Annex A

EMA Number	**(Invented) name**	**Strength**	**Pharmaceutical Form**	**Route of Administration**	**Immediate Packaging**	**Pack size**
EU/1/21/1566/001	Bylvay	200 µg	Capsule, hard	Oral use	Bottle (HDPE)	30 capsules
EU/1/21/1566/002	Bylvay	400 µg	Capsule, hard	Oral use	Bottle (HDPE)	30 capsules
EU/1/21/1566/003	Bylvay	600 µg	Capsule, hard	Oral use	Bottle (HDPE)	30 capsules
EU/1/21/1566/004	Bylvay	1200 µg	Capsule, hard	Oral use	Bottle (HDPE)	30 capsules

Annex IV

Conclusions on the granting of the marketing authorisation under exceptional circumstances presented by the European Medicines Agency

Conclusions presented by the European Medicines Agency on:

- **Marketing authorisation under exceptional circumstances**

The CHMP having considered the application is of the opinion that the risk-benefit balance is favourable to recommend the granting of the marketing authorisation under exceptional circumstances as further explained in the European Public Assessment Report.