DEcision flowchart for competent authorities for the control of IVMPs

IVMP
Released by MAH

CA of the MS requires additional systematic control of each batch before release?

YES

Risk assessment by the CA of the MS suggests repeat physical testing by the CA required?

NO

ASK for OBPR
Article 81 Procedure

MAH notified; network informed
OBPR certificate accepted
Voluntary Mutual Recognition by all (EU/EEA + MRA partners)*
* OCABR certificate also recognised – exceptional cases (see to right)

All Member States rely on: GMP inspections/periodic document control/post market testing to monitor MAH control tests for a given IVMP;

If no other indication is given to the MAH by the Competent Authority then:

Direct release on to the market

These activities should be coordinated within the EU/EEA to avoid unnecessary duplication of effort

Nevertheless a MS may decide on a case by case basis that OCABR is required for a non-shortlisted product for demonstrated reasons of human or animal health.

Article 81 Procedure
The majority of IVMPs should fall in this category

Article 82 Procedure
A small number of selected IVMPs with higher risk fall in this category

Exceptional cases: should only be a minimal number of examples

ASK for OCABR
Article 82 Procedure
Restricted test list

MAH notified; network informed
Only OCABR certificate accepted
Legally Bound Mutual Recognition by all (EU/EEA + MRA partners)

SHORTLIST of Higher Risk IVMPs
Codified guidelines developed for a common approach to restricted test list

Common agreement by concerned MSs on need to test?

YES

NO

MAH notified; network informed
In the case where there is no agreement among the concerned Member States on a reduced testing scheme for an IVMP for which a Member State nevertheless requires application of Article 82, paragraph 3 of said article requires that the OMCL performing OCABR repeats all of the tests carried out by the manufacturer on the finished product, in accordance with the relevant marketing authorisation. OCABR certificate mutually recognised by all.

ARTICLE 82 OCABR = MAY CLAUSE

No MS is obliged to require OCABR and may choose to apply the Article 81 procedure to shortlisted IVMPs instead. However a harmonised approach by all MSs would be preferred.

The decision by a MS should be applied systematically to all batches received by that MS for a given product.

Note that if OCABR is requested by another MS an OBPR certificate can not replace an OCABR certificate.

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