**Introduction**

- Infectious and parasitic diseases encompass some of the most deadly diseases including HIV/AIDS, the sixth leading cause of death worldwide.
- The USA and Japan are advanced economies within different geographic regions and thus is relevant to investigate the differences in drug approvals for infectious and parasitic diseases to understand any differences between these two countries' health priorities.

**Objectives**

- The aim of this study was to investigate the similarities and differences between the approval of new drugs for the treatment of infectious and parasitic diseases in the USA and Japan.

**Methods**

- Drugs approved from April 2004 to December 2013 were identified through publicly available reports on the USA Food and Drug Administration (FDA) and the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) websites.
- Relevant drugs were defined as related to the treatment of infectious and parasitic diseases, according to the World Health Organization (WHO) International Classification of Diseases Version 2010.
- Mortality rates for individual infectious and parasitic diseases were obtained from the WHO Mortality Database and the WHO Global Health Estimates.

**Results**

**Total Drug Approvals**

- Infectious and parasitic diseases made up a considerable proportion of the total new drug approvals for the FDA and PMDA, at 11.8% and 12.7%, respectively, making it the third largest category following neoplasms and endocrine and metabolic disorders (Figure 1).

- The FDA and PMDA approved similar numbers of drugs indicated for infectious and parasitic diseases at 31 and 28 drugs, respectively.

- Drugs indicated for the treatment of HIV/AIDS were by far the most common, making up 30% of the total infectious and parasitic new molecular entity approvals for both authorities.

- Nine HIV/AIDS drugs were approved by the FDA and 8 by the PMDA, of which 6 were approved by both authorities, each drug being approved by the PMDA in the same or following year after FDA approval, with an average 36-day delay.

**Infectious & Parasitic Disease Drug Approvals**

- With the exception of HIV/AIDS, mycoses and malariads, the indications of drugs sensorily compared between the FDA and PMDA (Figure 2). Following HIV, the most common infectious and parasitic drug groups for the FDA were hepatitis (20%), mycoses (13%) and bacterial (13%) whereas the PMDA has dealt incidences of drugs indicated for viral infections (excluding HIV/AIDS) and hepatitis (22%) and influenza and mycoses drugs (13%).

- The FDA approved two drugs for haemorrhage infestation and two for sexually transmitted infections other than HIV/AIDS and hepatitis, and the PMDA approved a single drug for tuberculosis.

**Infectious & Parasitic Disease Mortality**

- Both the USA and Japan are developed countries with sophisticated hygiene and healthcare systems, and as such, many infectious and parasitic diseases have a comparatively low prevalence to the rest of the world (Table 1).

- In addition, the climates of both the USA and Japan are less habitable to vectors of many infectious and parasitic diseases, such as mosquitoes and tsetse flies. However, viral infections such as HIV/AIDS and hepatitis that are more commonly transmitted directly by human actions (i.e., sexual transmission or infected needle drug use) are comparatively more common.

**Association between Approvals and Mortality Rate**

- There are a number of key differences in mortality of infectious and parasitic diseases between the USA and Japan.

- HIV/AIDS is considered a serious threat in the USA and remains in the top 3 causes of death. Although fatalities at 43,110 deaths in 1999, HIV/AIDS was responsible for 83.7% deaths in 2010 and in Japan just 13%, whereas pharmacological treatments for the disease are considered orphan drugs. Despite this vast difference in drug approvals, both the FDA and PMDA have approved a number similar of new drugs indicated for HIV/AIDS that constitutes almost a third of all new medicines for infectious and parasitic diseases. Hepatitis B has a high mortality in Japan, with a death rate of 2.8 per 100,000 population for hepatitis B and C, compared to a death rate of 2.5 in the USA. It therefore seems inconsistent that the drugs for hepatitis make up only 7% of the total for the PMDA and 20% for the FDA, given the differing burden.

**Discussion**

- It is clear from this analysis that there are a number of inconsistencies between the USA and Japan with regard to the approval of new drugs for infectious and parasitic diseases and the link with national mortality rates.

- For both countries, drug approvals for HIV/AIDS form the largest portion of total infectious and parasitic diseases. Whilst this is understandable for the USA in which HIV/AIDS has a high prevalence and has seen great advances in its treatment in recent years, in Japan it is considered an orphan disease and the annual mortality rate has not exceeded 100 persons.

- This analysis only rules out the influence of numbers of infectious classified under infectious and parasitic diseases by the WHO-I.CD-10 and therefore excluded pandemic strains such as H1N1 and H1N2 that pose a great threat in Japan.

**Conclusion**

- From the analysis presented here, it is clear that there are striking differences between infectious and parasitic disease drug approvals in the USA and Japan, and ,hearing seems that the association with national mortality rates.

**References**