



CIRM Access Plan Review Process¹ under CIRM Regulations effective September 6, 2018

What: A Commercializing Entity selling a Drug must submit a plan to CIRM to afford access to Californians “with no other means” to purchase the Drug. “No other means”: those not covered by a prescription drug benefit provided by any third-party payer (private or public) covering the Drug, and whose family incomes are below 300 percent of the federal poverty level.

When: Plan must be submitted within 10 business days following final FDA approval (unless extension is sought).² The plan may also be waived by the ICOC, as described further below.

Access Plan Scope: 1) Consistent with industry standards, 2) at the time of commercialization, 3) accounting for the size of both a) the market for the drug, and b) the resources of the company.³

CIRM Approval of the Plan: Plan is subject to approval by CIRM after a “public hearing” that “provides for receipt of public comment.”

Confidential components of the Plan: Proposition 71 protects from disclosure any documents containing or reflecting confidential intellectual property or work product. This exemption is intended to protect the interests of

¹ This primer is intended to introduce the reader to concepts contained in CIRM’s IP revenue sharing regulations. It is a summary only, and does not override or replace the regulations and should not be relied upon as legal advice regarding the operation of the regulations. Please review CIRM regulations and contact CIRM if you have questions about our rules or their application.

² Extension request must be submitted within the 10 days following FDA approval. An extension provides no more than 30 business days from FDA approval.

³ Burden on company to establish the plan satisfies these requirements.

both CIRM and submitters of information. Its very existence encourages submitters to voluntarily furnish useful commercial or financial information to CIRM and it correspondingly provides CIRM with an assurance that such information will be reliable. The exemption also affords protection to those submitters who are required to furnish commercial or financial information to CIRM by safeguarding them from the competitive disadvantages that could result from disclosure.

Accordingly, to the extent a company feels certain information or components of the Plan constitute confidential intellectual property or work product, the company should identify that information as such upon submission of the Plan and explain why it should be protected from disclosure under applicable law. CIRM will review the identified information and evaluate whether it meets the definition of protected records as provided in Proposition 71 and the Public Records Act and ensure confidential material is not shared publicly. If CIRM determines that information identified as “confidential” does not satisfy the applicable legal standard, it will notify the submitter and offer the submitter an opportunity to withdraw the original submission and submit a new one.

- 1) Upon receipt, and after evaluating any information identified as “confidential” (as described above), CIRM will post the non-confidential portions of the Plan on its website and schedule a 7 business-day public comment period. Interested parties may submit comment in written form via email to a dedicated email address, or by physical delivery to CIRM via the usual means.
- 2) CIRM will also schedule a time on the last day of the comment period to receive comment in person. Oral submissions will be recorded.
- 3) CIRM will adopt procedures to protect proprietary information submitted and identified as such by Company.
- 4) CIRM will render its decision to approve or disapprove the Plan within 5 business days after the close of the public comment period.

Petition for Waiver: The ICOC may waive the Plan requirement if, after a public hearing, the ICOC determines that in the absence of a waiver the development and delivery of the Drug will be unreasonably hindered, or that the waiver will provide significant benefits that equal or exceed the benefits that would otherwise flow to the state pursuant to the Plan. The petition to the Chair of the

ICOC must be submitted within 10 days of FDA approval, unless the Chair grants an extension. The burden rests with the petitioner to establish the standard is met. The petition will be posted on CIRM's website at the same time the Notice of the Board's meeting to consider the request is posted.