POLICY AND REQUIREMENTS FOR AVAILING OF COMPASSIONATE SPECIAL PERMIT (CSP) FOR RESTRICTED USE OF UNREGISTERED DRUG AND DEVICE PRODUCT/PREPARATION

Read online (full-text search, related cases, audio case brief): https://batas.org/library/b8881ee7f98c/

The Bureau of Food and Drugs (BFAD) recognizes the need for drugs and devices product/preparation which are not registered, or are in the process of registration in the Philippines by patients who are terminally or seriously ill. Access to these products for these patients is morally, socially, and ethically justified when there is no existing superior alternative therapy that can likely cure or adequately control their conditions.

Therefore, the BFAD shall henceforth provide for a Compassionate Special Permit for Restricted Use of Unregistered Drugs and Devices Product/Preparation when the conditions and requirements specified hereunder exist and are complied with.

A Compassionate Special Permit for Restricted Use of Unregistered Drug and Devices Product shall refer to a special permit signed by the BFAD Director granting a Specialized Institution (SI) and Specialty Society (SS) the privilege to avail of an unregistered drug and device product through a certain licensed establishment for certain kind/type of patients, specified volume, and period.

I

A specialized Institution/Specialty Society shall file a request for CSP only for patients suffering from the following conditions:

1. Acquired Immune Deficiency Syndrome (AIDS)

2. Cancer

3. Life-threatening conditions

The application shall include the estimated volume needed and the licensed drug/device establishment through which the unregistered drug may be procured.

It shall also identify the names and addresses of the specialists qualified and authorized to use the product.

II

Requirements

1. A written commitment on the part of all the authorized specialists to submit a Clinical Study Report for every patient given the product describing the quantity administered/use, therapeutic/desired effect and any adverse reaction, to the Institution or Specialty Society for BFAD, at the end of each year.

2. An estimate of the total requirement of the product for one year.

3. A waiver of BFAD responsibility from any damage or injury arising from the use of the unregistered drug or device to be signed by the responsible official of the institution or Specialty Society.

Turn this case into an audio lecture - facts, issues, ruling and doctrine - at batas.org

III

The specified drug establishment shall secure clearance to import from BFAD and its applications shall be accompanied by:

a. A certification that the product is currently registered in the country of origin.

b. a true copy of the CSP issued to the Specialized Institution (SI)/Specialty Society (SS).

IV

A. The SI/SS shall submit the Clinical Study Reports through the drug/device establishment at the end of the year.

B. The drug/device establishment shall be responsible for the submission of the Clinical Study Reports from the SI/SS and the report of the total volume of the drug/device imported for the year.

Failure on its part to submit these reports will be a ground to deny applications of CSP through or using its establishment and/or future applications for import clearances of the unregistered drug/device under a valid CSP.

This Order shall take effect fifteen (15) days after its publication in a newspaper of general circulation.

Adopted. 16 Nov. 1992

(Sgd.) JUAN M. FLAVIER, M.D., M.P.H.
Secretary of Health

Bar review courses, mock exams and a study planner that keeps you on pace - batas.org

ABOUT BATAS.ORG

Study smarter at BATAS.org

The Philippine bar review and law-school companion built around how your brain actually remembers.

The complete Philippine law library - free for everyone.

More than 100,000 Supreme Court decisions, Republic Acts, and executive issuances - full-text searchable, browsable by category and year, and always free. No paywall, no login. This PDF came from it.

Audio case-brief lectures.

Any decision becomes a podcast-style lecture - facts, issues, ruling, and doctrine - with read-along highlighting and a hands-free presentation mode. Study while commuting, working out, or resting your eyes.

Bar review built on the science of memory.

Complete, sequenced courses for all eight bar subjects, narrated like podcasts and reinforced with retrieval practice and spaced review - the study techniques with the strongest evidence behind them.

The full law-school curriculum.

One subscription unlocks the entire J.D. curriculum - every subject, every lesson, with your progress tracked down to the paragraph so you can pick up exactly where you left off, on any device.

Mock exams that tell you where you stand.

Timed multiple-choice exams graded instantly, with per-subject score breakdowns and focus suggestions that point you at your weakest topics first.

A study planner that keeps you on pace.

Set your schedule and BATAS tells you every day whether you are on track for bar day - and exactly which lesson to take next.

Start free at https://batas.org

The law library is free forever - and your first lesson is one click away.

The text of this document is an official public record and remains in the public domain. Formatting, presentation, and compilation © 2026 batas.org.

Downloaded free from the batas.org Law Library. Share it freely - the library is free for every law student, bar reviewee, and practitioner.