

READ THIS FIRST (guidance, not part of the agreement)

What this is. A format for the agreement that Rule 84D of the Drugs and Cosmetics Rules, 1945 requires between a marketer and the manufacturer whose drug the marketer adopts. This is the **October 2026 edition**, prepared by Laafon Galaxy Pharmaceuticals (laafon.com) from the 2021 format, and updated for the changes listed on the last page.

How to use it.

1. Copy the agreement text (pages 2 to 8) into your own word processor, or print it. Complete every highlighted field in square brackets.
2. Where the text shows OPTION A and OPTION B (clauses 8.2 and 15.2), keep one and strike out the other.
3. Clauses marked [Optional] can be left out if you do not need them.
4. Stamp duty on an agreement is set by the stamp law of the State where it is signed, so there is no single national figure. Check the current schedule on your State e-stamping portal.
5. Have an advocate vet the final text before signing. Rule 84D requires an agreement to exist; the sources reviewed do not list mandatory clauses, so most clauses below are commercial terms that you can negotiate.
6. This page and the last page (“What changed since the 2021 format”) are guidance only. Leave them out of the signed copy.

Limits. This format is technical and educational information for pharmaceutical professionals. It is not legal advice. Indian rules, price-control orders and regulator positions change often. The text of G.S.R. 101(E) was read from legal-database and law-firm reproductions, so verify it on egazette.gov.in.

Edition: 4 October 2026. The latest edition is kept at laafon.com/agreement-for-marketing-format-pharma-companies-2021/

AGREEMENT FOR MARKETING

(under Rule 84D of the Drugs and Cosmetics Rules, 1945)

This Agreement for Marketing (the “Agreement”) is made at [place] on the [] day of [month] 20[] and is effective from [effective date] (the “Effective Date”).

BETWEEN

[NAME OF MARKETER], a [company / LLP / partnership firm / proprietorship] having its registered office at [complete address] (hereinafter referred to as “Marketed By”, which expression shall, unless repugnant to the context or meaning thereof, be deemed to include its successors, permitted assigns, marketing divisions, subsidiaries, godowns and associate firms);

AND

[NAME OF MANUFACTURER], a [company / LLP / partnership firm] having its manufacturing premises at [complete address of manufacturing site] and holding manufacturing licence no. [] valid up to [date] (hereinafter referred to as the “Manufacturer”, which expression shall, unless repugnant to the context or meaning thereof, be deemed to include its successors and permitted assigns).

“Marketed By” and the Manufacturer are together the “Parties” and each a “Party”.

RECITALS

- A. The Manufacturer holds a licence to manufacture the drugs listed in Annexure A and manufactures them at the premises stated above.
- B. “Marketed By” wishes to adopt those drugs, as drugs manufactured by another manufacturer, by labelling them with its own name for sale and distribution, and is therefore a marketer within Rule 2(ea) of the Drugs and Cosmetics Rules, 1945 (the “Rules”).
- C. Rule 84D of the Rules requires a marketer to have an agreement with the manufacturer before adopting a drug in this way, and Rule 84E makes the marketer responsible for the quality of the drug and for other regulatory compliances along with the manufacturer. These provisions were inserted by the Drugs and Cosmetics (Amendment) Rules, 2020, notified by the Ministry of Health and Family Welfare vide G.S.R. 101(E) dated 11 February 2020 and in force from 1 March 2021.
- D. The Parties are therefore entering into this Agreement.

NOW THIS AGREEMENT WITNESSETH AS FOLLOWS:

1. DEFINITIONS AND INTERPRETATION

- 1.1 “Applicable Law” means the Drugs and Cosmetics Act, 1940, the Rules (including Schedule M as in force from time to time), the Drugs (Prices Control) Order, 2013 as amended from time to time, the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, and every other law, order, notification and direction of a competent authority that applies to the Products.
- 1.2 “Products” means the drugs listed in Annexure A, as changed by written agreement of the Parties.
- 1.3 “Authority” means the Central Drugs Standard Control Organisation, a State Licensing Authority, the National Pharmaceutical Pricing Authority and any other competent authority.
- 1.4 Annexures A to C form part of this Agreement. If a clause conflicts with an Annexure, the clause prevails unless the Annexure expressly says otherwise.

2. PURPOSE AND ADOPTION OF THE PRODUCTS

- 2.1 The Manufacturer shall manufacture and supply the Products to “Marketed By”, and “Marketed By” may adopt the Products by labelling them with its name and address, and market them in [territory, for example India].

- 2.2 This Agreement is the agreement required by Rule 84D of the Rules.
- 2.3 Nothing in this Agreement makes either Party the partner or employee of the other.

3. MANUFACTURER'S LICENCE, GMP AND SOURCING

- 3.1 The Manufacturer warrants that it holds, and shall keep valid throughout the term of this Agreement, every licence and permission needed to manufacture the Products, and that the Products are manufactured under that licence.
- 3.2 The Manufacturer shall manufacture, test, store and release the Products in compliance with Applicable Law, including Good Manufacturing Practices under Schedule M of the Rules as revised and in force for the Manufacturer's premises.
- 3.3 The Manufacturer shall buy active pharmaceutical ingredients and excipients only from its approved vendors, shall use pharma-grade materials that meet the applicable pharmacopoeial standards, and shall keep records of that sourcing and of the testing of the materials.
- 3.4 The Manufacturer shall inform "Marketed By" in writing within [7] days of:
 - (a) any inspection observation, show-cause notice, suspension, cancellation or restriction affecting its licence or the Products; and
 - (b) any declaration that a batch of the Products is not of standard quality, spurious or adulterated.
- 3.5 [Optional] "Marketed By" may, on [7] days' notice and during working hours, audit the Manufacturer's premises, records and quality system in relation to the Products, not more than [once] a year, except after an event under clause 3.4 or a complaint about a Product.

4. LABELLING AND ARTWORK

- 4.1 The name of the Manufacturer, with its complete address and manufacturing licence details, shall appear on all goods supplied by the Manufacturer.
- 4.2 The name of "Marketed By", with its complete address, shall appear on all goods supplied by the Manufacturer, as "Marketed By", in the manner Rule 96 of the Rules requires of a marketer.
- 4.3 "Marketed By" shall maintain the address printed on the products and ensure that any communication sent to that address is duly received and is not refused or returned undelivered for any reason. If a communication is refused or not delivered, the address to which the Manufacturer raises its invoice on "Marketed By" shall be treated as the address of "Marketed By" for all purposes.
- 4.4 "Marketed By" shall give the Manufacturer approved label and carton artwork, and the Manufacturer shall print only approved artwork. Each Party shall make sure that the label particulars it is responsible for comply with Applicable Law, including the maximum retail price statement required by the Drugs (Prices Control) Order, 2013 and any bar code or QR code requirement that applies to a Product (for example under Schedule H2 of the Rules).

5. TRADE MARKS, DESIGN AND INTELLECTUAL PROPERTY

- 5.1 "Marketed By" is solely responsible for the trade marks and brand names (registered or unregistered), company name, logo, pack design, artwork, colour pattern and promotional material it adopts on the goods, and these remain the property of "Marketed By" only.
- 5.2 If any brand name, pack design, artwork or colour pattern clashes with that of any other person, the Manufacturer shall discontinue manufacture of the disputed product, and "Marketed By" alone shall be responsible for any violation of the Drugs and Cosmetics Act, the Trade Marks Act, 1999, the Designs Act, 2000 or the Copyright Act, 1957.

6. SUPPLY, QUALITY AND STORAGE

- 6.1 The Manufacturer shall supply the Products to “Marketed By” on the terms in Annexure B and otherwise on mutually agreed terms, against the confirmed purchase orders of “Marketed By”.
- 6.2 The quality of the Products as manufactured is the responsibility of the Manufacturer. Each batch shall be supplied with a certificate of analysis and shall conform to the specifications approved for the Product and to its label claim until expiry, when stored as labelled.
- 6.3 Maintaining the storage conditions stated on the label until the end of the shelf life, including protection against chipping, crushing, transit damage, excessive heat, moisture, seepage or leakage after the goods leave the Manufacturer’s premises, is the sole responsibility of “Marketed By”, and the Manufacturer shall not be held responsible for such deterioration. This clause does not apply to a defect that existed when the goods left the Manufacturer’s premises or that arose from improper packing by the Manufacturer.
- 6.4 The Manufacturer shall keep batch records and retention samples for the period Applicable Law requires, and shall make them available to “Marketed By” and to any Authority on request.

7. REGULATORY RESPONSIBILITY AND COOPERATION

- 7.1 The Parties acknowledge that under Rule 84E of the Rules a marketer who sells or distributes a drug is responsible for its quality and other regulatory compliances along with the manufacturer, and that this Agreement cannot limit what an Authority may do against either Party.
- 7.2 Each Party shall cooperate fully with any inspection, sampling, query or investigation by an Authority relating to a Product, and shall give the other Party the documents and access it reasonably needs, within [3] working days of a request, or sooner if the Authority sets an earlier date.
- 7.3 Each Party shall inform the other within [2] working days of any complaint, adverse-event report, sample failure or Authority communication concerning a Product.
- 7.4 As between the Parties, the cost of any such matter is allocated by clauses 8, 9 and 12.

8. RECALL, EXPIRY AND DISPOSAL

- 8.1 Where a recall of a Product is required by an Authority or decided by the Parties, “Marketed By” shall conduct the recall and the Manufacturer shall assist it.
- 8.2 [OPTION A: as in the 2021 format. Strike this out if you choose Option B.] Any recall of a drug or fixed-dose combination (including on a ban), the expiry of any drug and its disposal under pollution-control norms are the exclusive responsibility of “Marketed By”. The Manufacturer shall not be responsible for expired goods or their disposal under any circumstances.
- 8.2 [OPTION B: allocation by cause. Strike this out if you choose Option A.] The cost of a recall shall be borne by the Manufacturer where the recall results from a manufacturing defect, a failure to comply with clause 3, or a breach of this Agreement by the Manufacturer, and otherwise by “Marketed By”. The expiry of any Product and its disposal under pollution-control norms shall be the responsibility of “Marketed By”.

9. PRICE CONTROL

- 9.1 Where any amount is claimed or recovered under the Drugs (Prices Control) Order, 2013, as amended from time to time (including an overcharged amount with interest, or any amount payable to the Drugs Prices Equalisation Account), on account of the price, MRP or pack instructions given by “Marketed By”, that amount shall be payable by “Marketed By” only.
- 9.2 Where such a claim arises from an error of the Manufacturer in printing the MRP, or in issuing a price list or notice that the Manufacturer is responsible for, the Manufacturer shall bear it.

- 9.3 Each Party shall keep, and give the other on request, the price lists, notices and batch-wise production and distribution records that the Order requires of it, so that either Party can show compliance to an Authority.
- 9.4 The Parties acknowledge that the Order may allow an Authority to proceed against either Party. This clause allocates cost between the Parties only.

10. ADVERTISING AND PROMOTION

- 10.1 Advertising or promotion of any Product or brand in the Indian market is the exclusive responsibility of “Marketed By”, who shall comply with the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, the Uniform Code for Pharmaceutical Marketing Practices 2024 (as amended or replaced from time to time) and every other law that applies to such promotion.
- 10.2 “Marketed By” shall not make any claim about a Product that is not supported by the approvals and the label of that Product.

11. PACKING MATERIAL, DEVELOPMENT COST AND INVENTORY

- 11.1 “Marketed By” shall bear the cost of packing material, one-time development cost and inventory, including on switching off any Product, and shall settle these costs with the Manufacturer as set out in Annexure B or otherwise on mutually agreed terms.
- 11.2 The Manufacturer shall keep a record of the packing material it holds for “Marketed By” and shall share it on request.

12. INDEMNITY

- 12.1 Each Party (the “Indemnifying Party”) shall indemnify the other against losses, penalties, costs and reasonable legal fees that the other suffers because of a breach of this Agreement or of Applicable Law by the Indemnifying Party, or because of a matter for which this Agreement makes the Indemnifying Party responsible.
- 12.2 The indemnity does not apply to the extent the loss is caused by the act or omission of the Party claiming it.
- 12.3 [Optional] The total liability of each Party under this clause shall not exceed [amount, or the value of Products supplied in the preceding 12 months]. This limit does not apply to liability that cannot be limited under Applicable Law.
- 12.4 This clause allocates cost between the Parties and does not limit the powers of any Authority.

13. CONFIDENTIALITY

- 13.1 Each Party shall keep confidential the non-public commercial, technical and formulation information of the other that it receives under this Agreement, shall use it only for the purposes of this Agreement, and shall disclose it only to those who need it, or as required by law or by an Authority. This obligation continues for [3] years after this Agreement ends.

14. TERM AND TERMINATION

- 14.1 This Agreement is valid for a period of [3] years from the Effective Date and shall thereafter stand renewed for a further period of [3] years.
- 14.2 Either Party may terminate this Agreement during its existence by giving a minimum of [90] days’ written notice.
- 14.3 Either Party may terminate this Agreement at once by written notice if a licence of the other Party that is needed for the Products is cancelled or suspended, or if the other Party commits a material breach and does not remedy it within [30] days of notice.

- 14.4 On termination, goods and packing material shall be taken back or settled as set out in Annexure B. Rights that have accrued, and clauses 7, 8, 9, 12, 13 and 15, continue after termination.

15. GOVERNING LAW AND DISPUTES

- 15.1 This Agreement is governed by the laws of India.
- 15.2 **[OPTION A: courts, as in the 2021 format. Strike this out if you choose Option B.]** In case of any dispute between the Parties, the competent court at **[district / city of the Manufacturer]** shall have jurisdiction, to the exclusion of any other court in India.
- 15.2 **[OPTION B: arbitration. Strike this out if you choose Option A.]** Any dispute arising out of this Agreement shall be referred to a sole arbitrator appointed by mutual consent under the Arbitration and Conciliation Act, 1996. The seat of arbitration shall be **[city]** and the language shall be English. The courts at **[city]** shall have exclusive jurisdiction for matters in aid of arbitration.

16. GENERAL

- 16.1 Notices under this Agreement shall be in writing and sent to the addresses stated in this Agreement, subject to clause 4.3.
- 16.2 This Agreement, with its Annexures, is the entire agreement of the Parties on its subject and may be changed only in writing signed by both Parties.
- 16.3 Neither Party may assign this Agreement without the written consent of the other.
- 16.4 If any provision is held invalid, the rest of this Agreement continues in force.
- 16.5 This Agreement shall be executed on stamp paper or e-stamp of the value required by the stamp law of the State where it is executed. The stamp duty shall be borne by **[Marketed By / the Manufacturer / equally]**.
- 16.6 This Agreement may be signed in counterparts, each of which is an original.

IN WITNESS WHEREOF the Parties have signed this Agreement, or have had it signed by an authorised signatory under a resolution, on the date first written above, in the presence of the witnesses named below.

For “Marketed By” Name: Designation: Address: Authorised signatory:	For the Manufacturer Name: Designation: Address: Authorised signatory:
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In the presence of two witnesses:

1. Name: Address: Signature:	2. Name: Address: Signature:
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ANNEXURE A: PRODUCTS

Add one row for each Product. Attach a copy of the Manufacturer’s product permission or licence page if you wish.

S. No.	Product (name, dosage form, strength)	Composition	Brand name	Pack size	Permission or licence reference
1					
2					
3					
4					

ANNEXURE B: COMMERCIAL TERMS

Item	Agreed term
Supply price and basis (for example ex-works)	
Minimum order quantity and batch size	
Lead time from confirmed purchase order	
Payment terms	
Packing material and one-time development cost (item, amount, who pays)	
Stock and packing material on termination or switch-off	
Transport and storage after dispatch	Responsibility of “Marketed By” under clause 6.3

ANNEXURE C: WHO DOES WHAT

A summary for convenience. If it differs from a clause, the clause prevails.

Activity	Manufacturer	“Marketed By”
Valid manufacturing licence and GMP compliance (clause 3)	Responsible	May audit (clause 3.5)
Manufacture, testing and release of each batch (clause 6.2)	Responsible	
Label and carton artwork (clause 4.4)	Prints approved artwork	Supplies and approves artwork
Name and address of the marketer on the label (clause 4.2)	Prints	Provides the details
Maximum retail price and price instructions (clause 9)	Prints as instructed; bears own errors	Gives the instructions
Storage and transit after the goods leave the factory (clause 6.3)		Responsible
Trade marks, design and promotional material (clause 5)		Responsible
Advertising and promotion (clause 10)		Responsible
Recall (clause 8)	Assists; bears cost under Option B where at fault	Conducts; bears cost under Option A
Cooperation with inspections and complaints (clause 7)	Both Parties	Both Parties
Batch records and retention samples (clause 6.4)	Keeps	May inspect

WHAT CHANGED SINCE THE 2021 FORMAT (guidance, leave out of the signed copy)

Each row shows a change found in the sources reviewed and where this edition reflects it. Statements about 2025 and 2026 events come from news and law-firm reports; confirm them against the official notifications.

No.	Change	Source reviewed	Where reflected
1	Revised Schedule M notified in December 2023. The compliance deadline was 31 December 2025 for MSME manufacturers with an approved extension (G.S.R. 127(E), 11 February 2025). In November 2025 CDSCO asked state regulators to plan inspections.	Business Standard (CDSCO inspections, Nov 2025); CliniExperts (G.S.R. 127(E))	Clause 3 (licence, GMP); clause 14.3
2	Bar code or QR code on labels of the Schedule H2 (top 300) brands: G.S.R. 823(E) dated 17 November 2022, from 1 August 2023.	CliniExperts	Clause 4.4
3	CDSCO advisory of December 2023: use pharma-grade excipients from approved sources and vendors. This is advice, not a rule.	RAPS Regulatory Focus	Clause 3.3
4	Uniform Code for Pharmaceutical Marketing Practices 2024, issued by the Department of Pharmaceuticals on 12 March 2024.	Press Information Bureau	Clause 10.1
5	DPCO 2013 amended on 30 June 2026 (reported as S.O. 3516(E)): paragraph 14(2) now limits a manufacturer's overcharging liability to stock traded through the distributor or retailer found to have overcharged, where price-dissemination compliance is shown.	Medical Dialogues; Business Standard	Clause 9
6	Rules 84D and 84E: no later amendment found in the sources reviewed. The rule text comes from G.S.R. 101(E) dated 11 February 2020, in force from 1 March 2021.	TeamLease RegTech; Legitquest; Khaitan & Co.	Recital C; clauses 2 and 7

Corrections to the 2021 format. The earlier Clause 1 gave the gazette date as 11-02-2021; the notification is dated 11 February 2020. "Equal responsibility" is now "along with the manufacturer", the wording of Rule 84E. The earlier text said the 2021 guidelines require the clauses it listed; the sources reviewed do not list mandatory clauses.

Commercial choices, not law. The 3 + 3 year term, 90 days' notice, the court at the manufacturer's district, and who bears recall cost are negotiable. Clause 8.2 and 15.2 give you two options each.

Sources. teamleaseregtech.com (article 8062); legitquest.com (Drugs and Cosmetics (Amendment) Rules, 2020); khaitanco.com (contract manufacturing and marketers); business-standard.com (Schedule M inspections, Nov 2025; DPCO, 2 July 2026); cliniexperts.com (G.S.R. 127(E); bar code or QR code); raps.org (CDSCO excipients advisory); pib.gov.in (UCPMP 2024); medicaldialogues.in (DPCO amendment).

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