PUBLIC SERVANTS, PROCESS AND TIME: A CASE COMMENT ON STATE OF KERALA V. M/S PANACEA BIOTEC LTD. (2026 INSC 200)

by

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Case Commented On: *State of Kerala & Anr. V. M/S Panacea Biotec Ltd. & Anr.*, 2026 Insc 200 (Supreme Court Of India, 26 February 2026, Ahsanuddin Amanullah And S.V.N. Bhatti Jj.)

ABSTRACT

In *State of Kerala v. M/s Panacea Biotec Ltd.*, the Supreme Court restored a prosecution for misbranding a pentavalent vaccine under the Drugs and Cosmetics Act, 1940, which the Kerala High Court had quashed because the Magistrate did not hold the inquiry required by section 202 of the Code of Criminal Procedure, 1973. The Court held that limitation under section 469(1)(c) runs from the date on which the offenders' identity is established through the inspector's verification, and that a complaint by a public servant in discharge of official duty is not vitiated by want of a section 202 inquiry. It also held that whether directors are in charge of a company under section 34 of the Drugs Act is a question of fact for trial. This comment argues that the reasoning on limitation sits uneasily with the offender specific wording of section 469, that reading section 200 into section 202 conflates two different safeguards, and that substituting accused persons twenty years after the events raises fairness questions the Court left unexamined.

Keywords: section 202 Code of Criminal Procedure, public servant complainant, limitation, Drugs and Cosmetics Act, misbranding, vicarious liability, Bharatiya Nagarik Suraksha Sanhita.

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I. Introduction

Regulatory prosecutions seldom reach the Supreme Court on the merits of the regulatory wrong. They arrive on preliminary objections: the complaint is late, the Magistrate skipped a procedural step, or the company's officers cannot be made to answer. *State of Kerala v. M/s Panacea Biotec Ltd.* is such a decision.[2] The allegation concerns a vaccine for infants, but the questions decided concern procedure and time, and the same defences are raised in food safety, environmental and other regulatory prosecutions. The product at issue is a five-in-one vaccine that protects against diphtheria, pertussis, tetanus, hepatitis B and *Haemophilus influenzae* type b.[3] India's public Universal Immunisation Programme began using the pentavalent vaccine only in December 2011, first in Kerala and Tamil Nadu, years after the events in this case.[4]

II. Facts and Procedural History

The judgment records allegations only. In October 2005 a parent, Mr Joy Mandi, was told by a Primary Health Centre in Thrissur of a labelling discrepancy. He complained to the Drugs Inspector on 5 January 2006, and the complaint was received on 16 January 2006. The allegation was that the carton described the product as a pentavalent vaccine, "Easy Five", while the vial inside was labelled as a tetravalent vaccine, "Easy Four", without the hepatitis B component. Panacea Biotec Ltd. was named as manufacturer. The Inspector inspected the retailer and firms in the supply chain, seized records and recorded statements, and on 18 April 2006 obtained certified copies of the distributors' records. No bill of purchase was on record.[5]

On 20 January 2009 the Inspector filed a complaint before the Chief Judicial Magistrate (CJM), Thrissur, against the manufacturer, its Managing Director and the supply chain under sections 18(a)(i), 17(b) and 17(c) of the Drugs and Cosmetics Act, 1940, punishable under section 27(d) with imprisonment of one to two years and a fine.[6] The CJM summoned the accused on 29 January 2009. In 2011 the High Court directed the CJM to consider condoning delay under section 473, and on 10 July 2012 the CJM did so and summoned the accused

[2] *State of Kerala v. M/s Panacea Biotec Ltd.*, 2026 INSC 200 (Supreme Court of India, 26 February 2026), arising out of SLP (Crl.) No. 4524 of 2023, heard with the appeals arising out of Diary No. 18999 of 2023 and SLP (Crl.) No. 8867 of 2023.

[3] Harish Nair, Indrajit Hazarika and Ashok Patwari, "A Roller-Coaster Ride: Introduction of Pentavalent Vaccine in India", 1(1) *Journal of Global Health* 32 (2011), https://pmc.ncbi.nlm.nih.gov/articles/PMC3484747/.

[4] GAVI Alliance, "Nation-wide scale-up of Haemophilus influenzae type b (Hib) as Pentavalent vaccine in Universal Immunization Program of India: Introduction Plan v1.0" (6 January 2014), https://www.gavi.org/fr/actualites/librarie-de-documents/proposal-penta-scale-support-india-0; "Pentavalent vaccines: A new era in immunization", *BioSpectrum India*, https://biospectrumindia.com/news/95/4345/pentavalent-vaccines-a-new-era-in-immunization.html.

[5] *Panacea Biotec*, paras 3 to 6 and 9.

[6] Drugs and Cosmetics Act, 1940, ss. 17(b), 17(c), 18(a)(i) and 27(d); Drugs and Cosmetics Rules, 1945, r. 96.

again. On 14 July 2022 a Single Judge quashed the complaint for want of the section 202 inquiry, without disturbing the limitation finding. The Managing Director had died by the time of appeal.[7]

Two companion matters were heard together. The manufacturer's cross appeal pressed limitation. In the third, a Drugs Inspector had drawn syringe samples in 2014, the Government Analyst had reported them not of standard quality, and the complaint against the company and two directors was quashed by the High Court for non compliance with section 202 and for insufficient averments under section 34.[8]

III. Issues and Decision

1. From which date did limitation run, and was the complaint in time?
2. Was a complaint by a Drugs Inspector vitiated by the Magistrate's failure to hold a section 202 inquiry against accused residing outside his jurisdiction?
3. Could the complaint against directors be quashed at the threshold under section 34?

Ahsanuddin Amanullah J, for the Bench with S.V.N. Bhatti J, allowed the State's appeal and dismissed the manufacturer's.

Limitation. The offence carries a maximum of two years, so the period is three years. Under section 469(1)(c), where the offender's identity is not known, time runs from the first day it becomes known. The Court held that the complaint of 5 January 2006 began a verification process, that the identity of all the accused was before the competent authority on 18 April 2006, and that the complaint of 20 January 2009 and cognisance on 29 January 2009 were within three years. It called the intervening period an "inordinate delay", and held the High Court's earlier computation from 21 October 2005 wrong, though academic.[9]

Section 202. The Court read section 202 harmoniously with section 200, whose proviso exempts a written complaint by a public servant acting in official duty from examination of the complainant. Relying on *Cheminova*, which places the public servant on a different pedestal, it rejected the attempt to distinguish that case, distinguished *Birla Corporation* as a private complaint, and added, "to complete the loop", that the accused seller resided within the Magistrate's jurisdiction.[10]

[7] *Panacea Biotec*, paras 10 to 13 and 43.
[8] *Id.*, paras 51 to 54.
[9] *Id.*, paras 33 and 36.
[10] *Id.*, paras 38 to 41; *Cheminova India Ltd. v. State of Punjab*, (2021) 8 SCC 818; *Birla Corporation Ltd. v. Adventz Investments and Holdings Ltd.*, (2019) 16 SCC 610.

Directors and relief. Whether the directors were in charge of and responsible to the company was a question of fact for trial. In the vaccine matter, since the Managing Director had died and two respondents were companies, the Court directed that on the prosecution's application the trial court array the persons in charge at the relevant time and issue fresh summons, cautioning that its findings were confined to the facts.[11]

IV. Critical Analysis

A. Limitation and the identity of the offender

Treating an informant's complaint as not starting the clock is a defensible policy, since an inspector tracing a product through a supply chain cannot file against unnamed persons. The reasoning raises three difficulties.

First, section 469 runs time "in relation to an offender", so each accused has a date of his own.[12] The Court fixed one date for all. Yet the carton and vial both named Panacea Biotec as manufacturer, so for the manufacturer it is arguable that identity was known at the outset, and that section 469(1)(b), knowledge of the offence, was the apt starting point. On the High Court's computation from 21 October 2005 the complaint was well out of time, and even from receipt on 16 January 2006 it was a few days late, leaving the outcome to depend on condonation. The Court did not examine this.

Second, the Court said the State acted correctly "by virtue of" section 32 of the Act. Section 32 says who may prosecute, not when time begins.[13] Third, the Court itself called the two years and nine months between verification and complaint inordinate, yet the complaint fell within the period by under three months. A regulator told that time runs from the end of its verification has little incentive to hurry. Section 473 offers the better route, since the CJM had condoned delay and the public health interest was strong,[14] but deciding under section 469(1)(c) made condonation academic and widened the limitation rule.

The reach of such a rule is wide, because drug regulators prosecute in large numbers. The Minister of State for Health told the Rajya Sabha on 2 December 2025 that 961 prosecutions were launched in 2024-25 for manufacturing, selling and distributing spurious and adulterated drugs, up from 604 in 2023-24, in a year in which 1,16,323 drug samples were tested.[15] The

[11] *Panacea Biotec*, paras 43, 57 to 60.
[12] Code of Criminal Procedure, 1973, ss. 468(2)(c) and 469(1); *Panacea Biotec*, para 36.
[13] *Panacea Biotec*, para 33.
[14] Code of Criminal Procedure, 1973, s. 473.
[15] "Prosecutions for spurious drugs hit five-year high in 2024-25 even as detections fall", *South First* (3 December 2025), https://thesouthfirst.com/news/prosecutions-for-spurious-drugs-hit-five-year-high-in-2024-25-

reported figures are for spurious and adulterated drugs and not for misbranding, the charge here, but they show the scale at which these regulators bring complaints.

B. Section 202 and the public servant

The Court said section 202 must be "construed harmoniously" with section 200. That assumes the two protect the same interest. They do not. Section 200 concerns evidence: it spares an official the burden of oral examination because an official complaint rests on records.[16] Section 202, as amended in 2005, concerns filtering: it requires the Magistrate to apply his mind to whether grounds exist before summoning a person who lives far away and is least able to resist a mechanical summons.[17] That protection is the same whoever the complainant is, and arguably matters more where an official complaint is presumed reliable. The amendment took effect on 23 June 2006, and the note to the amending Bill explained that false complaints were being filed against persons living at far off places simply to harass them.[18] The Drugs Inspector's complaint in this case was filed in January 2009, after that change. Parliament, amending section 202 with section 200 before it, added no exception for public servants. The Court's answer, that the legislature has itself placed the public servant on a different pedestal, is true of section 200. Whether it travels to a provision strengthened for the absent accused is the real question, and it was not squarely addressed.

The respondents' strongest point was that in *Cheminova* a Government Analyst's report corroborated the complaint, whereas here there was no report and no bill of purchase. The Court brushed this aside by reference to the "clear enunciation" in *Cheminova*, though the exemption there was tied to the reliability of official material. In fairness, the complaint here rested on seizures, statements and supply chain records, and the Court cautioned that its conclusions are confined to the facts.[19] The decision is best read as holding that where an official complaint rests on a documented official enquiry, absence of a section 202 inquiry does not by itself justify quashing under section 482, not that every inspector's complaint is

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even-as-detections-fall/.

[16] Code of Criminal Procedure, 1973, s. 200, proviso (a).

[17] Code of Criminal Procedure, 1973, s. 202(1), as amended by Act 25 of 2005; *Vijay Dhanuka v. Najima Mamtaj*, (2014) 14 SCC 638.

[18] "Mandatory Enquiry/Investigation U/S 202 CrPC Before Issuing Process Is To Filter False Cases: Allahabad HC", *Verdictum*, https://www.verdictum.in/court-updates/high-courts/allahabad-high-court-r-shankar-raman-whole-time-director-and-chief-financial-officer-v-state-of-up-2024ahc-lko32822-section-202-crpc-mandatory-for-court-to-conduct-enquiry-1533248; Tax Management India, case law summary on s. 202(1) Cr.P.C. and the Criminal Procedure Code (Amendment) Act 2005, https://taxmanagementindia.com/visitor/Detail_Case_Laws.asp?ID=195817.

[19] *Panacea Biotec*, para 42.

immune. The "complete the loop" remark should be read the same way: section 202 concerns each accused residing outside the area.

C. Substituting accused and section 34

The direction to array persons in charge of the companies and issue fresh summons means that persons never named will answer for events more than twenty years old. The Court did not consider whether limitation affects the addition of accused, how the prosecution will identify them, or the effect of delay on their defence and on speedy trial under Article 21. Delay of this kind is not peculiar to this case: an August 2026 report put the number of cases pending in Indian courts at more than 5.03 crore, and said more than 10,000 had been pending in the Supreme Court for over ten years.[20] A rule that gives regulators time at the start can produce unfairness at the end.

On section 34, the Court held the High Court premature in quashing for want of averments. Yet the Court's decisions on vicarious liability require specific averments on a director's role, and have quashed complaints where they were absent.[21] The Court did not say whether the averments here met that standard, leaving unclear how far that case law applies to the Drugs Act.

V. The New Procedural Code

The Bharatiya Nagarik Suraksha Sanhita, 2023, in force from 1 July 2024, carries these provisions into sections 223 and 225.[22] The limitation provisions applied in this case also continue in the new Code, as sections 514, 515 and 519 of the BNSS, which correspond to sections 468, 469 and 473 of the Code of Criminal Procedure.[23] The question of when time starts against a regulator will therefore arise again under the new Code. Section 223 adds a requirement that cognisance not be taken without hearing the accused. If that applies to public servants' complaints, the question decided here will recur in a new form, since a right to be heard before cognisance sits more naturally with the section 202 inquiry than with oral examination of the complainant.

[20] "10,000 cases pending in SC for over 10 yrs, 80k in HCs for over 30 yrs", *Business Standard* (3 August 2026), https://www.business-standard.com/india-news/10000-sc-cases-pending-over-10-years-80000-hc-cases-over-30-years-126080300335_1.html.

[21] See *S.M.S. Pharmaceuticals Ltd. v. Neeta Bhalla*, (2005) 8 SCC 89; *Sunil Bharti Mittal v. Central Bureau of Investigation*, (2015) 4 SCC 609.

[22] Bharatiya Nagarik Suraksha Sanhita, 2023, ss. 223 and 225.

[23] "Limitation for Taking Cognizance of Certain Offences", *Drishti Judiciary*, https://drishtijudiciary.com/to-the-point/bharatiya-nagarik-suraksha-sanhita-&-code-of-criminal-procedure/limitation-for-taking-cognizance-of-certain-offences; "Section 519 of BNSS, 2023: Extension of Period of Limitation in Certain Cases", *Lexibal*, https://lexibal.com/?p=46364.

The Supreme Court has since read the hearing requirement strongly. In *Parvinder Singh v. Directorate of Enforcement*, decided on 19 May 2026, a Bench of M.M. Sundresh and N. Kotiswar Singh JJ. held that the first proviso to section 223(1) is substantive and mandatory, forms part of the fair trial guarantee under Article 21, and that cognisance taken without hearing the accused is void, even where the complaint was filed before 1 July 2024.[24] The complaint there was a prosecution complaint filed by the Enforcement Directorate, and a former Judge of the Jharkhand High Court has written that the ruling will carry the pre-cognizance hearing into official complaints and may delay cases under special statutes.[25]

VI. Conclusion

The decision gives regulators assurance: a complaint begun by an informant will not be time barred merely because it was received years earlier, and a Magistrate's omission of a section 202 inquiry will not defeat an official complaint. But it adopts a single limitation date although section 469 speaks of the offender, extends a protection designed for examination of a complainant to one designed for the absent accused, and permits substitution of accused two decades on without weighing fairness. None of this denies the result on facts concerning a serious public health matter and a documented enquiry. The decision should be treated, as the Court cautioned, as fact bound, and future cases should address the textual and fairness questions it leaves behind. Legislative change is also pending. A Draft Drugs, Medical Devices and Cosmetics Bill, 2026, which would replace the Drugs and Cosmetics Act, 1940, was reported in August 2026 to allow an inspector, with the regulator's prior written approval, to arrest without a warrant in suspected cases of adulterated or spurious drugs, and industry associations have asked for fresh consultation because the text is largely unchanged from the drafts circulated in 2022 and 2023.[26] For regulators the lesson is that clear time limits and short preliminary scrutiny would settle in advance what took twenty years here.

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[24] "BNSS S.223(1) Proviso Mandatory; Cognizance Without Hearing Accused Void Ab Initio: Supreme Court", *LiveLaw* (21 May 2026), https://www.livelaw.in/top-stories/bnss-s2231-proviso-mandatory-cognizance-without-hearing-accused-void-ab-initio-supreme-court-535124.

[25] Gautam Kumar Choudhary, "The Erasure of Statutory Distinction: A Critical Review of Parvinder Singh v. Directorate of Enforcement", *SCC Times* (3 July 2026), https://www.scconline.com/blog/post/2026/07/03/parvinder-singh-section-223-bnss-analysis/.

[26] Sneha Richhariya, "Why medical device makers are peeved with Modi govt's new Drugs Bill", *ThePrint* (12 August 2026), https://theprint.in/health/why-medical-device-makers-are-peeved-with-modi-govts-new-drugs-bill/3012834/.