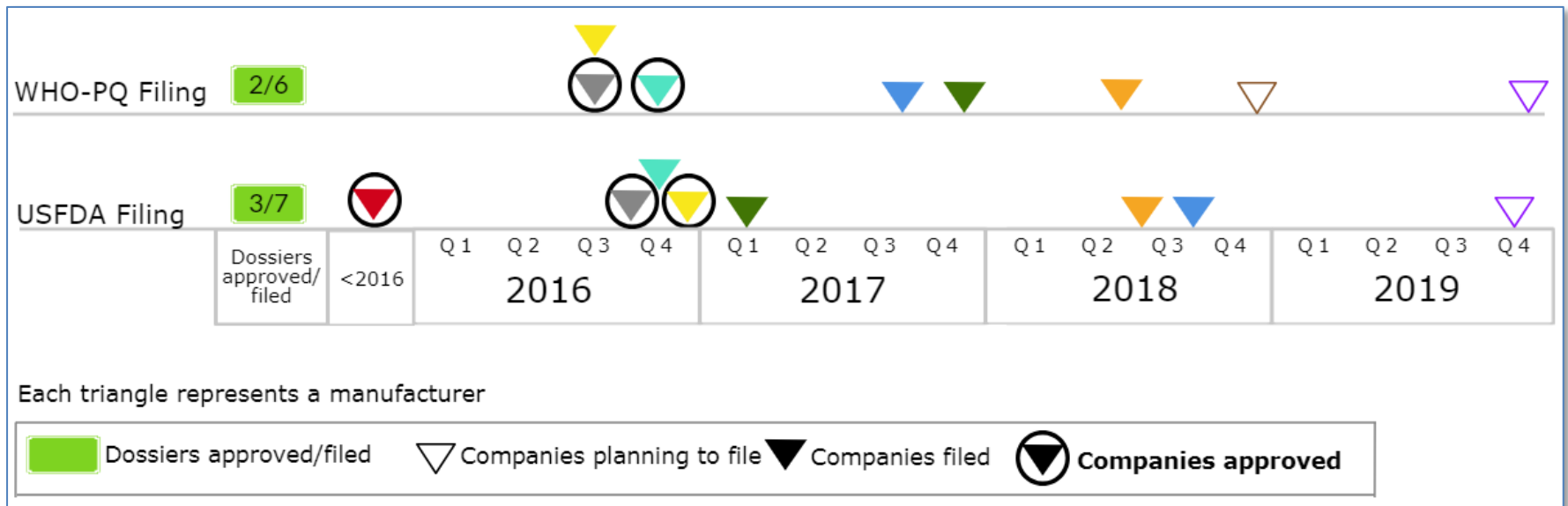


Dolutegravir



- The above chart shows nine MPP licensees are developing DTG 50mg, of which:
 - Six companies have filed with WHO-PQ; of which **Cipla** and **Hetero** have received approval
 - Seven companies have filed with USFDA; of which **Aurobindo**, **Cipla** and **Mylan** have received approvals
- **Emcure** and **Hetero** have received Expert Review Panel (ERP) approvals
- In total, **five companies** are ready to supply DTG 50mg

DTG 50mg: Country-wise Filing Status

Approved (9) 22.1% PLHIV

Botswana
Côte d'Ivoire
India
Kenya
Nicaragua
Myanmar
Tanzania
Ukraine
Uzbekistan

Filed (24) 66.4% PLHIV in LMICs

Burundi	Kyrgyzstan	Senegal
Congo	Malawi	Sierra Leone
DR Congo	Mauritius	South Africa
El Salvador	Mozambique	Sudan
Ethiopia	Namibia	Uganda
Gabon	Nigeria	Vietnam
Ghana	Pakistan	Zambia
Guyana	Rwanda	Zimbabwe

Generic DTG has been filed in 33 countries, of which approval is received from nine. Another 30 filings are planned for 2018 (covering an additional 11.5% of people living with HIV (PLHIVs) in LMICs)

WHO-PQ Filing 0/0



USFDA Filing 0/0



Dossiers approved/ filed	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4
	2017				2018				2019				2020			

Each triangle represents a manufacturer



Dossiers approved/filed



Companies planning to file

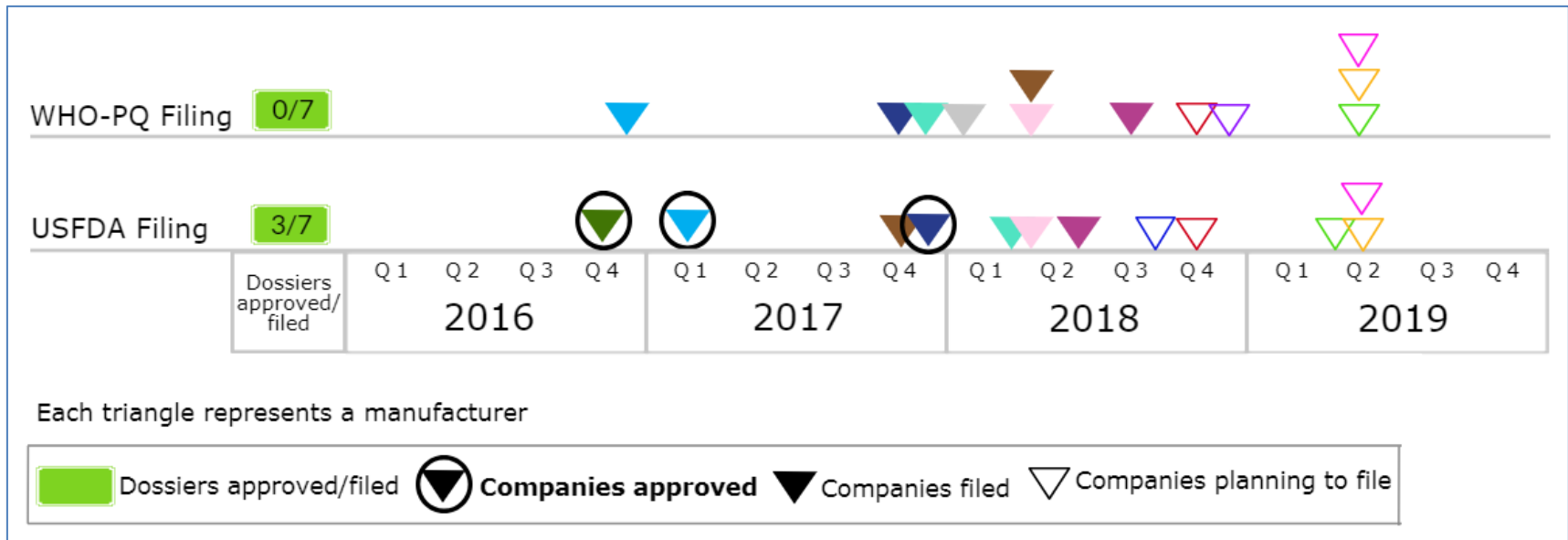


Companies filed



Companies approved

- Four MPP licensees are developing DTG dispersible formulation, of which:
 - Two plan to file with WHO-PQ in Q3-19
 - One plans to file with USFDA in early 2019 and another three by second half of 2019



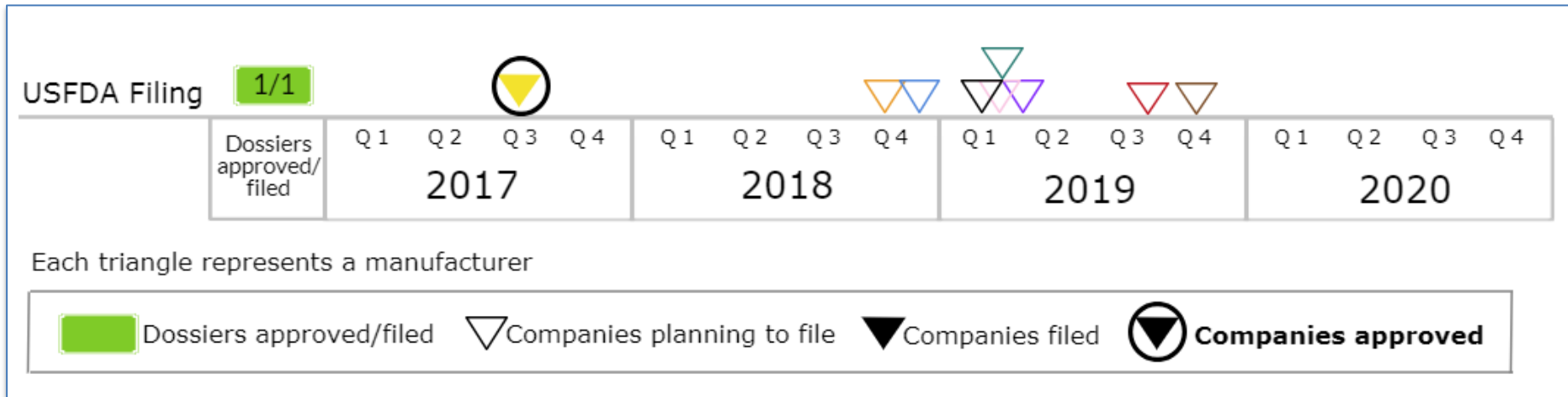
- 14 MPP licensees are currently developing TDF/3TC/DTG, of which:
 - Seven have filed with WHO-PQ
 - Seven have filed with USFDA; of which **Aurobindo**, **Hetero** and **Mylan** have received approvals
- **Cipla**, **Hetero**, **Macleods**, and **Sun** have received ERP approval
- In all, three generic versions of TLD are already in the market and an additional three are expected to be launched soon

TDF/3TC/DTG: country-wise filing status

Approved (6) (19.4% PLHIV in LMICs)
Botswana
Côte d'Ivoire
India
Kenya
Malawi
Uzbekistan

Filed (25) (69.2% PLHIV in LMICs)		
Benin	Ghana	South Africa
Burkina Faso	Madagascar	Tanzania
Burundi	Mali	Uganda
Cameroon	Mozambique	Ukraine
Congo	Namibia	Vietnam
DR Congo	Niger	Zambia
El Salvador	Nigeria	Zimbabwe
Ethiopia	Rwanda	
Gabon	Senegal	

Generic TLD has been filed in 31 countries, of which approval is received from six
 Another 25 filings are planned for 2018 (covering an additional 7.7% PLHIVs in LMICs)



- Due to lack of clinical data, TAF is not on the WHO Guidelines as of now. However, generics have already started developing TAF combinations
- 10 MPP licensees are developing TAF/FTC/DTG, of which:
 - **Mylan** has filed with USFDA and received approval
 - Two additional filings are planned by end of 2018
- We anticipate development by additional licensees to accelerate once there is an update on WHO's position about use of TAF-containing formulations