European Medicines Agency
Evaluation of Medicines for Human Use

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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

DRAFT

APPENDICES[a] TO

GUIDELINE ON EPIDEMIOLOGICAL DATA ON BLOOD TRANSMISSIBLE INFECTIONS

(EMEA/CPMP/BWP/125/04 Rev.1)

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TABLE OF CONTENTS: Tabular Format for the Reports on Epidemiological Data

[a] This document contains the Annexes to the Guideline on the Scientific Data Requirements for a Plasma Master File (PMF) Rev. 1

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1. "FIRST TIME TESTED DONOR" POPULATION

Results of NAT testing without confirmation and results of additional screening tests such as anti HBc should each be reported separately using an adapted copy of the tabular format below.

Calendar year:	No of donors tested in the given period (A)	HIV			HCV			HBV		
		No of positive donors		HIV Rate per 100 000 donors (B+C)/A x 100 000	No of positive donors		HCV Rate per 100 000 donors (D+E)/A x 100 000	No of positive donors		HBV Rate per 100 000 donors (F+G)/A x 100 000
		HIV 1/2 Antibody (B)	HIV 1 NAT only (C)		HCV Antibody (D)	HCV NAT only (E)		HBsAg (F)	HBV NAT only (G)	
Country 1										
Organisation A responsible for collecting										
Centre 1										
Centre 2										
Summary of Organisation A										
Organisation B responsible for collecting										
Centre 1										
Centre 2										
Summary of Organisation B										
Summary per country										

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2. "REPEAT TESTED DONOR" POPULATION

Results of NAT testing without confirmation and results of additional screening tests such as anti HBc should each be reported separately using an adapted copy of the tabular format below.

Calendar year :	No of donors tested in the given calendar year (A)	No of donations in the given calendar year (B)	Donation frequency[b] (B/A)	HIV			HCV			HBV		
				No of positive donors		HIV Rate per 100 000 donors (C+D)/A x 100 000	No of positive donors		HCV Rate per 100 000 donors (E+F)/A x 100 000	No of positive donors		HBV Rate per 100 000 donors (G+H)/A x 100 000
				HIV 1/2 Antibody (C)	HIV 1 NAT only (D)		HCV Antibody (E)	HCV NAT only (F)		HBsAg (G)	HBV NAT only (H)	
Country 1												
Organisation A responsible for collecting												
Centre 1												
Centre 2												
Summary of Organisation A												
Organisation B responsible for collecting												
Centre 1												
Centre 2												
Summary of Organisation B												
Summary per country												

[b] In cases where there are two sub-sets of donors (plasmapheresis and whole blood), give the frequency of donation separately for the two sub-sets.

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3. ASSUMPTIONS AND PARAMETER VALUES AND SOURCES USED IN RISK ESTIMATION IN STUDY PERIOD

Parameters to be reported by a) value and b) source, for annual risk estimates. One table is needed for each infection, and per country etc according to Table 4.

Parameter	***Description, use***	***a) Value[c]***	***b)Source[1]*** ***(notes)***
1. No. of newly acquired infections (seroconversions) in "repeat tested donors"	Numerator for incidence.		(Ideally an exact and total count. If an estimate from a sample, this should be explained and justified. Definitions must be given for seroconversions.)
2. Person years observed in "repeat tested donors"	Denominator for incidence.		(Ideally an exact total count of days between donations. Estimates also acceptable, e.g. from a count of a representative sample of donors, or from: No. of donations from repeat donors x mean interdonation(*) interval expressed in years (*) Interdonation interval derived from counts of donations and donors.
3. Ratio of the i) mean interdonation interval for all donors to ii) median[2] interdonation interval for seroconverting donors	Check for validity of method. If this ratio is far from 1, risk estimates may be over- or under-estimates and this should be discussed.		(must be based on data from this donor population)
4. HBsAg adjustment *For HBV estimates only:* *(see Section 7.1)*	Adjustment for the effect of the transient nature of HBsAg on detection of new HBV infections in repeat donors.		(must use interdonation interval values that are true/justified for this donor population)
5. New donors *If donations from "first time tested donors" are used:* *Options* a. New donor incidence estimate b. New donor incidence adjustment. *(see Section 7.1)*	a) Incidence: To use in formula 5 to estimate new donor window period risk b) New donor incidence adjustment: To multiply "repeat tested donor" incidence to estimate "first time tested donor" incidence (to then use in formula 5 to estimate new donor window period risk)		
3. Infectious window period	Period of time soon after infection for which testing does not detect infectivity.		(can be from: publications; own data from seroconversion panels; expert opinion and or expert-adjusted values from publications. Source must be explained and/or cited.)

1. Own/local data must be used, unless "publications" is specified as a suitable source. If published data from other countries/regions are used for any parameters, this should be explained/justified.
2. The median should be used because the distribution of interdonation intervals for seroconverting donors can not be expected to approximate to a normal distribution (as those for all donors can).

[c] Value for the same calendar year as per table 4

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4. RISK ESTIMATES – BY DONATIONS

Results of estimation of "window period" risk per million donations i.e. infectious donations undetectable by all routine testing performed prior to donation storage and/or pooling.

Calendar year:	**a)** Results of estimation of "window period" risk per million donations for **"repeat tested donors"**			**b)** Results of estimation of "window period" risk per million donations for **"first time tested donors"**			**c)** Results of estimation of "window period" risk per million donations for **all donors (i.e. weighted average of a) and b) according to % by collection from a) and b)**		
	HBV	**HCV**	**HIV**	**HBV**	**HCV**	**HIV**	**HBV**	**HCV**	**HIV**
Country 1									
Organisation 1									
….									
Sub-region* 1 of organisation 1 in country 1									
Sub-region 2 of organisation 1 in country									
….									
Country 2									
…									
OPTIONAL: Testing/collection system 1 of organisation 1 in country 1**									

* If an organisation collects from a country that contains distinct regions of substantial donation collection, e.g. states within the USA.
** If an organisation has significant variation in collection and testing systems that affect the risk, e.g. different window periods, or interdonation intervals (whole blood vs plasmapheresis), PMF holders may wish to show these different risks rather than only the risks for the worse case scenario.

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