sub-contracting of the Services other than the Supply.

19 INDEMNITY

- 19.1 Neither Party shall be liable to the other Party for any Loss or damage, Costs or expenses incurred or suffered by the other Party as a result of any breach of the terms of the Agreement, unless the same were in the reasonable contemplation of the Parties at the time when they entered into the Agreement.
- 19.2 Subject to Clause 32.10, the Contractor agrees to indemnify and keep indemnified NICE against all claims and proceedings and all liability, Loss, Costs and expenses incurred in connection therewith by them as a result of any claim made or brought by any individual or other legal person in respect of any Loss, damage or distress caused to that individual or other legal person against NICE as a result of the Contractor's unauthorised Processing, unlawful Processing, destruction of and/or damage to any Personal Data processed by it, its employees or agents in the performance of the Agreement
- 19.3 NICE agrees to indemnify and keep indemnified the Contractor and each Consortium Party against all claims and proceedings and all liability, Loss, Costs and expenses incurred in connection therewith by them as a result of any claim made or brought by any individual or other legal person against the Contractor or any of the Consortium Parties in respect of any Loss, damage or distress caused to that individual or other legal person as a result of the NICE's unauthorised Processing, unlawful Processing, destruction of and/or damage to any Personal Data processed by it, its employees or agents in the performance of the Agreement.

20 INSURANCE

- 20.1 The Contractor shall maintain appropriate insurance policies to cover its liabilities to NICE under this Agreement.
- 20.2 The Contractor shall (upon request from NICE) supply a copy of any relevant insurance policy to NICE together with proof of payments of all premiums for the duration of the agreement and for 1 year thereafter.

21 VARIATION OF THE SPECIFICATION

- 21.1 NICE and the Contractor may at any time propose any reasonable variation or addition to the Specification. If such variation is agreed then it shall be recorded in the form of the template variation letter in Annex 5. Any variation is subject to (a) both Parties agreeing the variation and (b) that such variation or addition can be achieved without need for additional funding; or (c) that NICE provides any additional funding reasonably required by the Contractor in respect of such variation or addition. The proposal shall give details of the variation or addition and the date on which it is to take effect.
- 21.2 Both Parties acknowledge that any variation to the volume of BNF Volumes will be addressed in accordance with Annex 4 and subject to the procedure detailed there.

22 DISPUTE RESOLUTION PROCEDURE

- 22.1 During any dispute, including a dispute as to the validity of the Agreement, but subject to Clauses 8.10 and 8.14, it is mutually agreed that the Contractor shall continue its performance of the provisions of the Agreement (unless NICE requests in writing that the Contractor does not do so). Subject to Clause 8.7 during a dispute NICE shall continue its performance of the provisions of the Agreement
- 22.2 If a dispute arises between NICE and the Contractor in relation to any matter which cannot be resolved by the Authorised Officer and the Senior Lead either of them may refer such dispute to the Dispute Resolution Procedure.
- 22.3 In the first instance NICE and the Contractor shall arrange for one representative more senior than those referred to in Clause 22.2 to meet solely in order to resolve the matter in dispute. Such meeting(s) shall be minuted and shall be chaired by NICE (but the chairman shall not have a casting vote). Such meeting(s) shall be conducted in such manner and at such venue (including a meeting conducted over the telephone) as to promote a consensual resolution of the dispute in question at the discretion of the chairman.
- 22.4 If the meeting(s) referred to in Clause 22.3 does not resolve the matter in question then the Parties will attempt to settle it by mediation in accordance with the Centre for Dispute Resolution ("CEDR") Model Mediation Procedure or any other model mediation procedure as agreed by the Parties. To initiate a mediation a Party may give notice in writing (a "Mediation Notice") to the other requesting mediation of the dispute and shall send a copy thereof to CEDR or an equivalent mediation organisation as agreed by the Parties asking them to nominate a mediator. The mediation shall commence within 28 days of the Mediation Notice being served. Neither Party will terminate such mediation until each of them has made its opening presentation and the mediator has met each of them separately for at least one hour. Thereafter paragraph 7 of the Model Mediation Procedure will apply (or the equivalent paragraph of any other model mediation procedure agreed by the Parties). Neither Party to the mediation will commence legal proceedings against the other until 30 days after such mediation of the dispute in question has failed to resolve the dispute. The Parties will co-operate with any person appointed as mediator providing him with such information and other assistance as he shall require and will pay his costs, as he shall determine or in the absence of such determination such costs will be shared equally.

23 ENVIRONMENTAL CONSIDERATIONS

- 23.1 The Contractor shall comply in all material respects with applicable environmental laws and regulations in force from time to time in relation to the Services and Supply. Where

the provisions of any such legislation are implemented by the use of voluntary agreements or codes of practice, the Contractor shall comply with such agreements or codes of practices as if they were incorporated into English law subject to those voluntary agreements being cited in tender documentation.

- 23.2 The Contractor shall meet all reasonable requests by NICE for information evidencing the Contractor's compliance with the provisions of this Clause 23.
- 23.3 When considering environmental impacts of the Services and Supply if all other factors are equal the Contractor will give favour to the process or system which gives greater benefits to the environment.

24 TERMINATION

- 24.1 Either NICE or the Contractor may terminate the Agreement by serving written notice on the other in any of the following circumstances:

- 24.1.1 a failure (in whole or in part) by the other Party to perform any of its material obligations under this Agreement provided that the terminating Party has served written notice of such breach and;

- (i) in respect of the first instance of such breach such failure has not been remedied (if capable of remedy) to the terminating Party's reasonable satisfaction within a period of 90 days following written notice demanding remedy of the failure in question being served by the terminating Party on the other Party; or

- (ii) in respect of a second or repeated instance of such breach, (whether capable of remedy or not) the terminating Party is satisfied, at its reasonable, sole discretion, that the other Party has not taken any steps to remedy or prevent the re-occurrence of such breach within 90 days of such written notice under this Clause 24.1.1

- 24.1.2 the other Party becomes Insolvent; or

- 24.1.3 if there is a change of ownership or control of the other Party which, in the reasonable opinion of the terminating Party will have a material impact on the provision of Services, in which case the terminating party must give at least six (6) months written notice to terminate; or

- 24.1.4 the other Party purports to assign the Agreement in breach of Clause 17; or

- 24.1.5 the other Party shall have offered or given or agreed to give to any person any gift or consideration of any kind as an inducement or reward for doing or forbearing to do, or for having done or forborne to do, any action in relation to the obtaining or execution of the Agreement with the terminating Party, or for showing or forbearing to show favour or disfavour to any person in relation to the Agreement or any other agreement with the terminating Party or similar acts have been done by any person employed by it or acting on its behalf (whether with or without the knowledge of the other Party); or

- 24.1.6 if in relation to the Agreement or any other agreement with the terminating Party, the other Party or any person employed by it or acting on its behalf

shall have committed any offence under the Bribery Act 2010, or shall have given any fee or reward to any officer of the terminating Party which shall have been exacted or accepted by such officer under colour of his office or employment and is otherwise than such officer's proper remuneration,

and in each of the sub-clauses above, reference to the other party or other Party shall in the case of the Contractor means any of (a) the Contractor or (b) any of the Consortium Parties, only to the extent that it results in the Contractor becoming unable to provide the Services or Supply to the Agreement Standard.

- 24.2 Promptly after the point at which notice is served, the Contractor and NICE will have agreed any final outstanding payments due, taking into account that NICE is paying for services in advance.
- 24.3 The Contractor may terminate the Agreement by giving NICE 6 month's written notice if, in the Contractor's reasonable opinion but evidencing the same with a financial report, the payments due to the Contractor under the Agreement are not sufficient for the Contractor to provide the Services and Supply to the standard required in the Agreement.
- 24.4 The Contractor agrees that upon termination for any reason or expiry of the Agreement it shall not be entitled to make a claim against NICE in relation to costs incurred by the Contractor in providing the Services or costs incurred in acquiring equipment and/or materials used in the provision of the Services or in engaging third parties in connection with the Services whether or not such costs were amortised in the calculation of the Agreement Price payable by NICE under the Agreement. For the avoidance of doubt, the Contractor will not thereby be restricted from making any claim for the Agreement Price to the extent the Agreement Price is outstanding and properly due and payable.
- 24.5 Any termination (in whole or in part) of the Agreement will not prejudice the rights, obligations and duties of each Party arising prior to such termination taking effect.
- 24.6 In addition to its rights under any other provision of the Agreement NICE may terminate the Agreement at any time by giving the Contractor six months' written notice if there is any change of government or NHS policy that directly or indirectly affects (or relates to) either the existence, role, objectives, purpose or services of NICE as pertains to this contract, including NICE being the body responsible for procuring the delivery of the Services and/or the BNF Volumes and/or the NICE Feed
- 24.7 Subject to 24.6 NICE may at any time novate this agreement to any other successor organisation.

25 ARRANGEMENTS ON TERMINATION

- 25.1 NICE and the Contractor agree that termination (in whole or in part) or expiry of the Agreement shall not affect either Party's obligations which the Agreement provides shall survive the termination or expiry of the Agreement or the continuance of the part or parts not terminated where the Agreement is terminated.
- 25.2 After termination or expiry all data, documents and records (whether stored electronically or otherwise) relating in whole or in part to the Services and/or the Supply (including any Deliverables which remain to be completed as at the date of termination or expiry) and which NICE is entitled to own or possess under this Agreement and all other items provided on loan or otherwise to the Contractor by NICE shall be delivered by the Contractor to NICE provided that the Contractor shall be entitled to keep copies

thereof to the extent that the information contained therein does not relate solely to the Services and Supply or to the extent that the Contractor is required by law to maintain copies thereof or to the extent that the Contractor was possessed of such data documents and records prior to the date of the Agreement. In addition, the Contractor shall co-operate with NICE during the hand-over leading to the termination of the Agreement and for a reasonable period thereafter. This co-operation shall extend to full access to all documents, reports, summaries and any other information required to achieve an effective transition without disruption to routine operational requirements. For the avoidance of doubt where the Contractor is entitled to ownership of any item within this Clause, the Contractor shall deliver up copies but shall not be required to deliver up original items save where NICE is entitled to the same.

- 25.3 The Contractor shall retain all papers, files, records and vouchers relating to the performance of the Services and Supply as provided for under Clause 25.2 for the period of 6 years after the date of the termination of the Agreement and thereafter shall not destroy them but shall, at the option of NICE, deliver them to NICE.
- 25.4 The provisions of Clauses 1, 3.6, 10, 11.5, 14, 15, 19, 20, 25, 26 and 27 shall continue after this Agreement terminates.
- 25.5 The Contractor hereby warrants that the information provided to NICE under clause 25.2 is not deficient or inaccurate.
- 25.6 For the avoidance of doubt, on termination of this Agreement, all content licences and other licences granted to either Party under Clause 11 shall terminate.

26 RE-TENDERING AND HANDOVER

- 26.1 Within 21 days of being so requested by NICE at any time during the 6 months prior to the termination of this Agreement, the Contractor shall provide such information as NICE reasonably requires and deems reasonably necessary to enable NICE to issue invitations to offer for the future provision of the Services or Supply or services or supply similar to them. Such information shall not include any commercially sensitive data or information.
- 26.2 The Contractor shall provide reasonable assistance to NICE during the hand-over arising from the completion or earlier termination of the Agreement. This assistance, during the setting up operations period of the new supplier, shall extend to allowing such access to, and copies of all documents, reports, summaries and other information that the Contractor deems necessary in order to achieve an effective transition without disruption to the routine operational requirements.

27 TUPE

- 27.1 The Parties understand that neither (a) the commencement of the supply of the Services to NICE nor (b) that the termination of this Agreement shall constitute a service provision change as defined in regulation 3(1)(b) of the TUPE Regulations. Nonetheless in the event that TUPE Regulations are held to apply at any point during or on termination of this Agreement, the Parties will work together in order to effect a smooth transfer of Employees and the provisions of Annex 10 shall apply.

28 WARRANTY

Each Party warrants to the other that it has all necessary corporate standing and authorisation to enter into and be bound by the terms of the Agreement. At all times in connection with the Agreement, each NICE and the Contractor shall be an independent contractor and nothing in the Agreement shall create a relationship of agency or partnership or a joint venture as between the Contractor and NICE and accordingly neither Party shall be authorised to bind the other.

NICE warrants that it has authority to enter into this Agreement for and on behalf of the Departments of Health in England, Scotland, Wales and Northern Ireland and that NICE's acts or omissions in relation to this Agreement will bind these entities.

29 RELATIONSHIP TO THE PARTIES

Each of NICE and the Contractor shall not incur any liabilities on behalf of the other or make any representations or give any warranty on behalf of the other or, enter into any agreement or obligation on behalf of the other.

30 GENERAL

- 30.1 Subject to Clause 12, save as required by law and/or the requirements of any relevant stock exchange no publicity shall be made by either Party relating to any matter in connection with the Agreement without the prior written consent of the other.
- 30.2 Each Party shall from time to time upon the request of the other, execute any additional documents and do any other acts or things which may reasonably be required to implement the provisions of the Agreement.
- 30.3 Any provision of the Agreement which is held to be invalid or unenforceable in any jurisdiction shall be ineffective to the extent of such invalidity or unenforceability without invalidating or rendering unenforceable the remaining provisions hereof and any such invalidity or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provisions in any other jurisdiction.
- 30.4 Each Party acknowledges and agrees that it has not relied on any representation, warranty or undertaking (whether written or oral) in relation to the subject matter of the Agreement and therefore irrevocably and unconditionally waives any rights it may have to claim damages against the other Party for any misrepresentation or for breach of any warranty unless the representation relied upon is set out in the Agreement or unless such representation was made negligently or fraudulently.
- 30.5 Each Party shall bear its own expenses in relation to the preparation, execution and implementation of the Agreement including all costs legal fees and other expenses so incurred.
- 30.6 The Contractor warrants, represents and undertakes to NICE that there are no pending or threatened actions or proceedings before any court or administrative agency which would materially adversely affect the financial condition, business or operations of the Contractor and that there are no material contracts existing to which the Contractor is a party which prevent it from entering into the Agreement; and that the Contractor has satisfied itself as to the nature and extent of the risks assumed by it under the Agreement and gathered all information necessary to perform its obligations under the Agreement and all other obligations assumed by it.

- 30.7 The rights and remedies provided in the Agreement are cumulative and not exclusive of any rights or remedies provided by the general law, or by any other agreement or document. In this provision "general law" includes the law of a country other than England, and "right" includes any power, privilege, remedy, or proprietary or security interest.

31 THIRD PARTY RIGHTS

- 31.1 A person who is not a Party shall have no rights pursuant to the Contracts (Rights of Third Parties) Act 1999 to enforce any term of the Agreement.
- 31.2 All or any of the provisions of the Agreement may be rescinded or varied by the Parties in their entirety or in part without the consent of or the need to give any notice to any person not a Party to it.

32 LIABILITY

- 32.1 The Contractor and each Consortium Party individually each acknowledges and declares that the liabilities and obligations of the Consortium Parties to NICE by reason of their being the Contractor, shall be joint and several.
- 32.2 Nothing in this Agreement shall limit or exclude any liability of either Party which may not be limited or excluded by law, including without limitation liability for death or personal injury caused by its negligence or for fraud or fraudulent misrepresentation, or any liability to pay any sums when due pursuant to this Agreement.
- 32.3 Subject to Clause 32.2, the liability of NICE and each Consortium Party respectively for any default under or relating to this Agreement (whether in compensation for any breach, under any indemnity or otherwise and whether in contract, tort, for breach of statutory duty or otherwise) in any Year, when added to all liability of that Party in respect of all other defaults by it which occurred in the same Year, shall not in any event exceed a sum equal to the total charges payable to the Contractor under this Agreement in that Year.
- 32.4 Subject to Clause 32.2, the liability of each party in respect of all losses arising from the same event or connected series of events caused or contributed to by any default under or in relation to this Agreement (whether in contract, tort, for breach of statutory duty or otherwise) shall not in any event exceed the sum of £700,000.
- 32.5 In accordance with Annex 4 NICE will notify RPSGB of defects relating to design and condition of the relevant BNF Volumes as of delivery. Within six months from delivery NICE may give notice to RPSGB that individual BNF Volumes in use are defective in reasonable terms of structural quality for a book of this design. In both cases if it is found that they are defective, the Contractor shall at NICE's option replace the defective item(s) or issue a credit note or refund the purchase price for that item.
- 32.6 Subject to Clause 32.2, replacement, credit or refund pursuant to the preceding clause 32.5 shall be full satisfaction of all liability and obligation of the Contractor in respect of the defective BNF Volumes and the Contractor shall have no further or other liability nor shall NICE have any other remedy.
- 32.7 Subject to Clause 32.2, save to the extent that RPSGB is notified within the said six months from their delivery that BNF Volumes are defective, those BNF Volumes shall be deemed to comply with this Agreement and the Contractor shall have no liability in respect of the same even if they are found to be defective.

- 32.8 If RPS so requests, NICE shall return to RPSGB the defective BNF Volume in order to substantiate the claim that it is defective.
- 32.9 Subject to Clause 32.2, the Contractor shall not be responsible or liable for any failure to perform, or delay in performing, any Services or any delay in delivery or other breach of this which is caused or contributed to by a breach by NICE of its obligations under this Agreement.
- 32.10 Subject to Clause 32.2, no party shall be liable under this Agreement (whether in compensation for any breach or otherwise and whether in contract, tort, for breach of statutory duty or otherwise) for any loss of anticipated savings, loss of revenue, loss of profit, loss of data, loss of goodwill or reputation, liability to third parties, business interruption, loss of management time, loss of use of any asset or any loss which procedures and precautions implemented by the other party (or which would generally be implemented by a person exercising a degree of skill, diligence, prudence and foresight which would reasonably and ordinarily be expected from a reasonably and appropriately skilled and experienced person in the same or similar circumstances) could have prevented or reduced, or any special incidental or consequential losses or damages

33 NOTICES

- 33.1 Any notice to be given under the Agreement shall either be delivered personally, sent by first class recorded delivery post (airmail if overseas) or electronic mail. The address for service shall be as follows:

NICE: Level 1A

City Tower

Piccadilly Plaza

Manchester M1 4BT

Addressed to the Contract Manager and/or the Programme Director for Medicines and Prescribing Centre

The Contractor:

The Royal Pharmaceutical Society of Great Britain

FAO Managing Director, Pharmaceutical Press

66-68 East Smithfield

London

E1W 1AW

With copies to:

British National Formulary publisher

(For the attention of the Chief Executive, BMJ Publishing Group Limited)

BMA House,

Tavistock Square,
London WC1H 9JP; and
RCPCH Publications Limited
FAO: Managing Director
5 – 11 Theobalds Road
London WC1X 8SH

The Consortium Parties: their registered office

or such other address as they may previously have notified to the other Party in writing. If the notice is sent via email then it shall be copied to the Senior Lead, the BMJ Director of Partnership Development and the RPSGB Chief Executive Officer.

33.2 A notice shall be deemed to have been served:

- 33.2.1 if personally delivered, at the time of delivery;
- 33.2.2 if sent by email at the time of transmission;
- 33.2.3 if posted, at the expiration of 48 hours or (in the case of airmail seven days) after the envelope containing the same was delivered into the custody of the postal authorities; and
- 33.2.4 if sent by electronic mail, a telephone call is made to the recipient warning the recipient that an electronic mail message has been sent to him (as evidenced by a contemporaneous note of the Party sending the notice) and a hard copy of such notice is also sent by first class recorded delivery post (airmail if overseas) on the same day as that on which the email is sent.
- 33.2.5 In proving such service it shall be sufficient to prove that personal delivery was made, or that the envelope containing such notice was properly addressed and delivered into the custody of the postal authority as prepaid first class, recorded delivery or airmail letter (as appropriate) or that the time the electronic mail was sent.

34 FORCE MAJEURE

- 34.1 No Party shall be entitled to bring a claim for a breach of obligations under the Agreement by the other Party or incur any liability to the other Party for any Loss or damages incurred by that Party to the extent that a Force Majeure Event occurs and it is prevented from carrying out obligations by that event of force majeure.
- 34.2 In the occurrence of a Force Majeure Event, the Affected Party shall notify the other Party as soon as practicable. The notification shall include details of the Force Majeure Event, including evidence of its effect on the obligations of the Affected Party and any action proposed to mitigate its effect.
- 34.3 As soon as practicable, following such notification, the Parties shall consult with each other in good faith and use all reasonable endeavours to agree appropriate terms to

mitigate the effects of the Force Majeure Event and facilitate the continued performance of the Agreement.

- 34.4 If the Force Majeure Event continues and as a result a Party is prevented from carrying out its obligations for a continuous period of 3 months the party not so affected may then terminate this Agreement by giving 1 months' notice in writing to the other.

35 WAIVER

- 35.1 No waiver or delay in acting upon or by either Party of any of the requirements of this Agreement shall release the other Party from full performance of its remaining obligations in this Agreement.

36 WHOLE AGREEMENT

- 36.1 The Parties acknowledge that this Agreement contains the whole Agreement between the Parties and supersedes all previous agreements whether express or implied in relation to the subject matter of this Agreement.

37 VARIATION

- 37.1 Subject to Clause 21, this Agreement cannot be varied except in writing and signed by the lawful representatives of both Parties.

38 GOVERNING LAW

- 38.1 Each Party submits to the jurisdiction of the English courts and agrees that the Agreement is to be governed and construed according to English law.

ANNEX 1 – BNF Content Specification

1. The content will summarise key aspects and clinical guidance on the management of common and/or significant medical conditions and the medicines and devices used to manage those conditions. This content may be provided directly within the dataset, or by linking to the appropriate source (e.g. the UK anti-doping website for drugs and sport).
2. The content will have an emphasis on UK practice and will be written in a way that supports its use in apps, online, or in print. Phrases relating to specific presentation channels will be avoided.
3. In general, adult information will be presented in the BNF and paediatric information will be presented in the BNF (Children).
4. The content types in BNF 80 and BNF (Children) 2020-21 will be taken as the baseline for coverage, to include current content and headings. It is expected that this coverage will evolve over time. The baseline for coverage will be reviewed and set at each contract review point, typically to the content type in the current BNF and BNFC publication. Changes will therefore be specifically referenced in the Annual Business Plan.
5. Drug monograph content will focus on prescription only medicines, although some prescription-only medicines will be excluded (e.g. items not commonly prescribed or items used only in specialist areas). Some non-prescription medicines may be included where it may be of assistance to the clinician or patient (e.g. commonly prescribed non-prescription medicines or medicines which may be purchased cheaply in bulk). The drug monograph content will typically comprise a range of information to enable the safe prescribing and use of drugs.
6. Medical devices will also be included. Devices will be included if they are used to assist with drug delivery (e.g. spacers), manage a condition (e.g. peak flow meters and some emollients) or are for wound care.
7. Borderline substances, as defined by the Advisory Committee on Borderline Substances will be included.
8. General prescribing advice, including statutory information where appropriate, will be provided, covering areas useful to clinicians, such as prescription writing and the emergency supply of medicines and aspects of care pertinent to specific conditions, such as renal impairment, or specific patient populations, such as the elderly.
9. Information around the use of drugs in dental practice, including specialised information for dental practitioners and a list of the drugs that dentists may prescribe on an FP10 (or country equivalent) is included.
10. Information pertaining to community practitioner prescribing (V100 and V150 prescribers), known as the 'Nurse Prescribers Formulary for Community Practitioners', the list of drugs that they may prescribe, and content specific for this group of users (BNF (Nurses), is included.

Content creation and quality assurance

1. Methods and processes used for the content development will be published by the Contractor.

2. The Contractor will adhere to the published standards when creating content and quality assuring the content.
3. The content will be subject to an ongoing review processes to ensure it is up-to-date, with priority given to the most clinically important information. The ongoing review will aim to consider all content on a rolling 3- to 4-year cycle.
4. Content will be based on a variety of sources, with the highest quality sources used in preference to other literature. High quality sources will include guidance that has received a recognised accreditation standard or is known to meet internationally recognised standards (such as the AGREE II criteria). Manufacturer's product literature, approved by the relevant regulatory body, will provide the starting point for drug content, with the focus on the Summary of Product Characteristics (SmPC), to support the UK emphasis of the publication.
5. Other content sources will be used to supplement or enhance this information, with the varying quality of sources indicated in the content. For example, in some instances, expert opinion will be the only available source, and this will be identifiable by the application of an evidence category.
6. Where possible, treatment summaries content will link to the recognised guidance (e.g. NICE Guidance, SIGN Guidance) used in their creation.

ANNEX 2 – NICE Feed

The requirements set out in this Annex 2 will be reviewed and agreed by both Parties as new use cases emerge to ensure it retains an appropriate level of functionality as well as reflecting new and more appropriate standards as they emerge. All data models, structure and schemas shall be deemed Confidential Information belonging to the Contractor.

NICE Feed Structure

1. The BNF Content delivered in the NICE Feed conforms to the specification set out in Annex 1.
2. Content properties applied to BNF Content must be defined by and applied using an agreed data model. The model will be supported by a schema or equivalent appropriate documents, which will be delivered in a mutually agreed format.
3. The model must reference existing published schemas where appropriate to support increased interoperability.
4. Where metadata exists within the model, standard terminologies, such as the UK extension set of SNOMED will be used.
5. The BNF model and supporting schema in place at the Commencement Date will be considered the baseline. Changes from the baseline will be specifically agreed through the change control process described in this Annex.

NICE Feed Delivery

6. Releases and updates to the BNF Content must be provided through the NICE Feed, starting at agreed monthly intervals via the agreed delivery mechanism, and moving to more frequent updating over the life of the contract. The exact frequencies are to be defined and will be determined by factors such as the level of risk to the patient of an update not being made.
7. NICE will respond to any issues with the feed within 48 hours of receipt.

NICE Feed Change Controls

8. For the purpose of change control the Contractor will, where appropriate, submit notification of changes in batches and endeavour to provide 3 months' notice.
9. Both Parties agree to changes with shorter time scales where they recognise issues of clinical safety in the use of the content. Versions of the NICE Feed provided by the Contractor must be clearly labelled with a date and a version number. There should also be an indication as to whether or not it is the current live release version, a superseded version, or an in-development version for NICE to develop against.

NICE Feed Transformation

10. Content delivery will transition to a JSON serialisation format. During the transition, both XML and JSON formats will be required. XML will be retired on the adoption of JSON by NICE.
11. The transition period during which both JSON and XML is delivered will be used for development and testing with a timeframe agreed between the Contractor and NICE. Once the new format is signed off XML will be supported for no more than 3 months.

ANNEX 3 – BNF App

1. The BNF App must be available on iOS and Android platforms, accessible through the relevant UK app store, without charge.
2. The BNF App should be suitable for use on both mobile and tablet devices and work offline. The BNF App should conform to recognised standards for accessibility.
3. The BNF Content delivered in the BNF App conforms to the specification set out in Annex 1. The BNF App will include content from both BNF and BNF (Children).
4. Releases and updates to the BNF Content must be provided in the BNF App, without charge, starting at agreed monthly intervals via the agreed delivery mechanism, and moving to more frequent updating over the life of the contract. The exact frequencies are to be defined and will be determined by factors such as the level of risk to the patient of an update not being made.
5. The BNF Content download process must be optimised for speed and clinical safety. Users should receive notification of the availability of an update and confirmation of successful download. Following download users should be able to identify the BNF Content version downloaded and 'what's new'.

BNF App Functionality

6. The BNF App should support both browse and search for BNF Content.
7. The BNF App should support easy navigation and discovery of each section of the BNF Publications within the BNF Content.
8. The BNF App should clearly distinguish between content about adults and content about children.
9. The BNF App should track usage information in line with Data Protection Laws.
10. BNF App functionality will be optimised for each platform. To the extent that it is possible, the BNF App should support the same functionality across iOS and Android platforms.

Registration

1. The design, development and implementation of app authentication will be based on the following core considerations:

- User testing to inform best user experience
- Minimal barriers to prevent disruption to clinical workflows
- For new downloads, registration at the point of download and for existing users at least 3 opportunities to register in advance of implementation
- Agree implementation plans with NICE
- Development and thorough pre-launch testing
- Clear, targeted and planned communication to users, providing a suitable lead in time to launch, as agreed by the Parties.
- Launch and monitoring to inform any further improvements or enhancements to the process, based on user feedback

2. The BNF App registration process will be simple, collecting the following data:

- user's email address
- password
- single line user category information may be included, as set out in the proposal paper and dependant on the outcome of user testing

3. Future updates to user categories will be agreed with NICE as part of the ongoing monitoring process described in Clause 7.2.

4. The registration system will allow users to update their information.

BNF App Maintenance and Development

1. The BNF App must support current and previous 2 versions (if possible) of the major mobile platform operating systems.
2. Prior to the release of major updates of the operating system software of either the iOS, Android or other platform on which the BNF App is deployed, the BNF App must be retested on such releases and if defects are found, re-released with the necessary software updates to resolve defects.
3. The BNF App must be maintained and released at intervals necessary to maintain compliance with these assurance criteria.
4. The BNF App will be developed in line with changes to the BNF Content, user feedback and to ensure compliance with regulatory standards.

ANNEX 4 – BNF Volumes

Provision of BNF Volumes to NICE for the NHS and for students studying undergraduate healthcare degrees leading to prescribing within the NHS

1. BNF Volumes are supplied by the Contractor in accordance with Clause 3.1.
2. The Contractor shall ensure that the BNF Volumes have the contents of Clause 13 included with in them.
3. This is the Annex for provision of the paper copies of the BNF Volumes to the NHS.

Ordering

4. NICE will order BNF Volumes annually, taking 'even-numbered' BNF and the annual BNF (Children).
5. Three months in advance of September publication, NICE will inform the Contractor of the exact number of copies required. In addition, details of delivery addresses and relevant contacts to facilitate supply will be provided at this time.
6. Ad hoc orders can be made after confirmation of quantity for the main print run but are likely to incur higher costs.
7. Ordering should occur from the Authorised Officer to the Senior Lead.

BNF Volumes Price

8. The price per copy will be equal to the Unit Price of each of the respective BNF Publications when ordered according to point 5 above.
9. Additional copies ordered after publication, that is, those ordered according to point 6, above, will be charged at no more than 50% of the retail price prevailing at the time the order is received by the Contractor with the exact cost determined by the availability of stock and the requirement for reprinting.
10. The contractor should use reasonable endeavours to minimise the Unit Price of the BNF Volumes.

Design and condition

11. BNF Volumes from the original order should have 'NHS Property not for sale' clearly marked on the front cover. Subsequent ad hoc orders and replacements for defective copies may not carry this marking.
12. NICE will confirm acceptance or rejection of the delivered goods within 28 days of delivery to NICE, after a quality assurance and condition check of the delivered goods has been completed by the NICE mailing distribution contractor.

Content Extent

13. User surveys will be undertaken periodically within the duration of the contract but no less than once per Review Period.
14. User surveys will inform the optimisation of BNF Content, with a particular focus on BNF Content that no longer needs to be included within the BNF Volumes. This will support the Contractor's requirement to minimise the Unit Price of the BNF Volumes, possibly by managing page extent.
15. The actions indicated by the user survey will inform the annual efficiency proposals as set out in Clause 2.6 with the intention of reducing the overall cost of the supply. Agreed proposals will become part of the Annual Business Plan for the following contract year [or] in such timings as is reasonably agreed in accordance with the contract variation process in Clause 21 and Clause 37.

ANNEX 5 – Sample Variation agreement

VARIATION # []

Date: []

VARIATION to the Agreement between National Institute for Health and Care Excellence and the Contractor of on the Day of 20xx (“the Agreement”).

For the purposes of this Variation of Agreement:

“Commissioning Manager” means the individual from time to time appointed by NICE and notified to the Contractor in writing responsible for the co-ordination of the development specified below;

This Variation of Agreement is to effect and require the development of XXX (the “Further Services and Supply”) to be undertaken by the Contractor and is agreed by the Contractor and NICE as a current addition to annex [to be inserted] to the Agreement.

The Further Services and Supply will:

1. be developed by the Contractor in compliance with the specifications contained in this Variation of the Agreement, and
2. be developed and delivered in accordance with the terms and conditions of the Agreement.

This Further Services and Supply consists of:

[To be completed and inserted]

[Delivery Date]

The Milestones for Deliverables which are required by NICE are detailed below. NICE requires, and the Contractor will deliver quarterly, a Monitoring Report in the form and by the times set out within Annex 3.

Milestones

Due Date	Milestone

--	--

The Contractor shall be deemed to have completed a Milestone by the Due Date notwithstanding any delay beyond the Due Date if such delay would not have occurred but for any act or omission of NICE, or a Force Majeure Event.

Terms defined in the Agreement shall bear the same meanings in this Variation of Agreement, unless otherwise stated.

The Cost of the Variation is £ [to be inserted] and shall be invoiced on [to be inserted]

Agreed by

Signature on behalf of NICE

Name

Title

Date

Signature on behalf of the Royal
Pharmaceutical Society of Great
Britain

Name

Title

Date

Signature on behalf of the BMJ
Publishing Group LTD

Name

Title

Date

Signature on behalf of The Royal
College of Paediatrics & Child Health
Publications Limited

Name

Title

Date

ANNEX 6 – Annual Business Plan

This plan is intended to provide a basis by which the objectives, milestones, and targets described in this contract can be agreed until March 31st [year].

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

BUSINESS PLAN

[YEAR]

British National Formulary

Primary business objective

1. The primary objective of the British National Formulary is to [insert details].

a)

Business objectives and deliverables

2. Identify the key business and strategic objectives for [YEAR] that relate to your work programme and the related outputs and targets. Try to keep to between 5 and 8 objectives.

Objectives should include, but not be limited to, the following areas and be achievable, specific and measurable:

- *Business continuity*
- *Service development and improvement*
- *Maintaining quality*
- *Financial management and efficiency savings*
- *Human resources, including plans for staff development, recruitment and retention*

Business objectives	Deliverable	KPI	Timing
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			

Please add extra rows as required.

Workload analysis

3. Please describe your anticipated workload for [YEAR] by completing the table below, setting out agreed quarterly outputs and timings, providing further text below where necessary. This will form the basis of the monitoring for progress to contract at the quarterly review meetings.

		Deliverables	Timings
Quarter 1	April		
	May		
	June		
Quarter 2	July		
	August		
	September		
Quarter 3	October		
	November		
	December		
Quarter 4	January		
	February		
	March		

Workforce planning

4. The business plan should identify the key areas of operations and how they will be managed, such as:

- Details of services to be delivered (e.g. For example, plans for rectifying known issues, areas of priority etc)
- Plans for managing risks;
- Potential impact of any planned changes;
- Plans for additional or innovative work and the resources required;
- Plans for working on additional pieces of work with other organisations;

5. The business plan should include:

- Your 'current state' organogram for 1 April [YEAR].
- Your planned organogram showing your organisational and managerial structure for [YEAR], including work time equivalent for each position.
- Areas for development and the strategies that will be used to address this. This should include the training of staff.
- Recruitment and retention strategies.
- The names of the Governance Board of Directors (or equivalent) and any professional advisors.
- The timing and frequency of board meetings should be detailed.

Please make reference to the individual posts and staff costs set out in Appendix A (Budget spreadsheet).

Financial plan

4. Please provide a full financial summary.

5. Please note here any potential cost pressures associated with the business deliverables, for example new posts associated with new activity or increased costs relating to an existing contract.
6. Please comment in this section on your forecast for the financial year and any notable points per budget.
7. The business plan should clearly highlight any gaps and any assumptions made.
8. A budget spreadsheet is attached (Appendix A) and is to be completed. Please provide details of the actual budget, both pay and non-pay, and your financial projections for the year ahead based on a full year effect.

Efficiency plan and quality targets

9. The business plan should outline how the British National Formulary intends to improve efficiency/ productivity over the period and any proposals for service improvements. Any savings achieved for [YEAR], and information on savings that have yet to be delivered, including an expected timeline for delivery, should be detailed in this section.
10. Please set out what your organisation is planning for [YEAR] to:
 - Build on successes and lessons learned from the previous business year;
 - Embed new ways of working;
 - Maintain business continuity;
 - Maintain quality of outputs.
11. Please include any issues relevant to business planning for [YEAR]

Business plan strategic risk register

12. A business plan risk register is set out below. It should provide a focussed assessment of your strategic risks against your business plan for [YEAR]. This is separate from your operational risk register which you will work to throughout the business year and present at each Quarterly Review Meeting. The business plan risk register should link to the relevant sections outlined in the business plan.
Instructions for how to populate this table can be found in the Appendix B (Notes on quantifying and monitoring risks).

Ref	Risk (Identify prospective risk e.g. Failure to deliver XXXX due to XXXX)	Mitigation and assurance (List the planned actions that will mitigate the risk)	Rating following mitigation			Further actions (List further actions to strengthen mitigation and assurance)	Target rating			Date risk was last amended
			I	L	S		I	L	S	
1.										
2.										
3.										

Please add extra rows as required.

EXAMPLE ANNUAL BUSINESS LETTER

[Contract Lead RPS]
Royal Pharmaceutical Society,
66-68 East Smithfield,
Whitechapel,
London,
E1W 1AW.

[DD MMMM YYYY]

Dear [NAME],

RE: Business Letter 20XX-XX for the British National Formulary (BNF) for the NHS – Contract NICEXXX

Thank you for submitting your business plan for 20XX-XX, which has now been signed off. This letter will be appended to your final business plan and to The British National Formulary Agreement 2021; NICE contract number XXXX.

Looking to the 20XX-XX financial year, we can confirm a total fixed budget of £XXXX, excluding funding for the subcontracted printing of physical goods. This is the budget you should report and invoice against in year. Please submit invoices from the preceding quarter following the relevant Quarterly Review Meetings (QRM). Once all the paperwork has been received and approved, we will proceed with payment. Please submit quarterly invoices for the amount specified in the quarterly invoice schedule below.

Please find enclosed your final business plan documents:

- o Business plan (including strategic risk register, agreed objectives and deliverables)
- o Budget plan

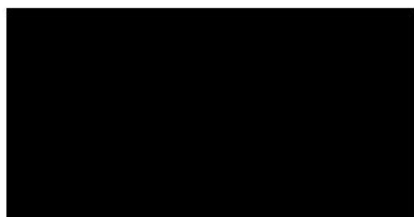
We will continue to ensure timely scheduling of QRMs. The QRM reporting templates have been updated for 20XX-XX and will be sent to you separately to this letter. They include:

- o Finance report
- o Risk register
- o Infrastructure report
- o Business objectives progress report
- o Business objectives summary report (QTR 4)
- o Monthly letters report
- o Digital Statistics report

These documents will form the basis for your reporting progress against your business plan. These reports should be completed quarterly and submitted to us at least five working days before each scheduled QRM. Reports that are incomplete may result in the QRM being delayed.

We look forward to working with you during the 20XX-XX business year.

Yours sincerely,



Programme Director
Centre for Guidelines

Copies:

[NAME] Managing Director - Pharmaceutical Press

[NAME] Chief Executive, The BMJ Publishing Group Limited

[NAME] Managing Director, RCPCH

Business Programme Manager, NICE

Quarterly Invoice Schedule – 20XX-XX

Quarter	Amount to be invoiced (excl. VAT)
Quarter 1	£XXX
Quarter 2	£XXX
Quarter 3	£XXX
Quarter 4	£XXX
Total	£XXX

ANNEX 7 – Milestones and Monitoring Reporting

It is agreed by all Parties that the Annual Business Plan will be appended to the annex each time the business plan is accepted by NICE.

Each year NICE will provide reporting templates for the Contractor to complete and submit ahead of each Quarterly Review Meeting. The report templates will contain a minimum of the following criteria for the Contractor to report against. The templates will be used to monitor progress against the agreed business plan in each quarterly review meeting.

The meeting will be attended by the following representatives of NICE and the Contractor:

NICE:

- Authorised Officer (typically Programme Director, NICE Centre for Guidelines)
- Contract Lead (typically Business Programme Manager – NICE Centre for Guidelines)
- BNF Project Manager – NICE Centre for Guidelines
- Medicines Advisor – (typically Associate Director – NICE Medicines and Prescribing Team)
- CLT Coordinator (Minutes and secretariat)

Contractor:

- Representative of joint venture partners (typically BMJ Director of Partnership Development)
- Commercial Lead from RPS (typically the Managing Director for Pharmaceutical Press)
- Content Lead from RPS (typically the Content Director)
- Operational Content Representative from Pharmaceutical Press (typically Expert Writer BNF)
- Contract Lead RPS (if role not held by one of the above)

Title	Purpose	Content
Finance report	To display actual and projected costs against budget by quarter, with	<ul style="list-style-type: none">• Senior management team pay costs (roles included in this total)

	comments/reasons for variance	<p>as mutually agreed in Annual Business Plan)</p> <ul style="list-style-type: none"> • Pay costs broken down by team, then role, then WTE • Non-pay costs, including governance, boards and committees, digital costs • Detail of remaining funds against projected/actual spend ('margin')
Risk register	A log of all risks identified by the contractor's Management team with details of how these were, or are to be, handled	<ul style="list-style-type: none"> • Name of reviewer and approver • Business objective that the risk relates to • Risk description • Planned actions to mitigate the risk • Risk rating following mitigation, as defined • Further actions to strengthen the planned mitigations • Target rating, as defined • Date of last review • Date of last amendment
Infrastructure report	A summary overview of performance and issues over the reporting period	<ul style="list-style-type: none"> • Successes and achievements • Challenges to delivery of outputs • Vacancy rate and workforce planning • Subcontractor feedback and performance • Issues for discussion with NICE

Business Objectives report	A summary of progress towards the completion of the business objectives agreed in the business plan	<ul style="list-style-type: none"> • Metrics to demonstrate performance against agreed KPIs • Narrative to explain progress in quarter against each business objective and Deliverable, • Narrative to explain progress towards financial targets • Narrative to explain progress on agreed efficiency savings
Monthly letters report	A summary of activity against KPI, in response to monthly letters from NICE that detail new guidance and changes to existing guidance and recommendations	<ul style="list-style-type: none"> • List of changes against KPI • Status of ad-hoc queries from NICE regarding BNF content (including enquiries received by NICE from third parties)
Digital statistics report	A report on the uptake and usage of the BNF App	<ul style="list-style-type: none"> • Number of users/sessions • Summary narrative of trends, usage and issues • Produce data on which sections of the app are most used • Details of Syndication requests for BNF content by NHS Users and third parties.
Business objectives summary report (Q4 only)	A report to summarise progress against business objectives at year-end	<ul style="list-style-type: none"> • Progress against business objectives and deliverables for the business year • Narrative to explain the reasons for non-completion of tasks, including barriers to completion.

The Centre Review Milestones

Task	Date to be Completed
------	----------------------

Year one, quarter 1 Review	July 2021
Year one, quarter 2 Review	October 2021
Year one, quarter 3 Review	January 2022
Year one, quarter 4 Review	April 2022
Year two, quarter 1 Review	July 2022
Year two, quarter 2 Review	October 2022
Year two, quarter 3 Review	January 2023
Year two, quarter 4 Review	April 2023
Year three, quarter 1 Review	July 2023
Year three, quarter 2 Review	October 2023
Year three, quarter 3 Review	January 2024
Year three, quarter 4 Review	April 2024
Year four, quarter 1 Review	July 2024
Year four, quarter 2 Review	October 2024
Year four, quarter 3 Review	January 2025
Year four, quarter 4 Review	April 2025

ANNEX 8 – Payment Schedule

The payment schedule for year 5 to year 12 will be in accordance with the total confirmed in the 4-year reviews and in the annual business letter.

Amount of Funding (000s)		Financial Year	Date(s) for Submission of Invoice(s)
Year one quarter 1	████	21/22	████
Year one quarter 2	████	21/22	████
Year one quarter 3	████	21/22	████
Year one quarter 4	████	21/22	████
Year two quarter 1*	████	22/23	████
Year two quarter 2	████	22/23	████
Year two quarter 3	████	22/23	████
Year two quarter 4	████	22/23	████
Year three quarter 1	████	23/24	████
Year three quarter 2	████	23/24	████
Year three quarter 3	████	23/24	████
Year three quarter 4	████	23/24	████
Year four quarter 1	████	24/25	████
Year four quarter 2	████	24/25	████
Year four quarter 3	████	24/25	████
Year four quarter 4	████	24/25	████
TOTAL	15,160		

* any increase on the level of funding from Year two quarter 1 is dependent on the delivery of agreed Deliverables set out in the Annual Business Plan.

ANNEX 9 – Authorised Signatories

31 Mar 2021

SIGNED by



**For and on behalf of the
NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

30 Mar 2021

SIGNED by



**For and on behalf of the
THE ROYAL PHARMACEUTICAL SOCIETY OF GREAT BRITAIN**

31 Mar 2021

SIGNED by



**For and on behalf of the
THE BMJ PUBLISHING GROUP LTD**

31 Mar 2021

SIGNED by



**For and on behalf of the
THE ROYAL COLLEGE OF PAEDIATRICS & CHILD HEALTH PUBLICATIONS LIMITED**

ANNEX 10 – TUPE Regulations Provisions

TUPE REGULATIONS PROVISIONS

1 Definitions

1.1 In this 1:

“Employees”	means any employee (as defined in the TUPE Regulations) who is assigned by either party to providing services similar to the Services or the Supply;
“Employee Liability Information”	means an up to date and accurate list containing for each individual the anonymised information listed in regulation 11(2) of the TUPE Regulations;
“Employment Costs”	means all pay, benefits, PAYE payments, national insurance contributions, pension contributions and other amounts payable to or in respect of the employment or engagement of any person;
“Employment Liabilities”	means all liabilities, including but not limited to claims for redundancy payments, unlawful deductions from wages, unfair, wrongful or constructive dismissal compensation, compensation for age, sex, race or disability discrimination or discrimination on the grounds of religion, belief, age or sexual orientation or claims for equal pay, compensation for less favourable treatment of part-time workers, and any other claims whether in tort (including negligence), contract or statute or otherwise, and any demands, actions, proceedings and any award, compensation, damages, tribunal awards, fine, loss, order, penalty, disbursement, payment made by way of settlement and costs and expenses reasonably incurred in connection with a claim or investigation, and any expenses and legal costs on an indemnity basis;
“Relevant Transfer”	means a transfer of the Services or the Supply for the purposes of TUPE
“Services Transfer Date”	means the date on which any Relevant Transfer is deemed to take effect;

“Transferring Employer” means the Party under this Agreement whose Employees are deemed to be affected by the Relevant Transfer;

“Transferee Employer” means the Party or Replacement Contractor under this Agreement to whom the Employees will be transferred under the Relevant Transfer;

- 2 Subject to any obligations under applicable data protection legislation, in the event of a Relevant Transfer, the Transferring Employer will provide the Employee Liability Information in respect of the Employees to the Transferee Employer no later than 90 days prior to the Services Transfer Date.
- 3 NICE shall be responsible for and shall indemnify and keep indemnified the Contractor and the Consortium Parties in full against:
 - 3.1 any Employment Liabilities and Employment Costs arising out of or in connection with:
 - 3.1.1 the employment or engagement of the Employees or any other person; or
 - 3.1.2 the termination of the employment or engagement of any person;in each case by NICE or the NHS Organisations during the period prior to the Services Transfer Date; and
- 3.2 any failure by NICE or the NHS Organisations to comply with its obligations under the TUPE Regulations.
- 4 The Contractor shall be responsible for and shall indemnify and keep indemnified NICE in full against:
 - 4.1 any Employment Liabilities and Employment Costs arising out of or in connection with the employment or engagement of the Employees or (except as provided in paragraphs 6 and 7 of this Annex 10) any other person by the Contractor on and after the Services Transfer Date; and
 - 4.2 any failure by the Contractor to comply with its or their obligations under Regulation 13(4) of the TUPE Regulations.
- 5 NICE shall not during the period of this Agreement assign any Employee to perform any aspect of the Services or the Supply or any services similar to the Services or the Supply without giving prior written notice to the Contractor.
- 6 If any person, other than an Employee, employed or engaged by NICE or any of the NHS Organisations transfers or alleges that their employment or engagement (or any liability related to it) transfers to the Contractor or any of the Consortium Parties or any sub-contractor of the Contractor under the TUPE Regulations or otherwise as a result of the Contractor or any sub-contractor of the Contractor providing the Services, the Parties will discuss how to address the situation. In the absence of any agreement, the Contractor, any of the Consortium Parties or any sub-contractor of the Contractor (as applicable) may dismiss any such person.
- 7 NICE will indemnify and will keep indemnified the Contractor and the Consortium Parties (for its or their benefit and the benefit of any relevant sub-contractor) from all Employment Liabilities which the Contractor, any of the Consortium Parties or any relevant sub-contractor may incur as a result of the TUPE Regulations applying or being alleged to apply, including any

Employment Liabilities, arising out of or in connection with any dismissal permitted by paragraph 6 of this Annex 10 (including the Employment Costs until the date of dismissal).

- 8 The Parties will comply with their obligations to provide information to a Replacement Supplier about the individuals assigned to the Services or the Supply and to inform and consult with affected employees in relation to any potential transfer to a Replacement Supplier under the TUPE Regulations.



Issuer National Institute for Health and Care Excellence

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Document fingerprint [REDACTED]

Parties involved with this document

Document processed

Party + Fingerprint

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Wed, 31st Mar 2021 15:26:24 BST	[REDACTED] - Signer [REDACTED]
Wed, 31st Mar 2021 15:26:24 BST	[REDACTED] - Copied In [REDACTED]

Audit history log

Date

Action

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	[REDACTED]		

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